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PATENT RIGHTS ON VITAL GOODS

An ethical inquiry into patents in biotechnology

Doctoral thesis

NTNU
Norwegian University of Science and Technology
Thesis for the Degree of
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PART THREE

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NOTE ON PUBLISHED ARTICLES

The thesis includes three independent articles; all three of them are published in academic journals.

Patent Funded Access to Medicines is published in *Developing World Bioethics* Volume 15, Issue 3, December 2015

Ethical Reasons for Narrowing the Scope of Biotech Patents has been published in *Medicine, Health Care and Philosophy*, Volume 18 Number 4 (2015)

The Distant Moral Agent is published in Etikk i praksis, Nordic Journal of Applied Ethics in No 2 (2017)

The articles are embedded in the style and format of the thesis and integrated in the pagination here. All three articles combined constitute Part two of the thesis. I have included the section *The choice of separate articles* (p. 12) to show how the articles are thematically related.

NOTE ON SUMMARY ARTICLE

It has been commented by the adjudication committee that large part of the summary would benefit from acquaintance with the articles beforehand. I have therefore deviated from the recommendation of the Faculty of the Humanities to place the entire summary article before the published articles and taken the liberty of splitting it in two parts. The second part, most benefiting from beforehand acquaintance, is placed towards the end of the thesis after the presentation of the articles.

PART ONE

INTRODUCTION

Ethical questions regarding inequality apply on multiple levels, from the local community through the national and regional domains all the way up to the global level. In recent years comparisons have been made between individuals, not states or regions – in a global perspective. Comparisons of groups of individuals in well-off countries with groups of individuals in less well-off African or Asian countries add valuable information to the traditional comparisons between countries.[1] New statistical approaches have been established to gain insight into the share of total income held by a country's richest one percent or five percent of the population. Corresponding to a persistent focus on inequality and poverty globally, there is an ongoing debate about the scope of wealthy nations' or indeed individual citizens' scope of ethical responsibility and duty to reduce inequality or to eliminate poverty.[2]

One area which has been brought into this focus is inequalities arising from the protection of intellectual property. Regulation of intellectual property rights, IP rights, is expanding from national jurisdiction to regional domains and through to the global level. One vehicle for this development can be found in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is in the process of being implemented in the legislations of all member countries of the World Trade Organization (WTO).

IP rights have repeatedly come under public debate and academic attention in recent years. Issues regarding IP rights imply discussions about whether these rights in fact put too many restrictions on use of new technology. More particularly, as vital goods like medicines

[1] Milanovic, B (2011: page X in the preface and p. 115f); Pogge, TW (2010b, Ch.5); Hans Rosling at http://www.gapminder.org/. Accessed September 17. 2015

[2] Miller, D (2007); Pogge, T & Moellendorf, D (2008); Risse, M (2012a); Singer/Kuper debate (2002)

for example are not exempt from patent protection, ethical questions may be asked regarding lack of access to essential medicines for patients who cannot afford to pay the inflated price of the market shielded products – the patent rent. The enforced restrictions on the distribution of patent protected goods have provoked the question whether IP rights can be justified in their present forms.[3]

The literature I discuss in this thesis, focuses particularly on the form of IP protection most preferred in biotechnology, namely patent-related restrictions of access to vital medication. For critics, the widespread use of patents is held to curb the circulation of ideas and goods and it is even implied that patents might turn out to be unproductive in achieving their overall aim of promoting, and not limiting, the innovative production of new and useful products.[4] It has been said that this unproductive effect is most conspicuously found in weak markets.[5] Concerning developing countries then, attention has been given to negative effects for healthcare in particular, due to the emerging WTO-wide patent system.[6]

The concern about weak markets brings us back, full circle, to the questions of inequality in access to essential drugs between country regions, countries, and population segments between countries.[7]

[3] Pogge, TW (2002, Ch. 9); Correa, CM (2000a); Sterckx, S (2005); Ashcroft, RE (2005); Brock, DW (2001); Resnik, DB (2004)

[4] Maxmen, A (2012)

[5] Milstien, J & Kaddar, M (2006)

[6] Matthews, D (2002), Ch. 5.; Cullet, P (2003)

[7] Although the current situation concerning access to Covid-19 vaccines is highly relevant for this discussion, I have refrained from updating the discussion of this thesis concerning this situation. The reason for this is that the articles were already published before the pandemic broke out and the project revolves around these articles. Still, the current situation demonstrates the relevance of the discussions I have taken part in here.

RESEARCH QUESTIONS

The thesis discusses three interrelated questions regarding patents on essential goods. Arguments from some critics of the minimum standard set out in TRIPS will be reviewed and particular attention shall be paid to difficulties in defending the current system on utilitarian grounds, which is found to be an often-used normative justification of patents.

Given that patents protect inventors from unlicensed use of their invention, but also that they might have negative consequences for circulation of ideas among developers and inventors, the first question asks: What degree of protection is justified in the utilitarian perspective? A report by the ASEAN Workshop on the WTO's TRIPS Agreement and its impact on pharmaceuticals[8] can serve as background for this question.

The inherent tension between promoting innovation on the one hand and protecting innovative ideas on the other, comes out in Carlos Correa's contribution to the report:

> The intellectual property rights system has been developed in order to achieve two contradictory aims:
>
> - to promote the publication of ideas, inventions and creations, in order to make them available to others, who can then further improve them; this will nurture scientific progress or artistic inspiration;
> - to provide an economic incentive for people to invent or to engage in creative efforts, by ensuring that the originator can reap financial rewards from his/her efforts.[9]

My first question concerns the contradictory aims brought out by Correa as well as broad critique raised by others to the effect that patents impede technological development more often than they stimulate it. Not aiming to resolve the empirical side of the issue, I discuss how extensive a protection inventors could reasonably demand, given two premises. These premises bear a relation to Correa's point on a contradiction between promotion and protection of ideas: Premise I: Patent protection will in many cases be conducive to critical financial investments in inventive technologies. Premise II: There is a tipping point where more protection would outweigh the advantages of the invention through an impeding effect on free research. The example considered in this discussion is human DNA material.

[8] Timmermans, K and Hutadjulu, T, eds. (2000),

[9] Ib. p.6

Recognizing the ethical critique of the current WTO TRIPS agreement, the second question asks how the current system of patent-driven invention can be revised to avoid limitation of access to medicines due to patents, for patients in globally poor regions. These regions comprise developing countries, most of all the 46 states listed by the United Nations as the least developed countries (LDCs). The aggregate population of the LDCs alone is more than 1 billion people.[10]

An improvement of the current patent regime is suggested. The suggestion goes further than merely presenting an arrangement where patent on medicines will be morally justified. More importantly, it points out how patents through a practicable modification of the current system can in fact serve as an effective tool to promote access in poor regions throughout the entire patent period. This question of how the current patent arrangement can be revised is dealt with in the article *Patent Funded Access to Medicines*.

The proposed solution to the access problem has a financial component. The third research question, which is normative, therefore addresses the question: Is there a moral imperative to pay the bill to make patented medicines accessible to people in poor regions? The question is answered in the affirmative, but only after a reinterpretation of moral imperatives, seeing them as one element in a pairwise relation with moral claims. The issue of financing access to vital medicine is addressed, accordingly, as a case under the more general problem of determining whose duty it is to respond to moral claims of individuals.

This general problem as well as the case at hand is treated in the article *The Distant Moral Agent*. The concept of a moral claim in that article is developed further in the summary part of the thesis. The concept of duty in the article is explained as a reinterpretation of duties in the global justice literature. Peter Singer's view of duties is taken as an example from the global justice literature. My reinterpretation takes inspiration from Joel Feinberg's idea of the relation between duties and moral claims.

A discussion of relations between moral claims, rights and duties follows in the summary sections after the articles and is limited to the task at hand, namely the duty to make patent protected essential goods accessible to those who need it.

As would be evident from the presentation of the three research questions, there is a particularly tight connection between the second article on patents and access to medicine for patients and the third question concerning a moral duty to make patented medicines accessible to people in poor regions. Fulfilling this duty implies financing reform structures

[10] UN-OHRLLS (2021)

to amend the negative effect of patents for the least well off. The articles are therefore treated as they are numbered, the latter immediately succeeding the former.

The first question, about tension between protecting and promoting new inventions, concerns patients and consumers indirectly. The whole issue of access for researchers to develop better or new methods and products based on previous inventive achievements, should not be regarded in isolation from questions about access to better medicines for patients, however. There is a close connection between freedom of research and invention of new medicines. As we see in the development of vaccines against Covid-19, having a wide range of medicines available increases the chances for access also for the least well off. In ordering the three questions I start with discussing the access for researchers by narrowing the scope of patents, and continue with access to essential medicines for patients.

Structure of the thesis

I shall begin by introducing in more detail the particular ethical challenges to IP protection as it is promoted by TRIPS. I will do so by selecting and presenting a limited, but representative, collection of critical texts. I then include an account of my choice of methodological starting point in discussing legitimacy as well as other methodological matters on how to give an ethical evaluation of purely legal rights. Next, I consider how I use my varied literary sources ranging from legal documents through the United Nations' declaration via news articles and interest groups website texts to philosophical literature in ethics. My own presentation of the TRIPS Agreement then follows, starting with an overview of the history of patents. The presentation of TRIPS will be concerned primarily with the paragraphs that are most critically significant for health issues in globally poor regions, that is, patents on biotechnological research and on pharmaceutical products. My representation of the agreement will not be comprehensive. In fact, it barely touches upon the other forms of IP protection given that the preferred form of protection in the biotechnology sector is patents.[11] Most of all I should emphasize that I will not provide a legal representation or interpretation of the agreement, but rather an ethical one. The TRIPS paragraphs on

[11] The other forms being copyright, trademarks, geographical indications, industrial designs, layout designs of integrated circuits and protection of undisclosed information. This is how they are defined in TRIPS (see WTO TRIPS), but derived from existing national law in WTO member states.

flexibility measures to avoid any unwanted effects for developing countries will naturally be given closer attention, as will the so-called Doha declaration on public health in developing countries, issued from the WTO's Ministerial Conference in November 2001 to address challenges that relate particularly to developing countries. The three articles follow after this first part of the thesis.

Part three goes more into details on each of the articles, elaborating further some of the arguments and the most central concepts presented there. Towards the end I pay particular attention to notions which are central in the third article, *The Distant Moral Agent*. Here, then, a closer presentation is given of legal rights, moral claims, universal rights and their significance for legitimacy of political power. The discussion in this part is a continuation of the topics raised in the first part, and it presupposes acquaintance with the articles in part two.

Ethical concerns

The purported contradiction between promotion and protection of ideas is to be found in the nature of the originator's reward, which is the exclusion of other inventors from developing the product further without a license agreement from the originator. The ASEAN report referred in the previous section thereby highlights one common restriction on the improvement of patented inventions: other inventors and researchers alike must negotiate for a license with a party that enjoys exclusive control over it. The patent holder is in a position to set the price without regard to competition.

Another general aspect of access restriction is seen in instances where the protected invention is a consumer item. Here the exclusion is not of innovators operating in the same field as the patent holder, but rather of copyists, able to produce that item at a considerably lower cost and therefore also able to offer the product on the consumer market at a lower price.

To obtain the right to sell the product, other commercial enterprises need to negotiate a license from the patent holder. As far as the public is concerned, we must pay the price asked by the patent holder or his/her licensee in cases of inventive consumer and patient goods. These are goods that have been developed under the economic stimulus of national patent systems, yet their price tends to be too high for many consumers. This ethical problem

is sometimes framed, as we shall see, as rights standing against rights – social rights against IP rights. Regardless of how it is framed, no solution has been agreed upon.

In developing countries where healthcare is one of the sectors that is typically underdeveloped, the patients' purchase costs related to pharmaceuticals are characteristically not covered by public healthcare or any alternative arrangement such as comprehensive insurance schemes. The high price for patent protected products makes them inaccessible to many patients. Even if universal coverage were in the planning, the cost of patent protected medicine would weigh heavily on the limited budgets, thus threatening to overburden the budget at the outset.[12]

The present system of IP rights is for a large part defined by the minimum standard laid out by the WTO. The TRIPS minimum standard was agreed in 1994. The last step in realizing TRIPS is taken when the least developed countries implement it into their jurisdictions, which is to be by 2033.

The criticism from the broad humanitarian or ethical viewpoint shared by the critics noted above, as well as others, is that the present IP rights regime, which restricts the use of new technology and allows patent on vital goods, is unjust. One main objective of the thesis is to investigate in what sense it could be said to be unjust. Separating between legal rights on the one hand and moral rights on the other, it explores the latter.

The ethical matter is not seen in isolation, however, from legal or political issues. The combined objective of the articles is practical and the normative issues will be worked out with regard to the discussion of legal implications and political reform.

The thesis concedes that the emerging legal IP rights protection arrangement needs to be improved to meet the ethical challenges pointed out by commentators and critics from various normative orientations. These normative orientations, however, do not line up to provide one common view about how best to rearrange IP rights protection to better balance the incentive concern on the one hand with the concern for the distribution of new inventions and goods on the other. This is hardly surprising, given the variety of outlooks on for example moral rights or global distributive justice. One issue that I consider central to this debate is the theoretical question about how to assign perfect duties to particular agents to

[12] The introduction of universal coverage of antiretrovirals for AIDS patients in Brazil is a well-known example of how the high costs however were forcefully reduced through Brazil's threat of issuing compulsory license for local production of the medicine. Brazil succeeded in bringing down the costs due to its considerable market strength, not negligible for the country's trading partners. Weaker market countries cannot expect to achieve the same results since they do not enjoy the same bargaining power. See Bird, R & Cahoy, DR (2008), also Nunn, AS et.al.(2009).

remedy suffering in foreign regions of the world.[13] Another issue is the question of the relation between rights and duties and if either of them is conceptually prior to the other.[14] This is the question whether there can be talk of rights if no one has duties to secure them. Vice versa, we can ask whether there can be moral duties absent people with rights. These issues are partly treated in the essay *The Distant Moral Agent*, but also attended to in the section below, Human rights, legitimacy, and moral claims.

In Joel Feinberg's notion of valid moral claims[15] there is support for a central normative argument in this thesis that at least methodologically, if not also normatively, a claim-based approach gives a promising prospect of finding sound criteria for assigning duties to particular agents. This quality of a claim-based approach is seen as a significant advantage compared to duty-based ethics. In the essay *The Distant Moral Agent*, I systematically explore the view from the claim-holder's perspective seeing the moral agent as the distant party, methodologically departing from the more common perspective of the distant victim or right-holder. The shift of perspective is carried out by using Singer's model of an expanding circle. His moral agent, located in the epicenter of the circle, is replaced with the claim-holder taking up this position. The aim of this shift of perspective is to investigate a

[13] Ashcroft, RE Ib., also the works of Singer, Pogge, Miller, and Young – some of which are listed in my references. My use of *perfect duties* in the thesis can be determined from two separate sources. First, Richard Ashcroft employs the term to describe duties that are ascribed to one or more specific agents. They are not general duties borne by every human being, like the duty to keep one's promises for example, but specific duties residing with particular and identified agents, personal or institutional. Ashcroft for instance identifies the national state as an agent with perfect duties to end a public health disaster due to the state's sovereignty. The other source is Kant's theory of rights in Kant (1797,6:240) where he separates between perfect and imperfect duties by seeing the former as corresponding to the rights of rational beings. The other category, the imperfect duties, he relates to human ends, or interests. Kant separates here real duty from transcendental duty, the latter being a *duty for which no corresponding external subject imposing the obligation can* be given*, so that the relation here is only* ideal *from a theoretical point of view, that is, a relation to a thought-entity. We ourselves* make *the concept of this being*[.](Ib. 6:241, enhancements in the original). Thus there are several distinctive components to a perfect duty, as I understand the concept here. First, the duty falls upon a named agent. Second, regarding stringency, the duty is non-negligible in that it is not a mere call for support to achieving the *end* or *interest* of a person or a group of persons, but rather a claim on the agent's resources to meet the *rights* of others. Third, O'Neill, O (1993:120) distinguishes between perfect and imperfect duties by reference to rights, that is, whether or not rights apply. Corresponding rights entail perfect duties, and absence of rights leaves duties imperfect.

[14] O'Neill (2004), Feinberg, J (1980); Nagel, T (2005) and Dworkin, R (1977). My use of the term *perfect duties*, as just introduced, and intended as a workable concept in applied ethics, sees the concept as derivative of the actual claims of other people, i.e. claims which have been presented. Its derivative nature separates perfect duties from imperfect ones, together with other criteria noted above.

[15] Feinberg, J (1980)

method for identifying particular moral agents by reference to an expanding scope of moral claims.

The two other articles *Ethical Reasons for Narrowing the Scope of Biotech Patents* and *Patent Funded Access to Medicines*, deal with the two aspects of IP rights indicated above. The first discusses the issue of patent restricted access to do innovative research, taking research on human DNA as its example. The second addresses the topic of access to innovative and essential medicine in poorer regions, globally.

ON METHOD

The methodological basis of the project is taken from analytical philosophy. Ideally theory-independent, it provides tools to investigate moral topics and other philosophical subject matters by the clarification of concepts rather than using historical traditions, or reference to value sets. For example, the approach can be used to explore the conceptual connection, suggested by patent law, between invention and product. Another example, also pertinent to my project is the distinction between judicial and moral justice, and their relation. A third example is the distinction and/or relation between utilitarianism and communitarianism through the discussion of an imagined community where members were predominantly utilitarian. The discussion would center on whether they are utilitarians or communitarians, and the result would depend on what aspects of their moral choice are highlighted. One consequence to be drawn from the mere analysis of concepts is that utilitarianism and

communitarianism, often thought to be conflicting theories, are not necessarily irreconcilable. This conclusion is implied in my discussion of moral scope in *The Distant Moral Agent*, section II.

I follow Bernard Williams' view on analytical philosophy as essentially involving "argument, distinctions and [..] plain speech."[16] Attention is given to the clarification of central concepts, like justice, obligation and rights, and what functions they have in current global justice debate. For example, in order to discuss the correlativity of rights and obligations, a sufficiently coherent understanding of the meaning and use of this pair of concepts is necessary. Moral concepts like the above-mentioned are treated systematically, as distinct from historically, in a practical discussion of intellectual property rights.

The literature studied spans various genres from news reports via official documents and law texts to philosophical theory. The latter category sets the premises for my normative analyses of the subject of IP rights, and I stay close to well-established ethical and political theories on questions of private property generally. For support in presenting a fair understanding of the legal document from WTO stating the Trade-related Aspects of Intellectual Property Rights, I have taken advantage of explications and commentaries from legal sources. The same goes for the legal case Association for molecular pathology et al. v. Myriad Genetics, Inc. et al. discussed in the article *Ethical Reasons for Narrowing the Scope of Biotech Patents*. For the defense of its Glivec patent in India by Novartis, I have relied on information from news reports and the company's own website. In all of them, the literature is chosen that is suited for a generalist but provides sufficiently precise understanding of the cases to discuss their normative aspects. This means that I have no ambition of providing a legal analysis. The discussion is ethical, and the legal sources are consulted from a perspective of moral philosophy. The official documents issued by WTO and the World Health Organization, seen in relation with academic literature, give useful guidance in assessing what normative issues have entered the broad discussion of decision makers.

Legal texts, even if they are not philosophical texts in themselves, often carry philosophical ideas.[17] An obvious example is rights jurisprudence, where ethical presuppositions are given legal expressions and social functions. The resulting law has binding force through sanctions, if not argument. Several theorists have occupied themselves

[16] Williams, B (1985: the preface)

[17] Dworkin, R (1977: Ch. 1, Jurisprudence)

with the relationship between law and ethics and arrived at a number of different philosophical justifications for legal rights.[18]

The relation seen, in this thesis, between utilitarian public-interest arguments, human rights considerations and the Feinbergian notion of moral claims deserves clarification as these concepts are much in use in the text. I do not treat this methodological issue of clarification here, but reserve it for the section Human rights, legitimacy and moral claims, below.

True to the tradition of analytic philosophy I have separated the complex subject matter of inventors' IP rights vis à vis other inventors on the one hand from questions regarding the inventor's rights towards producers and consumers on the other, in two separate articles. A common ethical background on why the problems taken up in them matter and to whom they arguably should matter is reserved for the third article (*The Distant Moral Agent*). In this article, I explain that the choice of the strict separation of closely related matters is mostly due to methodological concerns. In this article I present my methodological loan of Singer's model for investigating moral duties. I explain how I apply it in an investigation of moral claims instead of duties.

The choice of separate articles

In the Introduction, I separated two distinct aspects of intellectual property protection. One was the exclusion of other inventors or researchers from developing and improving the originator's product without license, an exclusivity of ideas. The other was the implicit rejection of consumers who cannot pay the patented products, dependent on which market the patent holder finds most profitable, an exclusivity of goods. In the case of medicines, the group of consumers we are talking about is patients everywhere. Legal IP rights protection, in the form of a patent, covers both instances.

However, as is evident from the presentation of connected normative issues so far, their considerable variety and number calls for a methodological scheme to treat them in any systematic fashion. I therefore bundle them, so to speak, in two groups, each corresponding to one of the aspects. I do this by choosing two examples, one for each of these IP rights areas.

[18] Among those treated here are, besides Dworkin, Li Westerlund; Mark Sagoff; David Resnik.

First, with regard to the exclusion of researchers, I discuss patents on human DNA, or the right to exclude others from developing further uses of synthetically produced DNA. Second, concerning consumer access, lack of access to available vital medicines as a consequence of patent protection is discussed.

Separation of IP protection in research and market areas respectively, does not entail that the two areas are considered mutually exclusive categories in this discussion. True, a research-based medication improvement might make the distribution of a given drug more practicable, and therefore contribute to more widespread access to it, like for example medicines that do not need cooling for preservation. In the big picture, one could argue that all successful research in biotechnology eventually and ideally is to the benefit of patients. Many of the refined products will in turn be patented, however. Therefore, there is still reason to focus separately on access in the market to find countermeasures to negative effects of patent there.

Despite being intimately related issues by being two aspects of the same rights system, the two aspects have different characteristics separating them. In short, I will now refer to this distinction as access for researchers and access for the public. Treating them separately will prove beneficial, I hope, not only for the sake of clarity but also in preparing the ground for the corresponding inquiries of the scope of IP rights against other researchers on the one hand and the scope of patient rights on the other. Hence, I think there is sufficient reason for treating one aspect at the time, in two separate articles: *Ethical Reasons for Narrowing the Scope of Biotech Patents* and *Patent Funded Access to Medicines.*

The second problem is generally more recent than the first in that many developed nations have not issued product patents until now. Therefore empirical support for claims of any effects of the introduction of the TRIPS standard in developing countries is scarce at this stage.[19] We are working with so-called foreseeable effects, but as I mentioned earlier there is considerable consensus on a number of them. The consensus is clearly demonstrated in the fact that the exemption provisions were included in the Agreement and also by the ministers at the Doha meeting later finding it required to reaffirm the rights to use them.

[19] Duggan, M; Garthwaite, C; Goyal, A (2016) in a large survey finds that several years after India introduced patents on medicines the price increase for these medicines averaged at 3%. The article suggests that the modest increase can be explained by factors such as fear of compulsory licenses and the capacity for license production in India. Cockburn, IM; Lanjouw, JO; Schankerman, M (2016) studies the impact of patents and price regulation on diffusion of new medicines in 76 countries. The study finds that stronger patent rights and absence of price regulation strongly accelerate launch of new medicines.

Furthermore, the cost-intensive biotechnological industry with its research on DNA and other fields is largely hosted by developed states in which product patents are nothing novel. This leaves the TRIPS-promoted IP legislation issue particularly prominent for the developing countries. It is reflected in the LDCs being granted a later deadline for implementing the Agreement into their respective legislations. Initially, they were set to comply fully by 2016, as the last group of countries in a progressive schedule for the implementation of the Agreement by all WTO members. Two rounds of extensions have been granted since then. In 2013 the LDCs were given an 8-year extension for implementing TRIPS. Thus, they had until July 1, 2021 fully to comply with the Agreement. For pharmaceuticals in particular, the TRIPS Council decided, in 2015, a new extension of the transition period until January 1, 2033 for LDCs.[20] For LDCs the provision of patents on medicines is in other words not required for WTO membership until 2033.

The first aspect of IP rights above, concerning biotechnological inventions, is certainly not an old issue, due to the rapid developments in that field the last few decades. For example, my discussion of patents on biotechnology includes reference to the fairly recent court decision in the so-called Myriad case where Myriad Genetics' DNA patents were up for trial.

Regarding the need to modify the emerging IP rights regime, one can hardly discuss modification independently from the question of who or what social institution should take responsibility to see it through. Much is written about responsibility in this respect, not least in recent literature on global justice. The debate is still ongoing and is now being fueled by reports on a persistent economic inequality globally, among individuals and countries.[21] If the current IP regime is to be changed, the question of responsible agents is inextricably attached to it.

How the issue of responsible agents is resolved will have bearing for the view on access for researchers as well as on public access to vital goods. The discussion of assignment of responsibility is nevertheless not treated in either of the articles on access to intellectual property goods. Instead, it is treated separately, as already indicated, in the article *The Distant Moral Agent*. That article clarifies more fundamental ethical issues on moral responses, issues that were bracketed in the other two articles.

[20] WTO

[21] Milanovic, B (2011)

PATENT HISTORY

Historical relevance

Even for a work in applied ethics, with primarily a systematic approach, some historical background is helpful in order to appreciate the normative issues involved. The origin of the patent institute indicates what tradition is strongest, the rights tradition or, alternatively, concerns for the benefit of society. The history of a social institution can, more generally, give good indications as to how socially rooted the institution is. The historical significance of property shows itself in Drahos' statement that "[p]roperty rules, more than most rules, are rooted in the fundamental morality of a given society."[22] For these reasons I shall include an account of the historical background for patent rights.

Assuming for any social practice that i. it has a long history and ii. it has been widespread, i.e. involved many people, then we could safely hold that it is socially rooted to a certain extent. A social practice thus entrenched has greater legitimacy simply in virtue of the greater number of people (historic and present) that have affirmed it by exercising it. Patent protection of inventions in fact has a long tradition. If the origin of the patent system showed a relation to a moral right to property in ideas, we would have support for the rights argument from the very conception of the patent institute. As we shall see, however, an historical survey seems not to suggest this. It is evident that the tradition of patents runs further back in history than the notion of the property of ideas. The following overview indicates that even the idea of individual rights is more recent than the practice of patents.

[22] Drahos (1996:15, in the chapter on the history of intellectual property)

Historical overview

The origin of the modern patent system is commonly ascribed to England and the Statute of Monopolies from 1624.[23] The new law replaced the old order of monopolies granted by the Crown. The old practice of issuing monopolies goes back to the fourteenth century when England lagged behind its competitors industrially. King Edward III started granting so-called letters patent in order to attract foreigners to come and train the English in trades developed overseas.[24] As centuries passed the practice of monopolies came to grow unpopular, particularly under Elizabeth I who granted a considerable number of trade monopolies during her reign, many of which had no observable function beside the protection of the privileged party from competition. Paired with income for the royal house from the fee attached to the privilege, the development of the nation's industry had become less visible.

One of the most famous benefactors of the Queen's royal charters was a group of London traders in products from South East Asia. In 1600 they obtained monopoly on all English trade at sea east of Cape of Good Hope (South Africa). Pepper and other spice had come in demand in the London markets and the group of merchants, later to develop into the East India Company, got their privilege in order for England to compete with the Dutch who had already established trading routes from the Far East to Europe.[25]

There is no imminent concern for the protection of inventive technology in this or similar cases of the Elizabethan reign. The consideration seems to be limited to trade concerns rather than production environment. Public dismay over interference in free trade, evident in the many monopoly decisions, is clearly expressed in 1601 in the so-called Case of Monopolies, or in legal parlance: Darcy v. Allen. In this famous court case, the defense claimed that the monopoly of Darcy was unlawful.[26] The case tested the monopoly of trade in playing cards enjoyed by Edward Darcy. In fact, it was not brought as an attack on

[23] Stenvik, A (2006:16)
[24] Mossoff, A (2001:1259)
[25] The permanent exibition at The National Maritime Museum in Greenwich, London, UK
[26] Calabresi SG and Lebowitz LC (2013:992)

monopolies. It was raised by the patent holder himself, Darcy, to put an end to an apparent breach of his monopoly in the import and selling of cards.

The Queen had extended the patent to Darcy to be valid for a period of twenty-one years. For that, the Queen received a yearly fee of 100 marks.[27] The case produced, however, a number of arguments in Darcy's disfavor. Thus, the court ruling stated that the royal monopoly was void. The conclusion was that any exclusive license to import and sell cards was against the common law.[28]

The court considered the legality of this particular grant of royal monopoly. Historically, it is significant of course, that the court could accept the case at all. It could do so due to ongoing parliamentary proceedings to outlaw royal monopolies altogether, during which Queen Elizabeth offered to allow cases concerning the legality of patents to be heard in a common law court.[29] The Case of Monopolies thus asserted the court's jurisdiction vis à vis the royal house.

For ethical considerations, and therefore more to the point here, it is significant that the court conveyed the growing dissatisfaction with the Queen's all too generous routine in granting of monopolies and, importantly, made a principled justification for its opposition. The justification given was that the monopoly benefited one private party only, a person and his house, and not the public at large. To support it the court applied a law from Parliament stating that restrictions of import of particular goods was a justified deviation to free trade only if it served to promote domestic education, production and trade in the goods concerned:

> "Parliament has made an Act to restrain pro bono public the importation of many foreign manufactures, to the intent that the subjects of the realm might apply themselves to the making of the said manufactures [..] and thereby maintain themselves and their families with the labour of their hands; now for a private gain to grant the sole importation of them to one, or divers (without any limitation)

[27] Coke, E (1602:1261)

[28] Coke, E (1602). Coke's report states that the court declared the monopoly granted to Darcy void (Coke, 1260). Later commentators, like for example Ramon Klitzike, confirms that the court voided the monopoly and thus held for the defendant, Allen (Klitzike, RA 1959; 645). Vishwas Devaiah's otherwise thorough, but undated article on this topic must therefore be mistaken when it declares that Darcy's monopoly grant was upheld (Devaiah, V). Most importantly however, is the shared point that arguments against «odious monopolies» (Coke) like the grant to Darcy were presented and recorded through this case.

[29] Calabresi SG and Leibowitz LC (2013:991)

> notwithstanding the said Act, is a monopoly against the common law, and against the end and scope of the Act itself;"[30]

A couple of observations should be made at this stage, with regard to the Case of Monopolies. First, there is no explicit mention of natural rights in Coke's report from the legal proceedings. Secondly, it makes no reference to inventions. Concerning natural rights, the case takes place in the early 17th century, the period in which John Locke lived and worked. The court concluded 89 years before the publication of his Second Treatise, though. It means the conclusion was in fact reached before Locke's birth.

The report comes close to applying a conception of right, however, when it refers to what is regarded as God-given, namely a man's trade. I quote this short argument, presented against monopolies, because it shows, quite clearly, the significance of labor and its judicial standing in England in the time immediately preceding Locke: "[E]very man's trade maintains his life, and therefore he ought not to be deprived of it, no more than of his life."[31] Coke leaves little doubt about the significance of a person's trade or work, and the likely merits in building arguments upon it in court. Here, this view of a person's trade is expressed as a negative right, one that should not be violated by anyone, queen or court.

Another often cited source that confirms that a person's work should be protected as his right, by actually employing this term for it. It is the report from the Clothworkers of Ipswich case in 1615 about the guild of textile workers in the town, referred to as the corporation in this quote by Mossoff:

> [T]he King might make corporations... but thereby they cannot make a monopoly for that is to take away free-trade, which is the birthright of every subject.... But if a man hath brought in a new invention and a new trade within the kingdom, in peril of his life, and consumption of his estate or stock, &c. or if a man hath made a new discovery of any thing, in such cases the King of his grace and favour, in recompence of his costs and travail, may grant by charter unto him, that he only shall use such a trade or trafique for a certain time, because at first the people of the kingdom are ignorant, and have not the knowledge or skill to use it: but when that patent is expired, the King cannot make a new grant thereof: for when the trade is become common, and

[30] Coke, E (1602:1265)
[31] Ib. p. 1263

> others have been bound apprentices in the same trade, there is no reason that such should be forbidden to use it.[32]

These lines provide a window to much of the thinking about patents at this time in history.[33] First, they state clearly what is held to be the fundamental right. This is a person's freedom to trade, that is to exercise his skills and to offer his products on the market. Secondly, the court condemns the use of patents if it interferes with this right. Third, and lastly, exemption is given for inventions and new discoveries – as the terms are applied by the courts at the time.

In this period, if there is a right, it rather seems to lie with the laborer rather than belonging to a privilege holder, even if he carries a royal letter. The right to continue one's line of work without interference from authorities is here presented as a moral principle. It is the liberal principle, soon to be advocated by Locke, of being free from interference from authorities, which lies at the heart of this conception of a right. Calabresi and Leibowitz write about the period, from the libertarian perspective, that "intellectuals and lawyers began to truly recognize the rights of Englishmen to work for a living and to compete with each other without interference from government grants of special economic privilege."[34]

As concerns the second observation, the fact that Coke's report from the Case of Monopolies did not make any reference to inventions, nothing in his report in any way suggests that the trade in cards, or any quality of the cards themselves, was considered a novelty worthy of protection. The court considered the trade policy involved in rejecting domestic production and sale of playing cards and decided that the monopoly was unlawful interference in free trade.

The original rationale for the monopoly practice, to stimulate import of new techniques and materials, or new trades, is not an issue in this argument on playing cards. It is, however, in the broader debate on monopolies. And that debate, at this stage in history, did not discriminate between invention and import.[35] Whether the product or method in question was invented in England or abroad did not matter as long as it was new in the realm, i.e. new with respect to English industry at the time. If so, it would have the possibility of creating new jobs and livelihoods here. Even if the product was known in England before, and had

[32] Mossoff, A (2001; 1270)
[33] Ib.
[34] Calabresi SG and Leibowitz LC (2013:989). They thus give a formulation of standard political liberalism.
[35] Mossoff, A (2001)

been in use in earlier times, to reintroduce it and find a market for it was considered an invention in legal terms.

These two issues, i. the lack of natural rights concerns on behalf of the patent holder, and ii. the absence of attention to, and discussion of inventive industry, together suggest that the Case of Monopolies is not straightforwardly instructive in the debate on ethical justification of IP rights for original ideas in a modern sense. For the more specific review of the history of patents, the legal right, it is nonetheless a significant case, of course. In that particular perspective, the case serves to show that concerns regarding freedom of labor (in the sense of a man's trade) had the highest priority at this stage in history.

A perspective which is absent in Coke's presentation besides natural rights and inventions is attention to the labor aspect of the efforts of inventors. It would make sense to compare an inventor's efforts with that of any other laborer, to highlight the inventor as a laborer, with the rights following from it. Drahos touches upon it briefly, but does not seem to find a regular occurrence of this perspective in his sources: "Inventors and authors, like others, labored and were entitled to a reward, but the reward which they could be given consistently with God's design was no more than a temporary privilege."[36] In light of this, it would seem that inventors (and authors) were not considered laborers precisely for the reason that they were active in an inventive trade. Their labor was hence not protected like the labor of workers, but instead rewarded in accordance with another scheme, one which allowed for limited temporality. This might well have to do with another observation on Drahos's part, that inventions were held to be too important for the public benefit to be left in the hands of their inventors.[37]

The historic background of patents on medical treatments supports his observation. Later, in 1862 in America, the case Morton v. New York Eye Infirmary resolved Morton's charge against the hospital for infringement of his patent on ether. Morton had obtained a patent after his discovery that ether would render a patient insensible during a surgical operation. The court's verdict was that although the discovery ranked high among all modern discoveries, "its value was too great to be estimated in dollars and cents."[38] It was not until 1952, in Becton-Dickinson v. Seherer, that a patent were granted for a medical procedure.[39]

[36] Drahos, P (1996:32)
[37] Ib.; Loff, B and Heywood, M (2002:622)
[38] Loff, B (2003:6)
[39] Ib.

The historic context of the Case of Monopolies was that the institution of royal monopolies had a long history in the medieval privilege system. This was a centuries old system where Royal privileges were granted at the king's discretion, to promote the importation of "new arts."[40] The case took place at a time when the Crown obviously had relaxed the requirement that the imported good should represent a new and inventive craft or technique not in use in England already. Instead, the quality of being an income source for the royal house became more imperative.[41] The term in use, then and now, for this royal grant – privileges, and not rights – itself suggests the pragmatic attitude towards the practice of royal monopolies, not least in England. Drahos may therefore safely say that they were thought to be privileges rather than rights.[42] According to Drahos, even at this early stage rights were not carrying expiry dates and that, if nothing else, made them a poor match for the handouts of royal time-limited patents. Later on, when rights were to be a central notion in the French revolution and also for the American Constitution, they were not given the same weight in the work on patent law.[43]

The new-arts-requirement was honored in the old privilege system, not only in England, but also in the European mainland and it dates back at least to the glass trade of the Venetians in the 15th Century.[44] This particular requirement must however be distinguished from the novelty requirement familiar from more recent patent law. Today's novelty requirement for patents is the stronger demand that requires of an invention that it is new in the sense never before seen. The old system however, going all the way back to the Venetians, already favored inventions whether they were new or merely imported. The Venetians themselves traveled and brought their techniques with them. As foreign craftsmen they sought protection for their trade, often in glass, and the Crown granted them temporary protection provided that the techniques were made known to domestic traders who were then free to enter the trade as soon as the patent expired.

Along this route, the import of the techniques stimulated the spread of the Venetian protection system as well. It is however not settled whether the trade protection system also originated in Venice and spread to the rest of Europe or if there were similar developments

[40] May, C & Sell, SK (2006:52)
[41] Drahos, P (1996:29)
[42] Ib.
[43] Ib. p. 32
[44] Devaiah, V

occurring concurrently, across the region, in Florence for example and in England.[45] In any event, the Venetian statute of 1474 is the earliest example of patent legislation from this period, and thereby the first known instance of a legislation of patents.[46] It was enacted by the Venetian Senate specifically to promote inventions and import:

> "Therefore it is enacted by the authority of this body that whoever makes in this city any new and ingenious device, not previously made within our jurisdiction, is bound to register it at the office of the Provveditori di Comun as soon as it has been perfected, so that it will be possible to use and apply it. It will be prohibited to anyone else within any of our territories to make any other device in the form or likeness of that one without the author's consent or licence, for the term of ten years."[47]

With this statute, regulation of patent monopolies was historically established. The system replaced the arrangement of more occasional privileges, well known also in Venice.[48] One famous benefactor of the Venetian patent system was Galileo. In 1594 he was granted a patent on a machine for raising water. The machine was used in a Venetian garden, and Galileo enjoyed the exclusive right to make and operate such a device for a period of twenty years.[49]

The statute includes a noticeable exception of the exclusive right of the patent holder. It can be considered an early version of the compulsory license on behalf of the granting state, known from current patent legislation:

> "It being, however, within the power and discretion of the Government, in its activities, to take and use any such device and instrument, with this condition however that no one but the author shall operate it."[50]

The statute marks a transition from privileges to legal rights. Any inventor now could apply for the monopoly privilege from the authority in Venice, valid for the city of Venice's territory, provided he could justify that his invention met the requirements specified by the

[45] Devaiah, V
[46] May, C (2002)
[47] Quote borrowed from May, C (2002:162)
[48] May, C (2002:163)
[49] Klitzike, RA (1954; 618)
[50] Devaiah, V

new law. The legal right of a monopoly would be extended to the inventor by a favorable decision from the patent authority.

This legal right must be distinguished from the moral right now also established in this particular jurisdiction, namely that the opportunity to file a patent application should be the same for all. The moral right is not to be considered a universal moral right as it could only be valid and would be protected only within the jurisdiction of the state. These considerations invite a clarification on the use of rights notions in these paragraphs, and indeed throughout the thesis.

Two categories of rights are in play here. First there is the legal right given by a patent and next, the equal right to apply for patent. This second right belongs to all and is itself not a legal right, or at any rate not only a legal right. It is the right of every citizen wanting to operate in the market. The market itself is regulated by a designated authority and the right is towards this authority, most typically the city or the state. The right to apply for patent, then, is clearly a representation of the moral right to equal treatment.

Even if we find that the right to patent is given statutory form, like in Venice in 1474, I refer to equality before the law, like the equal right to apply for patent, as a moral right whether it is manifested in positive law or not. For now, we merely observe the link between the right to apply for patent and the existence of a patent system. The equal right to apply for patent cannot itself be understood as independent of there being a patent system in place. It is therefore not a natural right in Locke's sense, derived solely from a property of the human being. The more abstract right to equal treatment is however not linked to a designated system or authority. The only indispensable association of the right to equal treatment is the condition that there is someone treating your case. I shall return to the question of the nature of this right in taking up Dworkin's theories of rights later.

The very practical purpose of the statute of 1474 does not suggest any moral motive behind the first patent law in Europe. The wish to promote inventive industry within the borders does not point in the direction of a felt responsibility to respect any natural rights on behalf of the inventor. I find no suggestion of an underlying moral right of the individual person in the historic surveys cited here.

To choose two separate crossroads in the historical establishment of the Western individual, the statute was decided some forty years before Martin Luther's emphasis on the individual person's independent standing before God seen in his theses. We may well note that they, in turn, preceded the publication, in England, of Locke's work on natural rights by

two whole centuries. Hence, we could not even expect to find a line of influence from the idea of individual rights to the origin of patents.

In England, the controversies surrounding royal monopolies that culminated in The Case of Monopolies, led further to the Statute of Monopolies of 1623. In its first paragraph, the statutes declare all monopolies to be contrary to law.[51] [52] Next, it makes one exception, for inventors of new manufactures. The patent duration for such new products is set to a maximum of fourteen years. Patents were to be granted on the condition that they were not mischievous to the state, and one example cited for such possible fault was when they occasion a raise in prices (sect. VI).

The terms of patents laid out by the new law determined patent practice in England for the next couple of centuries and were used as a model for patent legislation abroad, not least for American patent law. The terms, in seven points, as presented by Bebe Loff read:

1. It must be for a term of twenty-one years or under.[53]
2. It must be granted to the true and first inventor.
3. It must be in respect of new manufactures.
4. The privilege must not be contrary to law.
5. It must not be mischievous to the State by raising the price of commodities at home ('In every such new manufacture that deserves a privilege, there must be Urgens necessitas, and evidens utilatas.' – urgent necessity and evident utility).
6. The privilege must not be to the hurt of trade.
7. It must not be generally inconvenient (for example it should not put men out of work).

A good part of the modern legal notion of patents is already present here. One key issue missing however, is the later requirement of disclosure through a complete description of the invention. Another is novelty, in the modern sense. Both missing issues (in hindsight) could be seen in conjunction with the legal concept of inventor at the time, still in use when the statute was written, and still not discerning between inventors and importers.[54] We should keep in mind that governmental concern in patent was guided by the interest in stimulating the use of new crafts and materials in its domain. The working and quality of the new

[51] The National Archives (UK) online

[52] Drahos, P (1996:32)

[53] The term was apparently extended to 21 years by the time of the passing of the law (in 1624).

[54] Mossoff, A (2001:1264 and 1288)

manufacture was more important than the question of the original inventor as long as the trade was introduced in the economy.

This thoroughly instrumental view on patents is highlighted throughout by Drahos, who pronounces his support for the view against the "proprietarian view" and in favor of instrumentalism.[55] English instrumentalism is at any rate evident in the practice throughout the years, and before the implementation of TRIPS, in extending the patent to the first applicant whether this person is the true inventor or not.[56] In the United States there is a requirement that the applicant is, in actual fact, the true inventor.[57] American law therefore acknowledged a right belonging to the inventor, which the English did not acknowledge.

The legal distinction between inventors and importers developed only gradually in the late seventeenth century through a number of legal cases.[58] It was the modern-day novelty requirement however, that finally reserved the right with the true inventor and no one else.[59]

The first half of the 1600s were, notoriously, times of war across much of Europe. In England, the civil war took place in the 1640s. Relatedly, this is also the time when the pioneer groups of colonists left for America. More than a hundred years later, the English practice of issuing monopolies played a central role in American discontent with the colonial regime. The English colonies in America inherited English laws, and the laws where enforced from London. The American Revolution grew out of opposition not least with the old monopoly system, and how it was used to secure monopoly in colonial trade for English merchants.[60] The frustration over this was strongly felt among the colony's own merchants and materialized in the action, to be known as The Boston Tea Party. Vessels from the East India Company were boarded in Boston Harbor in 1773 and emptied of their tea load as a protest against the company's monopoly in colonial tea trade.

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[55] Drahos, P (1996:9). Proprietarianism, he holds, is the view that grounds justice in natural rights theory from the Lockean tradition (Ib. p. 200). One need look no further than the sources cited here to see an indication of the politicization of the history of patents. Drahos says in his overview of the chapters of his book that "The final chapter argues that proprietarianism is a creed that has come to dominate the evolution of intellectual property law." He proposes to replace this natural rights-influenced theory with instrumentalism. Mossoff, quite the contrary, holds that natural rights theory has been largely ignored by historians and argues against "the prevailing view that the ideas of the natural rights philosophers did not influence the early development of patent law." (Mossoff, A (2001:1257). He quotes sources that serve to testify this prevailing claim that "everyone agrees that natural rights theories played no part whatsoever in this story" (Ib. p. 1256).

[56] Even as late as in 1959 Klitzike writes about the still ongoing English practice.

[57] Hestermeyer, H (2007:24-5)

[58] Mossoff, A (2001:1280)

[59] Ib. p. 1288-9

[60] Calabresi, SG & Leibowitz, LC (2013:1007)

Another frustration concerned, more generally, the colony being taxed without having representation in government. As these two related issues combined were central forces in the movement towards independence from England, the role of monopolies should not be underestimated in a historical survey of the forming of the new nation. The further developments in America, from outspoken resistance to monopolies from Thomas Jefferson and others involved in drafting the Constitution, through to opposition against privileged enterprises for postal services and railroad operations,[61] are developments which concern monopolies in general and not protection of intellectual property in particular.

Patents for inventions were granted through the whole period, as prescribed by the Statute of Monopolies.[62] Regardless whether the colonies saw themselves bound by the statutes or not, they included some form of patents for inventions in their own legislation. Some states passed less comprehensive or articulate laws compared to the English model.[63] Still, protection of intellectual property, as we have come to call it, was no integral part of the discussion of monopolies.

Regarding the United States we might, following Fisher, see the historical development towards current debates on intellectual property as going through three stages: i. Until the late 1700s the American colonies were agricultural societies, with only a fraction of the workforce involved in manufacturing of other goods; ii. The nineteenth century saw the development of industry; iii. but it was not until the twentieth century that the information industry became a major sector of the economy. At this third stage, we see "an increase in the perceived need for intellectual property rights" in Fisher's words.[64] Information has become a commodity and it is traded like any other commodity. Since trade essentially is the transfer of property from one party to another, there seems to be no way around the fact that information, in the economic sense, is property.

At this latest stage, patents had developed from being an instrument of importing new arts for the domestic industry to catching a sense of property to ideas, at least under its most general name: intellectual property. The term has come to stand for a larger range of goods than mere products of manufacture. In the United States intellectual property includes authors' rights to their work of literature, photographs, musical recordings, computer

[61] Calabresi, SG & Leibowitz, LC (2013:1012 and 1057f)
[62] Ib. p. 1016
[63] Ib. p. 1004
[64] Fisher, WW (1999:11)

software and, from 1990, architectural works.[65] For all these categories, the applicable type of intellectual property is, however, not the patent but copyright.

The historically recent development of the idea of property to artistic work was preceded by the period, in the nineteenth century, when the accomplishments of the individual artist were seen in a new light. The romantic movement in literature and arts gave birth to the idea of the genius, the extraordinarily talented visionary who could see and show the zeitgeist to the masses. The very special skills of the avant-garde, the visionaries, were valuable guides for the masses in understanding life and world. According to Fisher, ideas from the romantic era had a "powerful impact on American copyright law."[66] He reminds us that before the romantic age, the trade of being an author was not very unlike other trades in terms of skills and know-how. Where tradition and study had been central qualities before, originality now came to the forefront. Earlier, artists and authors had been regarded representatives of a trade. Now they were seen as endowed with special genius or talent. Their individual work was therefore something particularly associated with the artist who produced it.

Even if the current IPR regime has a global scope, by being sanctioned by the WTO member states, the history of ascribing individual property rights to ideas is predominantly Western. The area of copyright is a clear case, in its conceptual relation to the notion of individual creativity, which is a typical Western conception without a clear Oriental counterpart.[67]

Artists and authors were the true heroes of this period and copyright was an outcome of it. Fisher sees a historical continuity carrying over from the art field to the success and acclaim of later inventors like Thomas Edison and Steve Jobs. It may well be that the artistic genius, praised in the days of Nerval and Novalis, in part explains the later idea of the individual inventor and the associated idea that creative minds should have some sort of property to their creation.

The individualism from the romantic age is however a poor fit for modern day pharmaceutical invention because it is mostly done in the collaborative research departments of big industrial enterprises. The pharmaceutical industry can therefore serve as an example, along with modern enterprises in the communications industry to name one more, of a sort of enterprises that do not make themselves dependent on one individual inventor. Musical

[65] Fisher, WW (1999:4)

[66] Ib. p. 15

[67] Drahos Ib.

composers and authors of literary fiction can with greater credibility lean on the romantic tradition of the individual artist. For heads of development divisions in pharmaceutical corporations, the connection to this tradition is not obviously available. The same applies for research institutions. The long lists of contributors to research publications, common in the field of medicine for example, testify to that.

The tradition from the romantic era therefore seems more closely related to copyright protection than to patents. Patent on medicine is in light of this tradition an uneasy match. Pharmaceutical inventions also stand out by the fact that they became eligible for protection quite recently in many legislations. Thus, Germany introduced patent protection for pharmaceutical products in 1968. In Spain, Portugal, and Norway patent of pharmaceuticals were legislated as recent as 1992, in preparation for the creation of WTO two years ahead. The US is a notable exception to late introduction of pharmaceutical patents. There, patents for pharmaceuticals have been granted at least since 1793.[68]

Copyright protection, together with patented inventions, were at the core of the trade disputes prior to the WTO. USA in particular saw domestically protected products copied elsewhere, particularly in Asian countries with less extensive patent legislation. The markets in these countries (South Korea, China and Japan, to name the most important ones) were lost for the American inventor company or the producer of a cinematic movie or computer software for example. To make things worse, lower priced copy products from Asia found their way to the US market. The pressure for a global minimum standard of IP protection thus for a considerable part came from exporting enterprises in the US, as will become clear later, in the chapter Critics of WTO's TRIPS agreement, and in the article *Patent Funded Access to Medicines*. For a detailed account of this development, I have arleady referred to Matthews, D (2002).

Conclusion

I conclude this historical survey in three points, each of them bearing a close relation to the issue of patents on medicine.

First, protection of inventions has a long and unbroken tradition. From the early times in Venice, through the strifes between the English Parliament and the Royal house on

[68] Hestermeyer, H (2007:28)

monopolies and over to the new American colonies, patent protection of new arts has been offered to the inventor and the importer.

Second, justification of patent protection has shifted from being derived from the wish to promote the importation of new arts to be, for moralists, based on inventor's rights. The conception of rights to ideas gained support in the 19th century, not for industrial inventions, but for artists' copyright. Concerning national policies, the old incentive to establish new arts, or technology, is still the dominant principle. Here we should keep in mind that industrial production methods are a novelty in the 19th century. Hence, one could make the case that the notion of property of ideas is as old as modern industrial production of goods and materials, but originated by influence from the fine arts and literature.

Third and last, patent on essential goods, like lifesaving medicines, enjoys a long tradition in the US, but was introduced much later, and in historical terms quite recently in many other countries, often in order to comply with TRIPS.

Reservation regarding historical record in ethical argument

I shall end this historical overview with a couple of remarks concerning references to historical theory in works of ethics. The first refers to what Adam Mossoff says on the relation between historical statements and ethical judgement. He notes that the natural rights philosophy of Locke may well have *influenced* historical developments in patent law. Quite another question is, he holds, whether Lockean rights theory could serve as a *justification* of any grant of a patent. According to Mossoff, "The former is a factual determination made on the basis of the historical record, and the latter is a philosophical determination that can only be made on the basis of normative principles."[69]

As regards academic disciplines, history of patents belongs to legal studies like for example studies in legal history. It is not an integral part of ethics – the discipline exercised in this thesis. As a historical study, it could also fall under the academic discipline history of course. In either case, the study of the history of patents does not discuss ethical justifications even if these were to be cited as part of the background of the patent system. The arguments put forward by its proponents would be presented as ethical arguments about property for

[69] Mossoff, A (2001:1321)

example, but there would be no historical purpose in weighing the arguments in a contemporary or indeed in any context, as a philosophical inquiry would have to do.

History of patents concerns the creation of the patent institute and how lawmakers have administered patents since, including why and how they have maintained it. According to legal scholar Hestermeyer, "[a]lthough the natural law argument of the fairness of ownership in one's own inventions has certainly exerted an influence on the development of patent law, legislators have always tried to tailor patent laws to the goal of inducing the introduction of new knowledge within their territory with minimal disadvantages to society."[70]

One would expect that state leaders and legislators act from national interest. Thus, they have opened the borders for foreign arts and materials in order to create new trades and markets. The pragmatism involved in national interest does not promise fairness arguments based on natural laws. Arguments of this order are not to be expected. We need to keep this in mind when studying the historical justifications of patent law.

My sources in patent history are to a large extent works of legal theorists. Hestermeyer's book and Mossoff's article are examples of this. The subject matter of the legal texts is first and foremost, and true to delineation in academic disciplines, positive law - its history and scope. Hestermeyer concludes the paragraph just quoted: "The common claim that inventors traditionally (and everywhere) have a right to a patent is therefore misplaced."

The right in question here, is nevertheless a moral right to patent, and it is dismissed by Hestermeyer. The conclusion merely states that patent rights were not yet introduced in all national legal systems. Hence, nobody could claim a right to patent protection by reference to the principle of equality before the law. WTO member states have committed themselves through TRIPS to introduce these rights in their respective jurisdictions. It would therefore seem that patent rights are becoming more available globally even in regions where there is no tradition for it.

I include the paragraphs above to state that I am aware of the methodological limitations in efforts to see patent history as a source for intellectual property rights, taken as moral rights. Still, I have been interested in bringing out the origin of the patent right in order to determine whether it grew out from considerations of ethics or not. As the historical overview demonstrates, and as Hestermeyer implicitly concedes, the introduction of patents was based on national interest motives, and not the natural rights idea. Historical records of

[70] Hestermeyer, H (2007:21)

protest against the right point to interests of free exercise of personal trade or workmanship and free trade on the high seas.

The prevailing justification of modern patent right is utilitarian, maintaining that patents provide incentive for the development of new ideas and products.[71] I shall settle for the modest premise that patents can have the effect of creating incentives for new inventions[72] and also that the prospect of patent protection facilitates financial investments in technological development.[73]

My second remark regards questions whether historical development represents progress.[74] If it is the case that we (in some uneasy reference to all of us as one group of people) get better off little by little as generations pass, it can only be established by current standards, not historical ones. Let us suppose first, that we do all agree what it means to get better off and next, that we actually do get better off. What we mean by getting better off may concur with standards from historical times, but this is not necessary. It would be sufficient, and indeed required, that current expectations are referred to in deciding the matter.

Similarly, the historical development of intellectual property is, as Mossoff holds, the chain of events of influences and justifications that carried the notion through the centuries. The record of influences and justifications itself is not subject for assessment, other than as a fair record of events when sources have been considered and method is accepted. If the historical evidence represents an argument at all for the justification of IP rights, it must be in some indirect manner, for example by showing how widespread and how long lived a certain tradition is.

As an account of the history of patent rights, the record included in these chapters presents major events in the development of this idea, including the various justifications of it, given at decisive historical crossroads. To pursue a valid justification of the current patent system however, it is insufficient merely to present the record. For a valid justification it is necessary to engage in the assessment of the historically given arguments, for several reasons. One is that circumstances might well have changed since any particular historical epoch, rendering the old arguments obsolete. Another reason might be different priorities of our time compared to historical times.

[71] Hestermeyer (2007:31-2)

[72] Cf. the opening lines of the chapter Critics of the WTO's TRIPS Agreement below

[73] In the opening lines of the article Ethical Reasons for Narrowing the Scope of Biotech Patents.

[74] Questions about progress in history is not new, of course. See for example Popper (1957, chap.32)

The more principled reservation is a version of the problem introduced by Hume, the so-called is/ought problem in ethics, which concerns the invalid inference from is to ought, from fact to value.[75] The logical fallacy would imply an ethical positivism where that which is positively given, statutory law in our case, would serve as codified moral norms. An example would be any law against breach of contract. This instance of positive law would serve as necessary justification for the moral value of honoring contracts. In this sense the value is derived from an observable historical and/or legal fact – the law. When the fact/value problem is thus stated, it points to a new fact as it were, namely that no moral judgement is performed, and instead historical facts are consulted.

A closely related issue is the position that appears to be at least consistent with this particular positivism in ethics, if not following from it, that law has priority over moral norms. The position invites questions like: If law has priority, how can laws be codified moral norms; if, accordingly, moral norms are derived from law, what is law? One other, related, question is what is left of morality if law already expresses how it ought to be. In the chapter on Human rights below, I shall comment on these questions with reference to, among others, Herbert L Hart. There I also discuss Ronald Dworkin's ideas on the topic with respects to moral rights concepts. His works are well known examples of the position that moral norms precede laws and rules.

The historical justifications, as we find them recorded, must be validated by present generations. Validation has taken place whenever the old justifications are accepted, and people now therefore consider themselves bound by them. It goes without saying that the notion of present generations, in the wide sense, comprises all citizens and not only legal scholars. The validation that takes place is arguably of an ethical nature, and not the outcome of legal procedures.

Even if the historical record of patent debates indeed did not provide justification material for today's patent agreement in the WTO, it represents a centuries-long tradition of affirmation of the general idea of patent protection. The protests that have been reported against it, of which some are included above, were mainly directed at misuse of the privilege/patent system and not the proper workings of it.

In general, history can show widespread and long-term support for a certain policy. In demonstrating lasting and substantial support, one could say that the historical perspective contributes strength to arguments for legitimacy of a social arrangement. Even if it does not

[75] Hume, D (1739-40), Book III, Part I., sect. I.

provide binding normative conclusions, the historical perspective nevertheless conveys insight into the social position of the arrangement, and thereby possibly into its moral standing. My survey of the early history of patents show a long tradition for patent protection of inventions in general. Questions whether biotechnological developments in the last few decades fit the tradition, and moral arguments against it in the current debates of the TRIPS agreement, is dealt with in the chapter Critics of WTO's TRIPS agreement below.

A SURVEY OF THE WTO AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS – TRIPS

My project discusses three issues concerning patents: 1) patent scope; 2) access to inventive and essential medicine; 3) Legitimate claims from patients in distant global regions. The WTO TRIPS Agreement touches upon all three in various ways and the following presentation of TRIPS is intended to serve as a background for the project.

TRIPS regulation of pharmaceutical inventions

TRIPS is a cornerstone agreement within the WTO protecting IP rights by obliging all member states to provide enforceable legal tools to secure minimum standards of protection of intellectual property. Depending on product category, such protection could take the form

of geographical indications, trademark, copyright, and the strongest form of protection – patents. For pharmaceutical products the legal option is sales privileges in the latter form: product and process patents of intellectual property.

If a medicine is patented, the technology behind it will not be kept secret but is disclosed through the patent application in the country granting the patent. The argument from the World Intellectual Property Organization (WIPO) is that the alternative to patents is worse, as pointed out by its Director General Francis Gurry.[76] In his address to the symposium on access to medicines held at the WHO, Geneva in 2011 he stresses that ”one of the justifications for having a patent system is disclosure of technology.” He illustrates the value of disclosure through the example of the different production histories of the saxophone and the violin. The first was patented and could be reproduced and refined by other manufacturers. The family owned violin workshops in Italy, on the other hand, did never reveal how they made the Stradivarius or other violins and therefore nobody has been able to reproduce these fine instruments. The production secrets were passed on from one generation to the next over the years until it was lost. Gurry maintains that the patent institution contributes greatly to the disclosure and spread of knowledge and concludes that ”The disclosure function has led, in fact, to the patent system constituting the most comprehensive, the most accessible and the most systematic record of humanity’s technology.”

The trade secret could be kept for an indefinite period of time, and could well be the preferred option for an enterprise that thought it could actually keep the secret for more than 20 years, and thereby enjoy longer lasting market exclusivity than a patent normally offers. WIPO’s argument is that the patent protection with its disclosure function in this perspective much better serves the interest of research. And indeed it would be the case that if the pharmaceutical formula for a particular medicine was kept a secret so that no producer other than the inventor enterprise itself could make the medicine, clearly no government decision could be made to bypass the producer in order to manufacture and distribute the drug domestically. It can therefore be argued that patents not only serve research, but could contribute to public accessibility of goods also. These are certainly contested claims, as we shall see later.

[76] Francis Gurry, Director General of WIPO in a speech to The Technical Symposium on Access to Medicines, Patent Information and Freedom to Operate, Geneva February 18, 2011. See Gurry, F (2011). The subsequent citations of Gurry are also from the speech.

The minimum period of patent protection is set to 20 years from the date of application for patent.[77] This TRIPS minimum standard is transferred to the member states jurisdictions. This way the patent holder is given time to develop, test, refine etc. its invention undisturbed by any competing party, which happened to be in the process of developing a similar technology or product. In the case of pharmaceuticals, the time spent on developing and testing averages ten years or more.[78] Applying for patent as early as possible, they have about the other half of the twenty years of patent protection, a remaining ten years, to recoup their investments. If this cannot be achieved in a competitive environment, those ten years set the deadline to cover not only this particular investment, but also the less successful projects they might have undertaken. The products that failed the extensive testing or proved inefficient or just did not make it in the market or for some other reason had to be written off, all need to be covered by earnings in the successful products. On top of this comes the owners' legitimate demand for earnings and growth.[79] If ten years prove to be less than sufficient to make return of investments, member states are free to grant an extension period beyond the minimum 20 years set up by TRIPS.

So-called TRIPS+ agreements are also being used, notably between the United States or the EU and their trading partners. These are for instance bilateral or regional agreements that give stronger or longer lasting patent protection than required by TRIPS, or they oblige countries to comply with TRIPS regulations in bilateral trade before their transition period expires.[80]

Since the chart of the WTO members[81] now covers almost the entire globe (if we include the current applicants for membership) the agreement means that there will be few places left where generic products could be made without potentially coming into conflict

[77] WTO TRIPS Article 33

[78] Reports vary on number of years spent on developing, testing and approval of new medicines. The Pharmaceutical Research and Manufacturers of America, organizing member companies which spent in total an estimated $71,4 billion on developing new medicines in the year 2017, says the time spent is between 10 to 15 years. See their web page at https://www.phrma.org/Fact-Sheet/PhRMA-USMCA-Fact-Sheet (Accessed June 24, 2021). The WHO cites a report from the Centre for Medicines Research International Ltd showing a 10 year average development period for pharmaceutical products. WHO (2006)

[79] Last reported yearly earnings (for the year 2020) before tax for the two randomly chosen companies GlaxoSmithKline (£7.8 billion) and Pfizer ($41.9 bi.) should suffice to show that there is ample opportunity to make earnings in the pharmaceutical sector under the current regime. The numbers are collected from http://www.gsk.com/ and http://www.pfizer.com/home/

[80] Helfer LR & Austin GW (2011:40); Puymbroeck, RV Van (2010:532)

[81] https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (Accessed June 24, 2021).

with patent law. Even if a place to manufacture it could be found, there would be few places to sell it legally. If the product is patented, the generic version could not be imported, offered for sale, or even used without the consent of the patent owner.

The minimum standard of patent protection sets up a number of specific criteria for patents to be granted. These are familiar from national patent law in many jurisdictions prior to the agreement. In order to obtain patent protection a process or a product must be new, it must involve an inventive step, and it needs to have industrial applicability, which means it must be useful and possible to produce in large numbers. The criteria are not defined in the agreement, so any interpretations of them are left to the legislator or patent authority in the member states.[82]

A further requirement is that the invention is to be fully described, to the extent that any person skilled in the technology should be able to reproduce the product or apply the process.[83] The requirement is important in distinguishing the patent arrangement from one of its possible alternatives, the trade secret. By making the invention public, the patent institute is thought to stimulate technological transfer between geographical regions as well as enable wider research to improve processes and products as well as wider research in the field.[84]

Much discussion has evolved around the possible unwanted effect the agreement might have in developing countries, in particular with respect to medicines. Acknowledging the special challenges developing countries could face, the WTO gave them a later deadline for implementing the agreement. Most of them got until January 2000, but those that did not offer patent protection at the time TRIPS was agreed, like Brazil and India, were given an extended transition period until 2005.[85] The least developed countries still have until 2033 to meet the obligations, that is to pass the required patent laws, set up a patent institution and make its decisions enforceable.[86]

[82] Correa, CM (2000a:51)

[83] TRIPS Art. 29

[84] TRIPS Art. 7 states the objectives of the agreement, which is to "contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge."

[85] WTO (2006b); Goswami, R (undated).

[86] The initial transition period of ten years was extended for the LDCs in the Doha Declaration. See WTO Doha Declaration (2001) pt. 7. As indicated in the Introduction above, if the LDCs apply for a new extension in 2016, the 2013 decision of extending the deadline to meet the requirements in TRIPS other than for medicines might suggest that an application for pharmaceutical products in particular might be treated favorably. The decisive point still is that the determined goal is to have The Agreement fully implemented in all member countries.

Flexibilities in TRIPS I: parallel import

As I mentioned above, some flexibility provisions were included in the agreement. They were designed to give governments in developing countries opportunity to circumvent any granted patent in that country, recognizing that patent protection could mean a steep increase in prices for some medicines. The flexibilities are not extended exclusively to low income countries. They are not specified in that respect and so they are available to all members. The two flexibilities most discussed with regard to pharmaceutical products are those of parallel import and compulsory licensing.

The parallel import provision deals with products that are manufactured by the patent holder or by his licensee. That is, they are manufactured legally and protected through IP rights law. Parallel import takes advantage of the differential pricing of products depending on where the product is marketed. A price being the result of supply and demand, here the demand side varies significantly between countries due to varying purchasing power in dollar terms between them. This makes it worthwhile for an import agent to travel where the product is lower priced and import it to the higher priced home market. The TRIPS agreement itself does not consider this an infringement of IP rights. The legal principle at work is the exhaustion of rights principle, which means that when a patent protected product is first sold, the patent holder no longer has any rights with regard to the product. The principle needs some further explication.

TRIPS deals with it most explicitly in Articles 28.1 and 6 in the Agreement; and Paragraph 5 of the Doha Declaration.[87] Marco Slotboom discusses how the exhaustion of rights principle is handled in TRIPS,[88] and I follow his exposition here. My concern is to show that, even though the well-intentioned flexibility of parallel importation is made possible under the exhaustion principle, the effect of the flexibility itself is uncertain.

> Article 28.1 states that
>
> A patent shall confer on its owner the following exclusive rights: where the subject matter of a patent is a product, to prevent third parties not having the owner's

[87] WTO Doha Declaration (2001)

[88] Slotboom, MM (2003:432-434)

> consent from the acts of: making, using, offering for sale, selling, or importing* for these purposes that product

The note regarding making, using, offering for sale, selling or importing reads: "This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6." Article 6 then, states:

> For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Articles 3 and 4, referred to in the quote, regard national treatment, saying that nationals of other WTO members shall not be accorded less favorable treatment than what is accorded to co-nationals (Art. 3). Dealing with Most-Favored-Nations Treatment (the MFN principle), Article 4 says that any advantage, favor, privilege or immunity granted to the nationals of one member country shall likewise be extended to the nationals of all other members. Slotboom holds that systems of national or regional exhaustion do not discriminate between nationalities in either respect.[89]

Taken together, Articles 28.1 and 6 can be interpreted, according to Slotboom, as saying that a third party cannot sell a patented product without the patentee or his licensee's consent unless the product is already sold in the market. If it has already been sold in the market, however, and the patent holder's right has been respected, the Dispute Settlement Body within the WTO will not accept any claims on patent violation if the buyer resells it. If the market is a low-cost market, prices in general being lower than in the home market, the margin can make import profitable. The drugs can then be sold at a lower price than the home market price, but still with profit. WTO's exhaustion principle implies that the organization will accept no complaints from the patent holder for the medicine in the importing country.

Slotboom's interpretation is supported by Paragraph 5 in the Doha Declaration, which says:

[89] Slotboom, MM (2003:433)

> The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

This interpretation is, further, in conformity with the World Health Organization's view of the exhaustion principle.[90] The WHO also sees the parallel importation flexibility as a potentially useful solution for many countries:

> Since many patented products are sold at different prices in different markets, the rationale for parallel importation is to enable the import of lower priced patented products. Parallel importing can be an important tool enabling access to affordable medicines because there are substantial price differences between the same pharmaceutical product sold in different markets.[91]

It would therefore seem that a member state filing a complaint against another member which allowed a person or a company to import medicines, bought from a retailer in a patent protected market, and resell it at home, does not have a strong case. Several commentators support this view.[92]

We should however, not overstate the significance of the opening for the possibility of parallel imports found here. Even if the WTO itself will not hear complaints regarding parallel imports (will not "challenge" it), it leaves it open to member states not only to apply rules against WTO-wide exhaustion of rights individually, but also to exert pressure against trade partners to do so. Trading partners are free to include a point on the issue in their bilateral TRIPS+ agreements.

A member country could also come under pressure to do so from a stronger party. A developing country might fear that good relations towards another country, manifest in for

[90] WHO on the Doha declaration. See also Velásquez, G & Boulet, P(1997:46-7)

[91] Ib.

[92] Loff, B and Heywood, M (2002:629, n.20); Correa (2002:17-18) holds that the Paragraph 5 "provides the sought-after clarification" and that " it certainly reassures Members wishing to apply an international exhaustion principle that it would be legitimate and fully consistent with the Agreement to do so."

example aid money and defense cooperation, could come under pressure if they are reluctant to engage in TRIPS+ talks.[93]

Another consideration that diminishes the utility of parallel import is that if it were undertaken in order to fight a widespread disease in the population, the quantities needed would most likely be significant, and possibly have a price driving effect in the market where the purchases are being done. The effect can be a higher market price in both countries.

One last problematic side with the parallel import flexibility that I should include is that this opportunity, apparently meant to allow for less expensive products in lower income markets, actually gives drug producers an incentive to stay away from lower income markets to protect the more profitable ones. From a patent holder's perspective it would make perfect economic sense to calculate the lowest sustainable price in an all-markets-considered perspective and decide that any market which cannot support this limit price is left out of their market plans. If the price is set high enough, there will be no profit opportunity in importing the goods to a low-priced market. Thereby, if not for other reasons already discussed, the parallel import provision, established by the exhaustion principle, threatens to counteract its very purpose.

Flexibilities in TRIPS II: compulsory licensing

Compulsory licensing can be put into effect by a member state without any foregoing contact for agreement with the patent holder in cases of public non-commercial use, a national emergency or "other circumstances of extreme urgency."[94] In circumstances like these, a member state can legally extend a license to a manufacturer of choice within the country to produce the patented product. This exceptional measure is limited in scope and duration to the particular case at hand and so it cannot be counted on for public health planners or other agencies with long-term perspectives. On the face of it, it would seem particularly suited for fighting epidemic diseases and not for ordinary vaccination programs for example, even

[93] This has been pointed out by Hoekman, BM and Mavroidis, PC (2000) talking about why developing countries might be unwilling to bring cases for the Dispute Settlement Body within the WTO. The same kind of pressure could also apply to bilateral negotiations of TRIPS+ agreements. Hoekman and Mavroidis stresses that asymmetries in negotiating power within the WTO could undermine its mission being "a rule-based as opposed to a power-based system of trade relations," (p. 530)

[94] WTO TRIPS Art. 31(b)

though any emergency or extreme urgency can provide a sufficient reason to invoke it. However, the TRIPS agreement does not specify what sort of non-commercial use could qualify for taking advantage of the flexibility, or when a national health problem becomes an emergency. The Doha Declaration states that "[P]ublic health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."[95]

It leaves each of the member states to decide when government use of any patented medicine for example calls for a compulsory license. Immediately preceding the previous citation, it is declared that:

> Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency[.]

In a document published by the WHO, authored by Carlos Correa he draws the consequence that in cases where any such decision is contested, it is the complaining party that has the burden of proof and therefore must show that there is no emergency.[96]

As it turned out the use of compulsory licensing is not so readily available as one would think just by reading the TRIPS agreement. This is mainly due to pressure exerted on one member state by another, or on a generic drugs company by a brand name company and not from the WTO as such. This is not a minor matter when assessing the TRIPS agreement, because the soon to be ubiquitous patent laws provide a new tool, where no such effective tool existed before, for exerting pressure, of the prospect of trade sanctions for example, on any party that crosses the interests of a patent holder.

Furthermore, the compulsory license flexibility is practical only insofar as the member country in question has the resources and facilities required actually to produce the medicine which is needed there.

If the country does not have the technology, there is an opportunity for technology transfer through compulsory licensing of a patented product. The country still needs to possess the necessary financial resource and have suitable facilities in place in order to be capable of making good on the technology. In practical terms, it must have a pharmaceutical production capacity. Since this particular capacity is limited in many countries, not only

[95] WTO Doha Declaration article 5(c)
[96] Correa CM (2002), p.vii

developing countries, they are not able to make use of the compulsory license flexibility themselves, but need the cooperation from other countries that have the capacity.

Initially, TRIPS restricted the use of medicines made under compulsory licensing to the domestic market in the producing country. Imports from a cooperating country were not allowed. For a country with sufficient capacity within its own borders, the manufacturer was therefore cut off from the benefit of economy of scale, which could only be obtained by selling in a larger market. This country was not allowed to export to a country lacking capacity, but hosting patients.[97] Since the purpose of the provision was to keep the price on medicine at an affordable level for patients in a low cost market, the restriction threatened to render the compulsory license flexibility useless.

Therefore, through a WTO decision of August 2003, the import of drugs from a country with a pharmaceutical industry into a country lacking this resource was legalized. Correspondingly, it was legal to export to a country on these terms, under a compulsory license. The WTO does not have to be consulted for this. It is sufficient that they are being informed.[98] Several members have since reported that they have changed their laws to legalize exports of medicine under compulsory licenses, among them India and the EU. As it turns out, importantly, few if any medicines have found their way to the LDCs through this opening[99] indicating that this addition to the Agreement does not work according to the intentions of the Doha ministerial meeting instructing it.[100]

It remains a fact that a compulsory license has to be issued in order to start the production of the cheaper drugs and that the quantity produced must be limited to the importing country's need. The initiative for a compulsory license is more likely to come from health authorities within a country than from any generic drugs company. The generic drugs industry therefore loses its freedom to initiate the production of any medicine, a freedom they had in a not patent regulated market. The situation is very different from before TRIPS, when the generic drugs industry competed with the inventor corporations (on privileged terms, it should be noted), but also internally, with other generic companies. In economic terms, regarding the profitability of generic firms, consequences are uncertain. The reason is that the

[97] A concern later acknowledged by WTO. See WTO (2003:pt.6)

[98] WTO (2003:pt.2)

[99] As of 2010, according to Kohler, Lexchim, Kuek & Orbinski (2010). Their article tells a story, from Canada, indicating the complexity of export under compulsory license even after the license is given. Matthews (2004:97) also points to the "burdensome procedural arrangements" involved in making use of the compulsory licensing provision.

[100] WTO Doha Declaration (2001:pt.6); WTO (2003)

generic drugs industry is active also in the high cost markets of the industrialized world, and make much of it profits there. For example, its share of total prescription drugs in the United States in 2015 was 89%.[101]

Dispute settlement and enforcement

I include one point, which deserves particular attention, in my view. It concerns dispute settlement and enforcement of the Agreement. This is in fact a major point since it is what sets TRIPS apart from the preceding arrangements.[102] The legal opportunity to global enforcement of IP rights is introduced through TRIPS. It empowers the WTO with dispute settlement procedures available to members who want a neutral body to resolve conflicts instead of being left to the risk of unilateral sanctions from the other party in a conflict. In the last resort TRIPS' enforcement procedure provides the WTO with the capacity to authorize trade sanctions against a non-complying member. This enforcement capacity, central to the Agreement, is however more useful to big-market members than to weak-market members and therefore hands out a considerable advantage to the former.

The resolution and enforcement of disputes works not by the WTO itself surveying the markets. The WTO's function is to settle disputes among its members through its Dispute Settlement Understanding (DSU). Patent holders therefore watch the market themselves. What is provided by the Agreement is the commitment of the WTO member states to build and enforce legal provisions to protect IP rights themselves. If a patent holder suspects that a competing enterprise is violating its patent, a natural first step would be to seek to come to an understanding with the other party. Only if no result is produced from such attempts, the patent owner could turn to the country where the patent is granted (and supposedly violated) and test the legal case there. If the country does not provide the minimum standard of IP rights protection as laid down in the Agreement, the patent owner can appeal to the WTO, but not directly, only through a member state.[103] This state, most likely the patent owner's home state, can take the case to the Dispute Settlement Body (DSB) within the WTO. According to

[101] Institute for Healthcare Informatics, (2016:46)

[102] Correa, CM (2000:2); Lumina, C (2010:2).

[103] Matthews (2002:89ff.); Hoekman, BM and Mavroidis, PC (2000:529f)

the Agreement, the home country will not impose unilateral sanctions against another member. Instead, they are bound by The Agreement to take the case to the DSB.

The DSB has the mandate to allow for trade-related sanctions if a detailed and stepwise procedure of consultations and hearings does not result in a settlement between the parties. A complaining member can be released from the WTO trade commitments towards the other state. In other words it can, legally, impose trade sanctions towards that other state.

The sanctions weapon being the enforcement tool is, as just indicated, a problematic trait with the Agreement with regard to equal treatment of members. Since sanctioning powers vary between states it has been argued, reasonably, that some members benefit more from DSB rulings than others do.[104] The EU for example, which has single membership in the WTO, is a much bigger market of course, than say, a low cost market in one single African sub-Saharan member country. To shut out a member from the home market is therefore not, one can safely say, a tool distributed to all members in equal shares.

Arguably, this point about the unequal enforcement mechanism would suffice quite by itself to qualify a demand for compensatory provisions for the weak-market member countries. It is a significant weakness of the Agreement because it in fact reserves effective enforcement tools for rich countries.

The reason the developing countries accepted the terms in TRIPS generally, enforcement rules and pharmaceutical patents alike, was their access, promised through TRIPS, to agriculture and textiles markets in the developed countries.[105] The unevenly distributed enforcement tools raise questions about the justification of the Agreement, and the issue of how to compensate for the weakness.

[104] Hoekman, BM & Mavroidis, PC (2000:531); Rae, F (2010)

[105] Velásquez, G & Boulet, P (1997:10f); Loff, B and Heywood, M (2002:623)

CRITICS OF WTO's TRIPS AGREEMENT

This thesis does not question whether it is the case that the protection of IP rights stimulates the development of new and useful technology. This issue is a wholly empirical matter and conclusive evidence has not been provided.[106] The proposition that IP rights protection might have this wanted effect is taken as a premise. The discussion instead centers on how IP rights protection is defined, justified and enforced for biotechnological and pharmaceutical products and promoted by the introduction of the TRIPS minimum standard in the WTO countries.

Grossly uneven access to the inventive products is taken to be unwanted effects by all parties, the relevant authorities, the public and the industry producing the goods. Rather, uneven access is seen, by the drafters at least, as a price that is paid for the protection mechanism that brings about the new inventions. People not having access to the new medicines must be given a justification, explaining why uneven access is inevitable, if it is.

One such justification might conceivably be that the alternative to the patent system is that no other system exists that provides the opportunity to recuperate development cost through sale of medicines. Because they are fairly easy to copy but costly to develop, future lifesaving medicines need the protection. The resulting uneven access is preferable to a halt

[106] Sterckx, S (2006) holds that "The availability of patents does result in more inventions; this is a fact which should not be questioned [..]." DeCamp, MW (2007:87-90) cites reports on a positive effect of IPR protection in the form of patents for the investment-intensive developing of new medicines. Others dispute the high level of these development costs, and therefore the purported effect of patents. DeCamp discusses the methodological challenges connected with determining this empirical issue referring to disagreement on facts as well as reliance of conflicting and selective data sets (Ib. p.91). Mansfield, E (1986) is an empirical study suggesting that the effect of patents is generally modest except from two industries, pharmaceuticals and chemicals. Oddi, AS (1987) argues from a net social benefit perspective that even if patents create such benefit in the developed countries, there is no case to prove that the granting of patents to foreign enterprises stimulates foreign investment or development in general in developing countries. Mazzoleni, R and Nelson, RR (1998) finds that with the exception of the pharmaceutical industry, which is "a technological field where patents clearly are effective", the effect is absent in a broader picture. One important reason is, they argue, that patents raise the entry barrier for new firms, particularly in the developing world. Thus, countries like Japan , Korea, and Taiwan, which developed their manufacturing industries largely without enforcing patents from other countries, would have met difficulties accomplishing this development otherwise. For the related issue of access to inventive medicines for developing countries, Hestermeyer, H (2007:146) comments on economists' view of the system of differential pricing – which sets prices lower to optimize price against national demand: "The system is elegant in that richer countries contribute more towards the cost of research and development than poorer ones and it has been widely praised by economists." (Hestermeyer has reservations, referring to developing countries with a relatively large wealthy segment of the population sustaining prices comparable to those in developed countries).

in development of new medicines, which is an imminent threat if the patent system is removed.

This line of argument does not, however, solve issues of uneven access of existing medicine. Only if it were shown that the uneven distribution is an inevitable effect of patent protection, one could start to build a consequence-based normative defense of the uneven distribution of essential goods which is, supposedly, necessary to protect innovation itself.

A normative objection to a policy which allows that the least privileged pay the highest price for the introduction of IP rights could possibly be based on John Rawls' difference principle.[107] The principle says that whatever their level, if social and economic inequalities are attached to offices and positions (that is, they are systematically built into economic and social life), they are to be adjusted to be "to the greatest benefit of the least advantaged members of society."[108]

If the least advantaged get worse off by the nearly global IP reform it is clearly in conflict with any plausible interpretation of the difference principle. If the situation of the least advantaged is not affected it can be argued that any adjustment is unjustified. What it means for the least advantaged to enjoy the greatest benefit is, however, a disputable matter. In this formulation of the difference principle, from Rawls, we see at least two possible interpretations, that i. of any reform under consideration the one with the best outcome for the least advantaged is to be chosen, or ii. the alternative is to be chosen which favors the least advantaged the most in comparison to the relative improvement of the situation of the well-off. Only the second interpretation provides an argument against inequality.

Rawls himself, in a clarifying note, adds: "[E]xisting inequalities are to be adjusted to contribute in the most effective way to the benefit of the least advantaged."[109] In this note we find support for interpretation i. which allows for inequality to increase so long as the adjustment is the alternative that most favors the least advantaged. Indeed, this is how Thomas Pogge sees it in his critique of Rawls' neglect of a person's relative position.[110] Pogge sees no justification for the claim that people will choose (in the original position) to maximize their position in absolute terms as contrasted to relative terms. The requirement that they so choose "involves the assumption that in assessing institutional inequalities,

[107] Rawls, J (1993:6-7)
[108] Ib. p7
[109] Ib. n5
[110] Pogge, TW (1989)

persons (as represented in the original position) take an incommensurably greater interest in their *absolute* than in their *relative* index position. For the simplest case of income and wealth this assumption is quite clearly implausible, in Pogge's view. Some of "the good things in life" are positional goods. Access to them is scarce and therefore competitive."[111]

Whichever interpretation of Rawls' difference principle is applied, the principle can consistently provide a normative foundation for rejecting an adjustment causing the least advantaged to be the social group excluded from benefiting from new medicines, and particularly if an alternative can be presented that improves their condition in either terms.

It is a matter of debate whether the difference principle indeed has application outside the domain of enclosed societies like the state. Rawls himself rejects the principle's validity in the international sphere, not to mention on the global stage.[112] A global difference principle would, as I interpret it, be contingent on a global political institution being established with the authority to administer the principle and having powers to enforce it. The difference principle is however rarely advocated by critics of the international IP rights standard. This could be for the above reason and possibly others. A notable exception is Pogge, who criticizes Rawls for not taking the difference principle further, into the international realm.[113]

An opportunity is perhaps missed here, with regard to IP rights specifically. The opportunity is that a new institution would not have to be set up in order to administer the difference principle. In the case of IP rights this institution already exists. WTO is the global organization administering TRIPS as the minimum standard for IP rights in all member countries and also enforcing the Agreement. An argument could be made that the difference principle should have applicability for decisions in this organization, to the effect that they cannot imply that the least advantaged members will not benefit from them. The WTO members being states, not people, would imply that consequences for states, their markets, industries, healthcare systems etc. would have to be considered.

I consider Pogge's standpoint to be compatible with this argument, although he is more general in his critique of Rawls in the text just referred to. We see this in his reference to "the global economic order" and "global economic justice."[114] One could argue that abstract concepts like these invite further global institution-building compared to what is already in place and with having wider authority than today's global institutions.

[111] Pogge, TW (1989:198)

[112] Rawls, J (1999:116), criticized by Charles Beitz in Beitz, CR (1975).

[113] Pogge, TW (2002:110-5)

[114] Expressions taken from subchapter titles in Pogge, TW (2002).

Global justice cosmopolitanism is a recent addition to the classic theories on the distribution of goods, namely the Lockean natural rights tradition and consequentialist ethics. It is represented by, among others, Beitz and Pogge and runs parallel to Rawlsian liberal theory even if it, as noted, departs from it for example in the view on a global difference principle. Regarded as a moral theory, global justice cosmopolitanism arguably shares Rawls' liberalism, but not his state centered view. Assessed as a political theory however, the liberal status of global justice cosmopolitanism is more doubtful, in that in the last instance it would have to imply large, even global political bodies with far-reaching and strong authority. In line with his rejection of applying the difference principle on a global level, Rawls himself rejects the realization of a world government, the ultimate consequence of the idea of global justice cosmopolitanism, regarded as a theory of political institutions.[115] In The Law of Peoples, Rawls refers to Kant's rejection of the world state in Toward Perpetual Peace[116] and describes a world government with "the legal powers normally exercised by central governments" as global despotism.[117] The world state's only alternative to despotism, he holds, is a fragile empire characterized by internal strife, not obviously preferable as an alternative.

It is not the political version of global justice cosmopolitanism which will be discussed here and in the articles, however. The focus and attention is concentrated on the moral theory cosmopolitanism, following Pogge's distinction between the two forms of cosmopolitanism. This distinction is presented in *The Distant Moral Agent*, p. 102-3 below.

Two aims in introducing IP rights stand out in the ASEAN workshop report[118] cited in the Introduction. One is to promote new "ideas, inventions and creations," through exclusive property rights, the other is to make them available for others to improve them. In the case of vital goods such as medicines, the availability of the final products is the pressing issue. New therapeutic solutions are welcome for health sector policymakers, and even more so if there is wide distribution of the new products. The "contradictory aims" the report points to are, in the shortest possible version, promotion and exclusion.

In the following I shall use the texts already referred in note 3 above to present the normative criticism of IP rights established by TRIPS. I shall start with Thomas Pogge who

[115] The realization of this final idea has little support though, it is fair to say, even from political cosmopolitans.
[116] Kant, I (1796:91, Ak 8:367)
[117] Rawls, J (1999:36)
[118] Timmermans, K and Hutadjulu, T (2000), (eds.)

holds that there are grave foreseeable consequences of introducing the TRIPS standard as a minimum level of IP rights protection in developing countries. The foreseeable consequences are that a great number of people suffering from life-threatening diseases will not have access to new medicines due to high prices resulting from patents.[119]

Whether they had access to new medicines before TRIPS, is not a settled question. Generic medicines are the less expensive alternative to brand name drugs. The term refers to the chemical composition, not the brand name of the drug.[120] They may be produced by license from the patent holder. If there is no patent on the drug, or if the patent has expired, the generic drug is legally produced license-free. The quality of the drug is the same as the brand name drug because it is chemically identical to it. The explanation of its lower price is mainly that the development- and approval costs are lower or non-existent, and there is no need to recover such expenditures through the sale of the product.

Pogge's point is that poor patients could and should have this access, and that the situation is made worse by the introduction of IP rights in these countries, where product patents were not offered before.

Generic medicine may be legal and less expensive, but can be unaffordable nonetheless for the poorest, struggling to secure food and shelter. When patents on pharmaceutical products are introduced in these regions there are two immediate effects, 1.) The generic medicines available on these markets are made illegal by the introduction of patent on the brand name drug and therefore disappear from the market. 2.) The production of the generic drugs stops, so that even in the event of an emergency, supply of the drugs may be delayed, as new production must be set up to provide generic low-cost medicines.[121]

By 2005 the deadline had come for India to implement the Agreement, through its WTO membership. The Indian legal system had until then only provided for IP rights on processes, but not on products. Prior to the introduction of product patents the pharmaceutical sector in India was able to build a thriving industrial production of generic medicines. As long as they did not use the same process for manufacturing a particular drug, inventing around it instead, they could legally produce the same or a very similar product as the one under patent. With the introduction of product patents in 2005, this production was no longer legal.

[119] Pogge, TW (2002).

[120] Shiel, WC Jr. (undated)

[121] Cf. WTO TRIPS Art. 31(b) on "use without authorization of the right holder," discussed in the section above: The flexibilities within TRIPS II: compulsory licensing.

The two foreseeable effects of the new patent regime, that both the everyday sale and the supply of cheaper medicines in the event of emergencies came to an end, could have the consequence that many patients who until now had access to life-saving medicines now are left without such access. Others will be even further from getting access than they were before TRIPS. An ethical side of this is that since the supply of the goods stopped, not by a natural disaster like drought or some other external event, but through a political agreement, the termination of sale and supply needs to be justified to those negatively affected. It also needs to be justified why the agreement places the burden on this particular segment of the population.

Pogge asks why the rights of the inventor should outweigh the rights of the poor, instead of the other way around. In this framing of the problem, the right he ascribes to the poor is the right to life for those who lack medicine.[122] The property right he refers to is the natural right to the fruit of one's own labor in the Lockean tradition.[123]

Quite independent from the personal desert consideration, taken as a basis in the Lockean tradition, there is also the public interest justification of IP rights. Pogge describes it as the argument from beneficial consequences, thereby spelling out the consequentialist ethics behind it.[124] Whichever justification is chosen, it must outweigh the right to life of those who lack medicine, in Pogge's setup.

Further, he questions TRIPS as the only possible realization of a natural right to intellectual property, if there is any such right. TRIPS is now becoming the standard for how IP rights are to be defended and enforced. The duration and extent of protection following the forms of protection in patents, copyrights, and trademarks is only one possible interpretation of IP rights, he argues, and this is not necessarily a good one. Historically there have been many national intellectual property regimes and one may ask what makes this one a particularly apt vehicle for intellectual property rights. Pogge warns that we should not accept the false dichotomy asking us to accept the emerging IP rights regime or else have no invention at all.[125]

The third and last point I include from Pogge's critique is related to the previous. It concerns the process leading up to the TRIPS agreement. There was asymmetry in negotiating power between developed countries and developing countries that invited

[122] Pogge, TW (2002:227)
[123] Ib. p. 228
[124] Ib. p. 230
[125] Ib.

questions as to the fairness of the result.[126] The European Union, the United States, and Japan had formed an alliance, backed by their respective industry experts.[127] This alliance had a substantial advantage in terms of legal expertise and sheer manpower for enduring the long and complex talks. They produced a detailed proposal for an agreement, authored by intellectual property right specialists, laying down the premises for the talks through this initiative. Against the power play from the alliance, the negotiators on the side of the developing countries were bureaucrats from national trade ministries or even in many cases Trade Counsellors from the various countries' UN missions to Geneva.[128] Pogge refers to the detailed proposal from the alliance saying, "Back then, poor-country representatives were facing some 28 000 pages of treaty text drafted in exclusive ('Green Room') consultations among the most powerful countries and trading blocks."[129]

Moreover, it is recalled by Pogge that the home authority of some of the developing countries signing on to the Agreement (if there was any genuine choice) hardly kept a priority interest in the health and food situation of the respective populations at all. These states were run by corrupt leaders with other personal agendas and included Nigeria's General Sani Abacha and Suharto in Indonesia.[130]

One other matter has been brought up by Morten Tvedt who shows that even in liberal democracies,[131] the lack of public debate prior to the adaptation to new IP laws warrants questions as to the openness of the process of adapting the legislation to WTO demands.

Carlos Correa makes it clear that two major concerns were addressed after the Agreement was successfully completed, namely the situation in developing countries and specifically the potential negative effect of the Agreement for public health there.[132] Fronted by WTO's African group, developing countries pressed for an improved solution for countries with no capacity for a pharmaceutical industry, now with a prospect to be deprived of generic medicine. This pressure was productive in making the WTO ministers reiterate and

[126] Alternatively it could be seen as a grim example of how power makes right in the unregulated field of international negotiations.
[127] Matthews, D (2002:44)
[128] Ib.
[129] Pogge, TW (2002:233)
[130] Ib. p. 234
[131] Tvedt, MW (2010:81) Tvedt's studies concern Norway, which did not allow patents on pharmaceutical drugs prior to TRIPS implementation.
[132] Correa, CM (2000a)

also to a certain extent expand the exceptions already built into TRIPS to reaffirm the developing countries' right to use these exceptions.[133]

I regard the two exemptions, parallel imports and compulsory licensing referred to by Correa (in this document for the World Health Organization) and described in more detail above, central for the discussion of access to essential medicines in the least developed countries (the LDCs). I therefore chose to concentrate on these issues in my presentation of the TRIPS agreement and its weaknesses, above.

Sigrid Sterckx has pointed out that medicines cannot be excluded from patentability under TRIPS.[134] The instrument available to developing countries is therefore exceptional provisions to make up for any unwanted or harmful effects of patents. The unwanted or harmful effects, in my framing here, are thereby projected as more or less likely outcomes, or side effects, by the drafters themselves. Another aspect of the unwanted effects is that they present moral questions in addition to legal ones. If the effect of some new legislation is that the health situation for large numbers of people deteriorates substantially, that it must be expected that many people will end their lives prematurely as a result, the critique against this legislation will be of a moral character. In our case, the number of poor people living in developing countries is in the hundreds of millions.

Accordingly, the justification of the new measures needs to be of a moral type. Sterckx examines natural rights in the Lockean tradition, utilitarian ethics and distributive ethics based on fairness arguments. Like Pogge she holds that the extensive property rights conferred on inventors by the TRIPS standard are insufficiently justified by natural rights arguments, by fairness arguments, and finally by the incentive-based utilitarian approach. I will give a brief outline of some of her arguments here, in order to expand on the issue of ethical concerns around the new IP regime, postponing the discussion to later.

Sterckx sides with Peter Drahos in holding that intellectual property rights are "less socially neutral" than other property rights: "They interfere to a greater extent with the rights of others, because of the non-exclusive character of the objects of intellectual property rights."[135] Their non-exclusive, or non-rivalrous,[136] character is due to their distinct quality of being easily reproduced and distributed, like a recorded piece of music, but unlike physical

[133] WTO Doha Declaration (2001)

[134] Sterckx, S (2005:83)

[135] Ib. p. 82

[136] The term non-rivalrous is often used for describing goods whose use by one person do not diminish their availability to other persons. This term, borrowed from economic theory, describes some physical phenomena like light, but is a characteristic quality of ideal objects generally. See Tvedt, MW Ib. p.48-9

property like a piece of land. This trait sets intellectual property rights aside from rights to tangible property and, as a consequence, Lockean property theory is not a suitable match when it comes to justifying IP rights.

Sterckx also notes that a large majority of the new drugs are so-called me-too drugs, i.e. almost identical to already existing drugs apart from a minor and often non-consequential modification.[137] The amount of "labor" put into these products is clearly less than sufficient to qualify for ownership in the Lockean sense, she argues. Thus, the argument from mixing labor with nature, essential in Locke's reasoning,[138] fails in such cases.

Regarding her second type of arguments, from fairness, Sterckx attends to the consideration that scientists who serve society by the inventions they provide purportedly deserve protection from free-riders. Her first objection against this consideration is that if fairness were the primary concern, it would also have to cover patients and require their equal access to drugs. The patent system works against this aim, therefore the fairness argument is not successful.

It is also unsuccessful on other accounts, according to Sterckx, but I will not go into all of them. One other argument should be included, though, because it is particularly relevant for my discussion, especially in the article *Ethical Reasons for Narrowing the Scope of Biotech Patents*, below. Her objection is that the rewards granted to inventors are excessive, and thus fails on the fairness account. To justify it, she points to the fact that patent holders in the pharmaceutical industry often, and successfully, try to obtain extensions of the protection term of their patents. In the article below, I will use examples from gene technology to expand on why product patents in scientific research are systematically excessive. Unlike Sterckx however, I do not apply fairness arguments to show this, but look to the patent claim's unconditional connection with the product, inviting excessive claims, i.e. claims that go further than the anticipated usefulness of the invention. This approach will be explained in due time.

Richard Ashcroft and Dan Brock both discuss long-term versus short-term consequentialist concerns in respecting IP rights generally.[139] Directed at an argument made by David Resnik, implying that long-term losses will follow short-term gains if IP rights are not respected, Brock responds that this is not settled. The long-term loss is, as conveyed by Resnik, that inventive corporations are likely to be less cooperative towards countries that

[137] Sterckx, S (2005:86)

[138] Locke, J (1690) chap. V §27

[139] Ashcroft, RE (2005); Brock, DW (2001)

breach IP protection laws compared to states that comply. Therefore, if a short-term gain is achieved in the form of relief in a health crisis, the long-term price for this temporary relief is too high. Brock disputes that a long-term loss necessarily follows from ignoring patents in order to take care of immediate health issues in a population. As long as the effect in the long term is not certain, he holds that there is not sufficient moral reason for a state to oblige with IP rights agreements. Instead it should do what is required to save lives and protect health within the population.[140]

Ashcroft turns this around and argues that the prospect of long-term gains should not be relied upon unless the short-term need for protection of life and health is respected. Holding out the Hobbesian war as the abysmal alternative, he states that property rights are not fundamental, but instrumental for the state's very purpose – to protect citizens from violence. The most important function of the Hobbesian state, he reminds us, is to prevent the state of war. Private property is a tool, among other tools, invented by the sovereign precisely to accomplish it.[141] Property rights are thus to be considered one of the requisite instruments to maintain a stable society. Along with this goes government's "powers to protect the public safety in health emergencies."[142]

From this contract theory standpoint, he argues against natural rights theory which holds that "property rights can be created by natural ingenuity and labour alone, without state power being required to create them"[143] that even libertarians have to realize that state power, once established to protect property rights, also "could underpin special powers to protect the public safety in health emergencies."[144]

Ashcroft argues that even a strict libertarian theory of property rights would have to admit of a minimal state in order to protect property. The requisite state powers to "protect the public safety in health emergencies" would therefore already be in place[145]. His conclusion is that there is no strong libertarian argument against government involvement in meeting the health needs or rights of the population.

Ashcroft takes up another issue, which is treated at some length here, namely the question of how to identify specific agents with perfect duties to assist in cases of any public health disaster. He assigns this responsibility to states, which is reasonable given the fact that

[140] Brock, DW (2001:36)
[141] Ashcroft, RE (2005:132)
[142] Ib. P. 139
[143] Ib.
[144] Ib.
[145] Ib.

this is the social institution managing the IP rights through legislation and enforcement and membership in the WTO. The issue is particularly relevant for my discussion in the article *The Distant Moral Agent*. Ashcroft grounds this perfect duty in the sovereignty of the state.

Through sovereign jurisdiction over an area where the victims of a disaster are situated, duty follows. He thereby relates the duty of the state to aid the victims with the very legitimacy of the state, as I see it.[146]

Brock argues that states are justified in rejecting "the cooperative strategy" of the international IP rights regime, or the contract between states in his case, by referring to the significant circumstance that profits of the pharmaceutical industry from patented products are earned in developed states, not in developing ones. Therefore he concludes that "whether or not developing countries respect product patents will not significantly restrict research and new product development[.]"[147] I discuss this issue in the article *Patent Funded Access to Medicines*.

[146] More precisely, I am referring to the legitimacy of government here. More on the separation of state and government and legitimacy in the section Human Rights, Legitimacy and Moral Claims below.
[147] Brock, DW (2001:36)

PART TWO

The articles

Ethical Reasons for Narrowing the Scope of Biotech Patents

Introduction

The patents that are commonly issued for innovations in the biotech field have provoked questions about whether they actually stimulate or impede technological development through their exclusive rights to use information. This article argues from the assumption that patents can stimulate investment in technological development, but shares a widespread concern that they often come with an unjustified broad scope of protection.[148] The World Intellectual Property Organization describes this worry when noting that "there is concern that some gene patents are, for example, drafted too broadly, with the effect of over-compensating the patentee by covering all future applications."[149] I argue that their overly broad scope of protection comes from extending the protection to products, in other words that applying the product category is what gives the excessive protection. Whereas, traditionally, property rights were held for products, in a time when trade in material goods was the rule, trade in gene code or other biological information is, by comparison, less dependent on specific products. Information intensive goods that are not protected by copyright but rather by patents take up a middle ground between the two areas and I argue that a revision of the product patent needs to be considered regarding these goods.

[148] Nuffield Council of Bioethics (2002); Macer, DRJ (2002)
[149] Ropp, A & Taubmann, T (2006)

Through a discussion of the traditionally strongest justificatory resources of patents, namely Locke's theory of property[150] and utilitarianism, I argue that the justification and delimitation of patents on today's DNA products need additional resources. I suggest that an analytical focus on the product patent category indicates that this category must be reconsidered in the case of information-intensive technologies like the industrial exploitation of DNA material. The article starts from the debate on the distinction between inventions and discoveries that has played a prominent role in the debate on biotechnology patents, due to inventiveness requirement of patent law.

The invention criterion

For a technological product or process to be generally eligible for a patent it must meet certain criteria laid down in patent law. One such criterion is that the invention is new. Hence, it must be settled through the application process that the product or process represents a novel thing or method with regard to the current state of art. Next, it is a requirement that the invention is useful; a point that indicates that what is at stake from the lawmaker's point of view is not first and foremost the protection of property rights, but rather to promote inventions that benefit society. Lastly, the new product or process must meet the non-obviousness requirement,[151] or inventive step requirement.[152] Distinctive for the non-obviousness- or the inventive step requirement is that the new product or process is to represent an invention and is not merely a discovery of some already existing natural thing, process or method. This last requirement has proved particularly problematic in the field of biotechnology where it might be hard to draw the line between what is an invention and what is a mere discovery.[153]

Traditionally the distinction between inventions and discoveries was not too hard to make. David Resnik makes the point that more recent technologies have made it a challenging task to separate between invention and discovery or between products of nature

[150] Locke, J (1690)
[151] 35 U.S. Code § 101-3
[152] The European Patent Convention Part II, Art. 52 (1); WTO TRIPS
[153] Westerlund, L (2002) ch. 2, Invention or Discovery

on the one hand and products of human ingenuity on the other.[154] He points to the non-contentious fact that when Galileo observed Jupiter's moons in his telescope, and he was the very first to see them, this was clearly a discovery and not an invention.

According to Resnik completely different cases are to be found in more recent events in the natural sciences, like when the existence of neutrinos or other subatomic particles was established. These particles, that are non-observable without sophisticated laboratory equipment, took a great deal of human ingenuity to find or to lay bare, so to speak. According to Resnik it is precisely the high level of human ingenuity in advanced science that makes it hard to distinguish between invention and discovery. To separate mere discoveries from patent qualifying inventions he asks, "[h]ow much human ingenuity is required to transform an item from a product of nature (or discovery) into a human invention (or artifact)?" (Ib.) Resnik traces the distinction between products of nature on the one hand and products of human invention on the other back to Locke's theory of mixing labor with nature, thus firmly grounding it in the liberal tradition's discussion of property rights.

Since what is advanced science today will become a standard procedure tomorrow it is however not easy to determine what levels of sophistication would qualify a discovery to pass as an inventive step. After all Galileo's telescope, outdated in our time, was a highly advanced instrument in his day. A great deal could be said, and has of course been said about his ingenuity as well. Still, we consider his finding of Jupiter's moons a discovery. For these reasons we should take care not to lean exclusively on the sophistication level in equipment and ingenuity to decide in invention/discovery cases.

In biotechnology, as in physics, the same distinction needs to be made in order to determine patent eligibility. Whether any biomaterial at hand qualifies as an invention, to be contrasted with an independently existing biomaterial, must be settled, given existing patent law, with recourse to some decisive criteria separating man-made from natural, or ingenuity in creation from ingenuity in detection and discovery. Here again the natural and unaltered entity would be possible to discover through instruments, microscopes rather than telescopes, or directly as when a new animal species is discovered. When the species is found in its natural environment we have a clear case of a discovery.

Considering biotechnology, why is it that matters become more intricate here? Even the very effective, but quite low tech method of animal breeding brings out the evasiveness of the demarcation. In conventional breeding modified biological entities, like plants with properties

[154] Resnik, DB (2001:36-9)

that are in demand, are patentable.[155] The Diamond v. Chakrabarty case in 1980 is commonly held to have been the opener of this legal opportunity. Chakrabarty's oil consuming bacteria were produced prior to recombinant DNA technology, using conventional methods that were nevertheless sufficiently ingenious to qualify as inventions in patent terms.[156]

Conventionally modified biological entities are products of manipulation techniques utilizing purely natural, or biological, processes. Because they would not have existed if not for human interference they have been regarded inventions as far as patent practice is concerned.[157] These organisms are purely natural creatures, the outcome of biological processes, but not indisputably natural products in the market place.

Why is it necessary to determine whether this living product of conventional breeding is an invention or a discovery? The distinction seems to be unjustifiedly imposed when applied to any particular breed of animal from a mere ontological viewpoint. Since it is a product of purely biological processes and there is no technological interference involved – the only interference being selection – one would be hard pressed to sort the final fish or mammal under the human inventions category in the ontological sense. On the other hand, the resulting fish or mammal is neither a discovery, in the same sense as a newly observed species in the wild is a discovery. An answer to the question why it is necessary to determine whether the animal is an invention or a discovery is, trivially, that patent law requires it. This answer however only explains why the distinction is required in any particular case, not that it makes good sense.

The evasiveness of the demarcation or the sense of an imposed distinction holds through the spectrum from low tech to advanced biotechnology although it does not systematically intensify with more intense use of technology as Resnik suggests. Examples of technology-intensive modified living things are transgenic plants or animals. They result from the insertion of one or more genes taken from another species into one plant or animal. The most famous example to date is probably the Harvard mouse with the added oncogene. Before a transgenic animal can be patented it has to be justified that the animal is an invention and not a discovery. From a legal standpoint the dividing line could feasibly be moved in order to accommodate political developments or aims, at least to a certain extent. In biology or philosophy this option is not available. If the legal meaning of an invention departs

[155] Sagoff, M (2002:424-5)
[156] Wilson, J (2002:25); Sagoff, M op. cit., p. 425
[157] Westerlund, L Ib. p. 29

radically from the conventional notion, in this case the biological and philosophical one, the concern is therefore that the ensuing regulation loses ground in terms of legitimacy.[158]

Li Westerlund shares Resnik's premise that it is increasingly the case that we cannot clearly distinguish between inventions and discoveries in biotechnology. Westerlund therefore sets out to "find a definition of 'invention,' which does not correspondingly further reduce the notion of 'discovery.'"[159] Resnik's conclusion is that we should not occupy ourselves much longer with a fading distinction but instead turn our attention towards the purpose of the distinction when it comes to patent eligibility:

> [T]here is probably no metaphysically significant difference between a DNA sequence in the wild and an isolated and purified sequence. A DNA sequence is a DNA sequence, wherever it occurs. Many DNA structures, functions, and processes are borderline cases for the PON/POHI [product of nature/product of human ingenuity], and we must decide how to classify them. To do this, we must ask ourselves, "what are the consequences of calling a DNA structure, function, or process a product of nature or a product of human invention?" In more general terms, we want to know the consequences of a particular classification for science, medicine, business and the economy, culture and society.[160]

Resnik does not regret this seemingly lack of a sufficiently clear criterion for separating between inventions and discoveries.[161] What we should be concerned about in discussing patent criteria is not the metaphysical question, but rather "the consequences of calling something a product of nature or a product of human ingenuity," he says.[162] The larger question concerns what benefits science and in turn patients and consumers, and what function patents have in creating incentives for the advancement of scientific research:

> If we call all DNA structures, even those produced under laboratory conditions, products of nature, then these materials would not be patentable. One possible result of this classification would be that biotechnology companies would not invest as much money in genetic research, on the grounds that they would not be guaranteed a good return on their investment. On the other hand, if we decide to call some DNA materials, such as isolated

[158] Westerlund, L Ib. p. 40
[159] Westerlund, L Ib. p. 34
[160] Resnik, DB (2001:39)
[161] Resnik, DB (2002)
[162] Ib. p. 38

> and purified compounds, products of human ingenuity, then they would be patentable, and biotechnology companies would have more of an incentive to invest in research on these structures.[163]

Resnik's argument, then, is that when the distinctive criterion for patentable inventions, separating them from mere products of nature is not available, as in the case of DNA, the overarching consideration should be allowed to take over. If the other patentability criteria are met and the product is wanted because of its beneficial effects for patients or consumers, it should pass as an invention for that reason. I argue that Resnik is too quick in dismissing the separateness between inventions and discoveries and therefore takes part in what Westerlund describes as "[t]he gradual expansion of the concept of an invention at the expense of discovery."[164] Given the evasive line between invention and discovery, the distinction between what "freely occurs in nature per se" and what cannot be said to have this status, seems to be serving as an alternative guide for determining patentability in biotechnology. According to Westerlund, the result has been an expanding notion of what is covered by the legal term invention. Her underlying concern as a legal theorist is that unless a robust definition of the legal meaning of invention, as distinctive from discovery is elaborated, the legitimacy of the patent system is threatened.

It can be argued that the distinction is under pressure precisely from considerations like Resnik's. When patent protection for elaborate discoveries is wanted, he proposes abandoning metaphysics and turning to utilitarian deliberations.[165] Sharing his concern and support for research incentives, if not his strategy, I will argue that they are better served by upholding the importance of the distinction, but relaxing the association between patents and products.

The intricacies involved in applying the distinction need not be viewed as a result of the patent eligibility requirement in itself. This requirement has traditionally proved appropriate, and I do not suggest that it should be abandoned, not even in the biotechnology field. Instead, my argument is that the traditional product patent category is a poor match for intellectual property rights. The position argued allows that an invention has taken place in producing the transgenic animal, but nevertheless holds it unreasonable that the whole animal, with all its untouched natural qualities and biological processes, should be regarded an invention.

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[163] Ib. p. 39

[164] Westerlund, L Ib. p. 53

[165] Resnik, DB (2004:86-8)

When one or a few genes are inserted into an animal's genome, which already contains tens of thousands of genes,[166] there is still good cause to argue that an invention has taken place to a larger or lesser extent. The distinction between invention and discovery holds in these and similar cases of intellectual property. It is the object for the property right that is incongruous. If the object, here an entire animal, is replaced by the intellectual achievement understood as the invention's quality of meeting public interest, then the traditional applicability of the patent criterion is restored

The argument, however, that the entire animal is invented, is a forced argument in virtue of its premise that the inventive quality must be ascribed to a compound of matter, an entity in its entirety. The premise is laid down in the traditional distinction between process and product patents in patent law. The object of the legal right is one or the other. If a transgenic animal cannot any longer be identified with the once discovered animal, a lack of distinctions places it under the invention category.

The dichotomy, implying that the inventive step has produced the one or the other, either a product or a process, is a poor match. This creates the sense, not only of an unclear, but also imposed distinction between invention and discovery in intellectual property. However, it is not the sense of the distinction that has become unclear. It is rather the scope of invention that has become so, after being unduly stretched to accommodate the product category taken from other fields of property right. The false sense of an imposed distinction is due to inventions having other objects than the ones belonging to physical labor. The traditional product patent category in patent law does not have the same applicability in these and similar cases as it has in other fields where the products in question are altogether of different classes like can-openers and carports, that is, man-made products in their integrity.

To summarize, Westerlund represents the position that the distinctive criteria for invention and discovery is under pressure in the patent area. The prospect of a patent gives an incentive to regard products as inventions rather than discoveries. The distinction therefore might end up differently inside the area of patents compared to how it is applied outside of it. If this development is allowed to go far enough the legitimacy of the patent criteria is threatened.

Resnik holds that biotechnological products like genes resist the distinction. He therefore abandons it. The position argued here is that Resnik is correct that the distinction does not apply to these products, but only as long as the products are seen in isolation from

[166] Westerlund, L Ib. p. 31

their functions. Therefore questions should be asked as regarding the meaning and role of the patent category in intellectual property, not the distinction that isolates the intellectual achievement.

I will now defend this position by pointing to an unreasonably tight connection between intellectual property right and classical property right theory from Locke which was elaborated with a view to physical objects. This defense will partly build on Peter Drahos' discussion of Lockean property rights.

Lockean natural rights and intellectual property

First let us note a few preliminary, but nonetheless central points regarding intellectual property rights. One is already touched upon above and concerns how the classical property-bestowing function of labor is very specific in IP rights theory. The intellectual labor here, translated into inventiveness in intellectual property law, is performed on what Drahos refers to as abstract objects in order to separate them clearly from physical objects.[167] The activity which is ascribed the property-bestowing function is the inventive step. This trait alone sets IP rights theory apart from classical property theory, where the mixing of labor with an object gave the right to appropriate it. The replacement of labor with intellectual labor or inventiveness is precisely a defining characteristic of IP rights. The question is how much is left of a resource in classical natural rights theory in the Lockean tradition to justify the intellectual rights.

If the inventiveness criterion were also to be abandoned, as a consequence of losing sight of the distinction between invention and discovery for intellectual property, it probably has consequences for how we regard IP rights. To answer the question if and why we need a replacement at all for the unqualified labor criterion in order to establish intellectual property therefore is important for how we view IP rights, as well as for how they could be justified.

From the public interest point of view, adopted by Resnik, we have the requisite alternative criterion in the best consequences for public interest. Along with the other existing

[167] Drahos, P (1996:47)

criteria from patent law: novelty and capability of industrial application,[168] it will serve the function that the inventiveness criterion fails to fulfill, according to Resnik.

The issue of determining the best consequences for public interest is, however, not a straightforward one. The public interest criterion is arguably not quite applicable if it is not aided by other, more specific, criteria. To illustrate this, let us assume that two competitors, one an inventor – the other a copier, apply for patent on the same product. The copier would present the convincing public interest argument that he is able to sell the product at a considerably lower price because he carries no cost burden from research, development and market approval. Thus, if it is a much needed product, like for example a diagnostic tool in medicine, the public availability will most likely be considerably higher if the copier was to be granted the patent.

A wider public interest perspective seeks to stimulate the production of new and useful goods through incentives covering all cases of IP rights, and it is not impressed by singular case examples. The criterion needed in this wider perspective is one that singles out the originator, and not the copier. Because originators are wanted for the provision of new and innovative solutions in the biotech field and elsewhere, the incentive for this particular group needs to be secured. This is the idea behind a public interest protection of intellectual property rights. To single out originators, the unqualified labor-mixing criterion proves insufficient in separating clearly between originators and copiers.

Whereas manual labor creates property rights to a singular piece of land or object in which the labor was invested, intellectual effort is not connected in this direct way to token objects, but rather to formulas, recipes and types – Drahos' abstract objects. These formulas could be applied by anyone in his labor to produce the same result, but only in qualitative terms, meaning not the same identifiable object of which there is only one or a limited number. The resulting object is the same in the other sense, like when the same idea is held by two or more people. IP rights theory redefines the concept of property from applying to physical objects only to cover mental, non-rivalrous[169] objects as well. It can serve as another defining quality of intellectual property that their objects are unnumbered, unlike physical property.

[168] This is how they are stated in World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights - TRIPS, Art. 27. See WTO TRIPS, Art. 27:1.

[169] They are non-rivalrous in the sense that one person's use of them does not negatively affect other persons' availability of the same good.

The fact that there are two very different kinds of object: physical and abstract, nevertheless calls for a correspondingly different conception of property for each. Regarding their property characteristics, a prominent difference is that the ideal objects cannot be isolated or removed from the commons like physical objects can.[170] The abstract object is still there after having been appropriated and it cannot be locked in or protected otherwise in a physical sense. The protection offered is thus the patent, copyright or other legal IP rights. To make sense of an idea of property to intellectual objects of unlimited instances the invention concept has been applied. It should come as no surprise that the scope of intellectual property is not congruent to traditional property scope. The consequences for a justifiable scope of product patents for inventions, which are still underexplored, need to be reviewed given this background.

Let us sum up the differences noted so far. One is that inventiveness has taken over the specific property-bestowing function regarding property theory, a function traditionally implied in the more general notion of labor. A second is the introduction of the copier. Since an appropriated piece of land, for example, could not be copied, traditional property theory had no need to deal with copiers. Intellectual property needs protection against illegitimate copiers in the form of copyright (for artistic, literary, and intellectual expressions) or patents (for physical carriers of inventions – the objects made from them). The third is related to the previous and concerns the non-rivalrous character of intellectual property. This quality alone implies a major revision of the concept of property when applied to ideas.

In Drahos' discussion of the difference between the two types of property, physical and intellectual, the function of labor-mixing is central. He questions the connection between labor and "the object of the property right,"[171] by asking about the boundaries of the intellectual property and argues that it is not determined by the labor effort. The labor-mixing merely establishes the property right but does not delimit the object of property. That is why Robert Nozick can ask about his property rights in the ocean if he has mixed his tomato juice with it.[172] Labor does not delimit the scope of property in the physical world, and Drahos points out that it does so even more poorly in the realm of abstract objects. There is consequently not much guidance to be found in Locke here as he had the physical world in mind when elaborating his property theory.

[170] Drahos, P Ib. p. 49
[171] Ib. p. 51
[172] Nozick; R (1974:174-5)

Drahos refers to Locke's 17th century contemporaries Hugo Grotius and Samuel von Pufendorf's supplement to the labor activity, namely of custom and convention to determine cases of property scope. Drahos reasonably holds that we will not find anyone in the natural law tradition who would argue that the clearing of space on a planet would give property rights to it (referring to another one of Nozick's examples, the private astronaut on Mars). The delimiting function of custom and convention may have worked sufficiently in the domain of physical entities. As we just noted however, ideal or abstract objects differ in that they are innumerable, for one thing. To delimit property in them, even when accepting that inventiveness may establish this relation, is quite another matter. In this field the resource of convention is hardly helpful, as the inventions tend to present new cases, that are not readily put into a known object category. Let human genes serve as just one example.

This issue of delineating intellectual property is not exclusively pertinent to natural rights theory of intellectual property. It will surface for any theoretical establishing of property of abstract objects, even for public interest-based theories like utilitarian ethics. An advantage of utilitarian theory over the labor-mixing alternative is that only the former allows for the question of when the principle is satisfied. Since it is not easy to see how labor in and by itself could delineate the object of property, recourse is made to custom and convention. For the utilitarian principle, however, not only does it establish the right to intellectual property, it can also serve to define the scope of this right by binding it to the incentive function. In the case of patents' incentive function, it is fulfilled when patents come in demand meaning when they are applied for. The most exact delineation of the utilitarian justification of patents would arguably be when it is just fulfilled, as distinct from overly fulfilled through a generous scope of protection over and above what it takes to put in place a workable incentive.

A central legal distinction between patent right and copyright is that only the former must meet a demand of being industrially applicable, or useful. Due to the requirement of industrial applicability, intellectual property is brought into the realm of the physical. The legal right to intellectual property in the form of process- or product patent firmly connects the abstract object with a material one. The requirement makes the product patent only available for inventions that are useful as products. These products are the objects carrying the invention and the issue of intellectual property scope is not whether the inventor's rights extend to all copies of the object. Rather it concerns the possible functions of each object and

whether the inventor of one function can claim moral rights over all the object's uses and functions.

In this physical realm of legal IP rights Locke's theory of property reenters the picture by one of its ethical constrains not commented on so far. This is his proviso that in appropriating goods from the commons, enough and as good must be left for others.[173] Concerning the patented objects, Locke's proviso will have applicability for these physical or biological entities. It is relevant for cases where a biological entity is a mere copy of a naturally occurring entity, like a synthetically produced gene, and a patent is sought for all functions of that copy-gene even though the copier knows of only one function.

Locke's proviso is stated as a necessary condition for approval of the appropriation of property. If all possible uses of a gene's information in effect is caged for the protection of one specific use, the question can be asked if there is enough and as good left for others to explore. Should it turn out that the proviso is not satisfied, a Lockean justification of intellectual property right is arguably not available for the object as such, but may still be available for the specific use noted.

Framed alternatively, as a public interest issue, the question is if the incentive to develop new products is satisfied with a protection of the function invented, or whether further incentives are required. The empirical answer to the question is, as indicated, to observe whether the incentive function comes in demand or whether innovators alternatively opt for the trade secret solution, alternatively choose not to market its product.

Drahos suggests that the extension of abstract objects into the physical world depends on their definition.[174] If this definition was precise, it might come a long way in delineating the scope of the inventor's property to the physical object, possibly more detailed than custom and convention could do for physical objects. Nozick, in more economic terms, suggests that the entitlement should follow the value that is added to the object, if it becomes more valuable. We assume that it does in patent cases, because it has passed the usefulness test there. Nozick's question regarding scope of intellectual property suggests an answer to the incentive issue in public interest theory: "Why should one's entitlement extend to the whole object rather than just to the added value one's labor has produced?" Indeed, both the public interest theorist Drahos and the libertarian theorist Nozick point to reasonable limitations of intellectual property in physical objects.

[173] Locke, J Ib: ch. 5, §33
[174] Ib. p. 52

Even if the entitlement issue is settled by some concurring notion of definition and added value, the question of sufficient incentive might still be regarded in isolation from the entitlement, or rights issue. In the conclusion I will add a somewhat hermeneutic argument that the reasonable expectation of reward on the inventor's part must be linked to his or her own conception of the scope of the invention. With this argument, the anticipated scope of the invention sets the horizon for reasonable intellectual property protection.

The Myriad case

In exploring a foundation for the invention criterion, one option is to investigate the possibility of a closer tie between invention and application, a possibility hinted to but not adequately considered in a discussion paper by Nuffield Council of Bioethics.[175]

By doing this, the incentive function of patents would be maintained. Moreover, by delimiting their scope to bring them more in correspondence with the predicted applicability as described in the patent application, a correspondence once given this legal expression: "It is basic to the grant of a patent that the scope of a patent should not exceed the scope of invention."[176]

DNA technology presents hard cases for establishing a sharp line as its product, a complementary DNA (cDNA), the isolated and manipulated DNA, might be understood as a copy of substances that freely occur in nature. Even though the copy itself is not part of the natural environment of the DNA, the isolated substance essentially needs to carry the informational content of the natural DNA, at least enough of it to be useful for diagnostic tests for example. A patent of this informational content, Westerlund points out, runs counter

[175] Nuffield Council of Bioethics (2002:53-4). They appear to separate between product patents and use patents, implying, misleadingly, that the inventor can choose between applying for product patent or use patent. The product patent in fact gives exclusive rights to make, sell or indeed use the invention. The use privilege is common to product patents and process patents, often therefore referred to by the common legal term utility patent. See USPTO (2013).

[176] Reference and quote borrowed from Sagoff, M (2002): Monsanto Co. v. Rohm and Haas Co. 312 F.Supp.778, 790 (E.D. Pa. 1970), aff'd 456 F.2nd 592 (3rd Cir), cert. Denied 407 U.S. 934 (1972). According to Sagoff the quote expresses an attitude that is no longer prevailing after, as he notes, patents have been issued for DNA, protein, and various cell lines through a "sea change in patent policy" (p. 424).

to a fundamental idea of the patent system, namely "not to take from the public what it already possesses."[177]

This fundamental idea is given a recent affirmation in the decision from the US Supreme Court in the so-called Myriad case.[178] The Court settled the legal issue regarding isolated DNA, which it ruled to be not patentable, contrary to what US patent practice had been up until this point. So far, the fundamental idea is affirmed. Its decision runs counter to the still valid practice of the European Patent Office following the EU directive 98/44/EC, which states that no element of a human body can be patented, provided it is not isolated from the body. If, on the other hand, an element such as a sequence of human DNA is removed from the body and isolated, it is eligible for patent.[179] The Directive's specification reads, "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."[180] There is no sign that this practice is changing in the European Union (Finnie and Liberto 2014).[181]

The more recent US Supreme Court decision, however, makes the following distinction. On the one hand, there is naturally occurring DNA, which could be found in a living body or even in isolated form in a laboratory, and which in either case is not eligible for patent. On the other, cDNA sequences, the synthetically produced near-copy of a gene sequence, which is the substance that is eligible for product patent.[182] Since the patented product carries exactly the same protein-coding information as its mother-gene, Westerlund's question about the informational content still stands after the Court decision.

In revoking Myriad's earlier patent on the BRCA1 and BRCA2 genes, through which the company had found a method for predicting the probability of breast cancer and ovarian cancer, the Supreme Court relied on the invention/discovery-distinction. Its statement reads, with reference to Myriad Genetics: "To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.

[177] One can question to what extent the public already possesses this content as a valid argument against allowing patents. It is probably more relevant to point to the lack of inventiveness and utility in merely isolating DNA.

[178] US Supreme Court No. 12–398

[179] EU directive 98/44/EC. Chapter 1 Patentability, Article 5.1

[180] Ib. Article 5.2

[181] German patent law is however a notable exception. I shall therefore present its purpose-bound patent protection of human DNA below.

[182] Sherkow, J (2013)

Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry."[183]

Paragraph 101 is cited in the court document as reserving patents for "new and useful ... composition of matter." In upholding the patent on cDNA, the Court refers to the same paragraph. Whereas the naturally occurring gene, even in its isolated form, is not judged to qualify as new composition of matter, the cDNA is. We might ask what the practical consequences of this distinction is if the affirmed patent on the cDNA blocks access to the gene information as effectively as a patent on the gene itself would have done. In what sense, if any, could the patent scope be said to get a clearer definition or demarcation by the Court decision?

The Court's reliance on paragraph 101 should be seen in relation to the premise of the case, the petitioners' challenging the patents' validity under this particular paragraph.[184] The Court accepted the claim that the cDNA substance is not identical with the natural DNA substance. The non-coding components of the original DNA are left out from the cDNA and this is the reason the Court draws the line here, between the mere isolated DNA and the cDNA. The removal of the non-coding parts (the introns) leaves the cDNA as an entity that is actually not found in nature, the Court observes.[185] Thus, it reasons, in removing the unnecessary information and keeping the protein-coding exons in their natural order and number, something new is created. As a new composition of matter, not occurring in nature, the Court concludes that the cDNA is eligible for patent.

What is not apparent from the ruling however, is in what sense, if any, the informational content of the natural gene is exempt from the product patent. Even if the cDNA is regarded a product of human ingenuity, the information it carries, all of it originating in the natural gene is not invented, a matter that is acknowledged by the Court.[186] It is therefore reasonable to regard it as a public good.[187]

The decisive argument for the Court in upholding the cDNA patents is not the amount of labor or strength of the inventiveness behind the cDNA. Neither could it, reasonably, take usefulness or public interest as a sufficient criterion for patent in this case, as it does not belong to the cDNA more than to the original DNA. Instead the Court puts the decisive

[183] US Supreme Court No. 12–398, II B

[184] US Supreme Court No. 12–398, p. 1 (the syllabus), and I C

[185] Ib. Syllabus

[186] Ib. II B

[187] Sagoff, M op. cit. p. 428

weight on the notion of being, or not being, a product of nature. The weight of the notion is not least carried by its product component, in that the natural occurrence is a product. The Court is not persuaded by the petitioners' argument that "[t]he nucleotide sequence of cDNA is dictated by nature, not by the lab technician."[188] "That may be so," it concedes, but adds: "the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a "product of nature" and is patent eligible under §101."

Since the genetic information carried by the cDNA clearly occurs naturally, the Court's decision is a clear instance of a specific sense of the notion of being a product of nature. The sense of being an object, a composition of matter to be protected in its entirety, is crucial. The Court's adoption of this notion of the object of intellectual property right was dictated by paragraph 101. The novelty and usefulness condition have applicability to this legal notion.

The novelty of the cDNA product consists however not by addition of new qualities but, on the contrary, of the removal of inessential parts, compared to the original. This alteration makes it novel in the sense that it does not exist naturally, even though one can ask how different it effectively is. In effect, it carries the exact copy of the protein-coding information in the naturally existing gene. Because of the alterations in the substance itself, rendering the cDNA substance non-identical to the DNA substance, the former qualifies for patent eligibility in a rigorous interpretation of novelty. The cDNA carries the unchanged protein coding information and in this form, i.e. as a new product, its use can be legally protected, as is affirmed in the Myriad case.

The novelty in question cannot be traced to the information expressed by the exons because this information is identical to the original DNA code. The novelty must instead be associated with the cDNA being viewed as a substance or a product. The substance as such has no prior existence in nature. The entire product is patentable in this capacity, although the information in isolation is not.

This perspective becomes less accurate as "products" of DNA sequences shift from collected samples to code, or from the corporeal to the informational. According to Bronwyn Parry, "there has been a reworking of conceptions of what exactly it is in collected samples of genetic material that biotechnologists' most value: that what is of most interest to them is no longer the genetic material *per se*, but rather the genetic and bio-chemical information that

[188] US Supreme Court No. 12–398, II C

can be derived from the sample."[189] According to Parry, and quite plausibly, there is a transition from cryogenically stored tissue samples over to databases for vehicles of DNA information. The databases then gradually replace the substances or products that used to be the carrier of this information and the focus of IP rights.[190]

I have not methodologically separated the two common arguments against the patenting of genes here: the product of nature argument and the common heritage argument.[191] Although I regard my argument to be fairly independent from them, I have adopted the product of nature argument in keeping the invention/discovery distinction. As for the common heritage argument, I believe that in not allowing for patents where there is no demonstrable invention my argument is compatible with it, even if I use other resources than the common heritage approach.

The German purpose-bound compound protection

Now it is time to separate between two other aspects regarding the patent protection of cDNA. First, no other person than the patent holder can make, sell or use the cDNA for the very same purpose as the patent holder without license from him. Second, no one can make, sell or use this composition of matter in any other way or for any other purpose without the patent holder's license. This is so even if the other use results from new insights into the protein-coding function of the gene itself, insights which are brought out by the new party and which therefore is unknown to the patent holder. It is this second aspect that concerns us here, not the first.

Now that the separateness of the cDNA as a product on the one hand and its informational content on the other is highlighted, my argument is that the second type of protection results from the product patent but would not follow from a specified application patent. By specified application I mean the industrial potential as determined and delimited in the patent description. We might note at this point that if the informational content of the DNA were itself to be regarded as a product, it would not meet the inventiveness prescription

[189] Parry, B (2005:83)

[190] See also Rebecca S. Eisenbergs discussion of this particular development in Eisenberg, RS (2002)

[191] Resnik, DB (2002:139)

and thus not be patentable. The position argued here is that a specified application patent might well be issued irrespective of the product status. The specification is authored by the inventor himself.

Interestingly, in Germany national patent law requires specified applications for DNA product patents, thereby distancing it from EPO patent law. Its "purpose-bound compound protection" (Zweckgebundener Stoffschutz) does not allow patents to exceed the use description as given in the application.[192] The justification for deviating from EPO patent law is stated in the letter to the Parliament following the government's draft of the translation of the EU directive 98/44/EC cited above, on biotechnological inventions, into German law.[193] The adopted law reads, from Part 1, The Patent:

> Section 1a
> (1) The human body, at the various stages of its formation and development, including germ cells, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
> (2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention even if the structure of that element is identical to the structure of a natural element.
> (3) The industrial application of a sequence or partial sequence of a gene shall be disclosed in the application specifying the function performed by the sequence or partial sequence.
> (4) If the invention concerns a sequence or partial sequence of a gene whose structure corresponds to that of a natural sequence or partial sequence of a human gene, the patent claim shall include its use for which industrial application is disclosed pursuant to subsection (3).[194]

Subsection 4 is new and not derived or translated from the EU Directive. Furthermore it is not to be found in the Government draft, but added by the Parliament and following up concerns from the government's justification. We may first note that the law text specifically concerns human genes and not patents generally. My argument is that this rationale, applied in German law regarding human genes, distinguishes IP property generally and that its wider

[192] Kilger, C et al. (2005); Haag, T & Kilger, C (2013)
[193] Deutscher Bundestag (2003)
[194] Bundesministerium der Justiz und für Verbraucherschutz (2013)

validity therefore should be explored. The case of concern in this essay is nonetheless human genes, the area singled out for special attention in German patent law.

Next, we note that the addition in the law text to the EU Directive does not explicitly state that the patent scope is to be bound to the use of the subject matter of an invention. This is merely the "clear intent" behind the introduction of subsection 4 (Kilger et al. op. cit. p. 574).[195] The intention is spelled out in the justification letter to the Parliament.

The main justification given by the German Government for a limitation of patent scope for human DNA is stated as ethical and concerns "necessary limits on patents of biotechnological inventions."[196] It builds on the stated ethical principle that "the human body, as well as the mere discovery of one of its parts – in particular a gene – can never be an invention." The conclusion is then given, with reference to patent law, that the human body or a human gene cannot be patented. The law draft is meant to make this "important ethical principle" clearer.

If, however a gene sequence is isolated from the human body through a technical process, it might be patentable. Other criteria come into consideration as well, one of them being the requirement that a description of the new product's industrial applicability is included in the patent claim. Far from being a mere procedural requirement, the text stresses its central role for the patent office's assessment of a gene sequence. The legislator must assume that the "narrowest possible and the most precise attribution of functions" is given in the application. Then this crucial passage follows, regarding the binding of protection to function:

> Based on the functional description the patent examiner must restrict the patent to that part of the gene for which patent protection was sought for and which is essential for the described function and shall exclude parts of the gene which are not essential for the described function.[197]

The Government apparently meant that this intention was covered by subsection one through 3 in the law draft, but the Parliament added subsection 4 to emphasize it.

[195] Kilger, C et al. op. cit. p. 574

[196] Deutscher Bundestag (2003) from the Chapter 3. "Reichweite des Stoffschutzes und ethische Grenzen." This translation and the ones which follow from this chapter are mine unless otherwise indicated.

[197] Translation borrowed from Kilger, C et al. op. cit.

From the utilitarian perspective usually accepted as lying behind the patent policy and justifying it,[198] one could argue that the object-bound protection, excluding any unlicensed use of the product carrying the invention, is unproductive. If new applications of natural DNA are blocked by a patent holder that is not at all involved in the new and inventive use of it, the instrument that should stimulate new inventions has turned unproductive or even counter-productive. In this perspective, the bio-information carried by the cDNA can be seen as held captive, if not appropriated, by the right-holder to the bio-information carrier.

The German Government's justification document addresses this particular concern making it clear that a function-limited protection will substantially lower the number of conflicts between patent holders, one of them holding the original patent to a product, the other being granted a patent on a new and inventive use of the same object. Traditionally, the new inventor is obliged to pay a license fee to the holder of the old patent. Based on the reasoning that ties protection to the function of the invention, a new paragraph 24, section 2 is included in the German patent law. The paragraph entitles a patent holder compulsory license for new inventions in patent protected entities.

United States guidelines

As things stand, biotech patents are unnecessarily broad in covering all potential uses of a gene sequence, known uses as well as hitherto unknown uses. The latter is not part of the description of the invention's capability of industrial application or usefulness.

The broad function of patents results from the demonstration of a clear utility of the invention. A clear expression of how the utility criterion is widely applied, the practice Germany departs from, is to be found in the Utility Guidelines from the US Patent and Trademark Office:

> If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not

[198] Mark Sagoff, accurately I believe, observes that the right holders themselves share the utilitarian justification for the patent system: "Industry leaders [..] regard patent policy as serving an entirely utilitarian or economic purpose that has nothing to do with natural property rights." See Sagoff, M (2002:421). A look at IP rights intensive corporations', like pharmaceutical companies, websites will confirm this.

> patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the ‘‘utility’’ requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.[199]

The more or less unrestricted scope of the patent is unwarranted by the fact that there might be other uses of the invention – not known to the inventor or any other party for that matter at the time of application – or simply not included in the description. It suffices to show one, and only one clear use to fulfill the eligibility criteria.

> The patentee is required to disclose only one utility, that is, teach others how to use the invention in at least one way. The patentee is not required to disclose all possible uses[.].[200]

> [O]nce a product is patented, that patent extends to any use, even those that have not been disclosed in the patent. A future nonobvious method of using that product may be patentable, but the first patent would have been dominant (Doll 1998).[201]

As long as a minimum of one clear use of the invention can be established, the patent scope in itself is in fact independent of the described utility. Any new discovered use of the product in the future will be covered by the product patent, in effect as IP rights to unforeseen applications of the invention or as mere IP rights by chance.

The United States Patent and Trademark Office (USPTO) addressed this point prior to publishing their guidelines in 2001, and rejected any concerns based on it:

> A patent on a composition gives exclusive rights to the composition for a limited time, even if the inventor disclosed only a single use for the composition.[202]

The justification for rejecting the concern is a reference to the statutory requirements that binds the USPTO[203]:

[199] Federal Register (2001:1093). This text is of course written before the Myriad case conclusion.
[200] Federal Register (2001:1094)
[201] Doll, JJ (1998)
[202] Federal Register (2001:1095)

> This result flows from the language of the statute itself. When the utility requirement and other requirements are satisfied by the application, a patent granted provides a patentee with the right to exclude others from, inter alia, ‘‘using’’ the patented composition of matter.[204]

Conclusion

I have argued that the patent protection following from the product patent, applied to biotechnological products and based on only one required use of it, is not justified by the ethical theories most commonly appealed to for the justification of IP rights. My example of a biological product has been the complementary DNA, used for diagnostic tests. In natural rights theory, the Lockean proviso that there should be enough and as good left for others has applicability and justifies an ethical constraint on the scope of legal IP rights. In the public interest perspective, on the other hand, the extensive scope in patents exceeds what is necessary to uphold the incentive function essential to the perspective.

If patent protection alternatively followed the inventing party's anticipation, not to mention its expectations, of how the product could be used, the inventor of the cDNA would still have protection for all conceivable uses of the product at the time of filing the patent claim. The anticipation is exhaustively described in this claim. It is the non-conceivable uses that would not be covered by the inventor's IP rights. If a future agent discovers or invents new applications for the product, that agent would be under no obligation to pay fees to the first inventor. The first inventor could therefore not hope for future remunerations by chance or by another party's ingenuity and investments. The revised patent requirement would mean no significant loss to the patent system's incentive function, as long as all described industrial applications are protected.

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[203] Brody, B (2006:110)

[204] Federal Register, loc. cit.

Patent Funded Access to Medicines

Introduction

Intellectual property rights get stronger protection worldwide as more countries implement the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The least developed countries (LDCs) are set to make the final step in the implementation of TRIPS no later than January 2016 by including pharmaceutical products under intellectual property rights protection. By then all WTO countries will offer legislative IP protection in every field covered by the Agreement, independently of each country's level of protection of health rights.

This article will concentrate on the WTO Agreement from the perspective of moral philosophy and discuss the apparent conflict between the legal right to intellectual property on the one hand and the human right to health when it comes to trade in essential medicines, on the other. The European Commission has expressed its concern in a working document:

> The EU has consistently led efforts to widen access to vital medicines in developing countries and to strike the right balance between the intellectual property rights of pharmaceutical companies and the need to ensure that medicines are available for poor countries facing public health crises.[205]

Despite its efforts to strike the right balance, the European Union opposed a text from South Africa at the United Nations' General Assembly Special Session on Social Development in 2000. This stated: "intellectual property rights under the WTO-TRIPS Agreement should not take precedence over the fundamental human right to the highest attainable standard of healthcare … and the ethical responsibility to provide life saving medications at affordable cost to developing countries and people living in poverty."[206]

A central motivation behind the introduction of patent rights on medicines and other cost-intensive product developments through TRIPS is that unless the investment is

[205] EU (2010:27)

[206] As cited in IIPI (2000). Also reported in Oh, C (2000).
The EU instead supported a text pointing to the options available under existing agreements.

protected; such development work cannot reasonably be carried out. Possible developments for the good of society will be lost without the patent incentive. For patients it would mean that fewer medicines are developed; to the detriment of all. Wealthy patients could find that there is no available cure for a particular disease; and for the poor – their situation is not best described as one where there is lack of access. That description is more fit in describing situations where a medicine actually exists, but some patients do not get it because it is priced so high that it is out of reach.

According to the line of thought seeing lost development opportunities as a consequence of not protecting investments, it is questionable whether the poor actually are worse off from the new patent regime than they would have been without it.[207] From a human rights perspective, it might be that they are, in the very specific sense that when a new medical treatment exists, the issue of access arises. What should be discussed rather from the human rights perspective is if the high cost of new essential medicines, not only for patients who cannot afford to buy them but also for their country's health budget, make them a non-attainable standard of physical and mental health. If it is so, that the new medicines represent a non-attainable standard of physical and mental health, would it then follow that these patients cannot claim a right to them based on the International Covenant on Economic, Social and Cultural Rights (ICESCR)?[208] The legal concept of "highest attainable standard" needs to be clarified as to whether it refers to the highest standard within any national health system, or whether it refers to the international standard of treatment for any particular disease. It has been suggested in a legal context with reference to the Covenant's Art. 2(1) on international assistance and co-operation, that the attainable standard should be interpreted as an international standard setting the bar for every person.[209] The Covenant itself states, in Art. 2(1), that the full realization of the stated rights is to be achieved progressively according to available resources, thus indicating that international standards is the measuring stick.

In a note to the General Assembly by the Secretary-General of the UN the issue of progressive realization is addressed. Here there is separation between the highest attainable standard on the one hand and essential medicines on the other. The latter is not subject to progressive realization, but is considered an immediate obligation.[210] The Secretary-

[207] The topic is discussed in Heins, V. (2008:9).

[208] The right is stated in Art. 12 of the ICESCR: "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."

[209] See Cullet, P (2007:408).

[210] UN (2006a), Art. 56.

General's note is in line with the General Comment No. 14 from the UN Committee on Economic, Social and Cultural Rights (CESCR) reaffirming its position (in its General Comment No. 3) on certain core obligations of states: "[..]States parties have a core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in the Covenant, including essential primary health care."[211] Comment No. 14 then makes clear that it includes the provision of essential drugs within the states' core obligations.

For the case in hand then, any ambiguity of the notion of "highest attainable standard" need not concern us. The mere accessibility of essential medicines could be dealt with separately, as is indeed done by the Secretary-General in his note.

In the following, I will consider the normative force of the right to this basic health service, and not focus on the highest attainable standard of health services. Here I will discuss the apparent conflict between IP rights and the human right to essential medicines, arguing that this issue could and should be solved.

This article explores how a solution might be found within the framework of the TRIPS arrangement. It concludes that the system of patent protection should be kept in place, indeed encouraged, but that the donations of essential medicines (as distinguished from financial donations) that are already being undertaken by the pharmaceutical industry on a benevolent but irregular basis should be systematized. A new incentive for the distribution of medicines and capacity building for treatment of patients would be a welcome effect of this shift.

Three main stakeholder perspectives

One striking feature of the patent requirements in TRIPS and its background is that in principle it does not differentiate between the various market segments of the products and processes it covers. This reflects the considerable industrial variety represented by the companies that were active in the inception of the Agreement, working for its creation through participation in consultation fora (mainly in the US). Among the activist companies, as they are framed by Duncan Matthews, represented in the interest group the Intellectual

[211] UN (2000), Art. 43.

Property Committee we find as diverse companies as Pfizer, General Motors, Warner Communications, Hewlett-Packard and Monsanto.[212]

The unifying goal of the various activist companies was to end the piracy and counterfeiting of goods in foreign countries and they articulated it as a concern for "strengthen[ing] intellectual property protection in foreign markets."[213] Corporate justification for this has traditionally followed two strategies. On the one hand there is the need for fair terms of competition between industrial actors; and on the other, the concern for future investments when it comes to much needed inventions.

Separating the two strategies, the focus of TRIPS seen as a trade agreement is on fair terms of competition and not on fair distribution of goods. If it is regarded as a policy tool, the focus is on facilitating needed inventions. TRIPS is designed to serve this end by promoting further growth and innovation through offering IP protection for movies, music, industrial design and innovation and not least for pharmaceutical products.

Tom Palmer makes the assertion that "[t]he sharp separation in contemporary moral philosophy between natural rights and utility, or the common good, is however, an artificial one[.][214] Espousing a very broad conception of rights arguments and utilitarian arguments, he sees both strategies as essentially "concerned with human flourishing or the attainment of man's natural end." Utilitarian arguments do this directly, he contends, whereas natural rights arguments do it indirectly – "through respect for general rights, or rules of conduct." Adopting his broad conception would amount to conflating the historically well-founded distinction between rights theory and utilitarian theory into a mere separation of rule-utilitarian arguments and act-utilitarian ones respectively.[215]

For the sake of clarity, however, I distinguish between three different concerns that are attributable to three affected parties with regard to the TRIPS Agreement. They can be seen as the three main stakeholders: the industry, political institutions, and the consumers:

- The trade perspective on fairness in competition held by an innovating enterprise. It holds that it is unfair to exploit another agent's cost and effort for your own advantage. Respect of property and natural rights in the Lockean tradition behind Article 27(2) of the Universal Declaration of Human Rights

[212] Matthews, D (2002:20)

[213] Matthews, D. Loc.cit. I discuss reasons for the pharmaceutical industry in particular to protect IP rights in developing countries in the section *Non-attainable standard of medical treatment* below

[214] Palmer, TG (1990:819n)

[215] If the conception is broad enough, any distinction between deontological ethics and consequential ethics might risk becoming artificial.

underlies this. It protects ”the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”

- The policy tool approach, from the law-maker’s viewpoint. Legal rights are not confirmations of universal rights. Instead they are policy tools aimed at accomplishing agreed goals or contributing to a sought after development. Consequentialist theory, often at odds with natural rights theory, supports this approach. Seen as a strict legalist view, the policy tool approach does however not seek moral justification of laws. Legal rights, such as patents, are regarded as mere privileges, to serve whatever end the policy makers set out to achieve.[216]

Apart from these two strategies for justifying IP rights, we have the third concern:

- The consumer perspective from human rights.

The perspective from human rights is clearly not an issue with regard to access to designer cars or new cell phone models. Since all kinds of innovative products and designs are eligible for IP protection, I should reiterate that here I am not concerned with the broad variety of pharmaceutical products. I discuss only and exclusively essential medicine - the kind of drugs that “satisfy the priority health care needs of the population” to cite the World Health Organization’s rather round definition.[217] These are for example antibiotics against pneumonia, or treatments for diarrhea, tuberculosis or noncommunicable diseases like hypertension and cardiovascular diseases.

The promotion of the human right to essential medicines might precisely be a long-term goal under the legalist perspective on IP rights, the approach of political institutions and leaders. The arguments of a patent intensive business like the pharmaceutical industry reflects this when they stress the utilitarian justification for patent protection of their products and plays down the trade perspective concerning theft of property of infringements of moral rights. Even if protection from theft has been part of the notion of legal enforcement of IP rights, as pointed out by Matthews, D (2002:8), it has played a subordinate role compared to

[216] Drahos, P (1996:29)
[217] WHO (2013)

the utilitarian motivations. One example of the utilitarian line of argument is clearly stated on the website of the International Federation of Pharmaceutical Manufacturers & Associations:

> Effective intellectual property systems - including protection of patents, trademarks and proprietary data - are critical for stimulating R&D. They provide some assurance that, if a new medicine is successfully approved, the innovator has a chance to generate revenues sufficient to justify the investments in R&D and so ensure sustainable innovation into the future. The vast majority of medicines available today would not exist without the incentive provided by intellectual property rights.[218]

There might be several different reasons why arguments from utility predominate over the natural rights arguments in documents from an industry, which - like any other industry - is geared towards promoting shareholder value. One reason could be strategic, sensibly assuming that arguments for greater overall welfare are more likely to impress state officials than an appeal to the protection of investments in a very profitable industry. A second reason might be that arguments from the natural rights of corporations risk running into conflict with the concern for human rights of people.[219] If IP rights were framed within the natural rights context, the outcome would be highly uncertain for the industry.

It is hard to establish whether these are really the reasons for the pharmaceutical industry's choice of argument. The fact that utilitarian arguments are most prominent is in any event a sufficient reason for me to choose to concentrate on this line of argument in the following discussion of the industry's justification of patent rights on essential medicine.

There have been several cases, a recent and typical one is Novartis' legal defense in India against a number of generic companies contesting their patent application for the cancer drug Glivec. Novartis applied for patent in 2006, one year after India's transition period for implementing TRIPS expired. The application was rejected on the grounds that Glivec was considered only an incremental improvement on Novartis' earlier cancer drug, from before 2005. The company took the case to court and lost twice, in 2007 and the appeal 2009. In April 2013, India's Supreme Court ruled against Novartis.[220] The court's conclusion is taken to set the standard for how India interprets its patent criteria.

[218] IFPMA (2013)
[219] UN (2006b) §7
[220] Krishna, RJ & Whalen, J (2013).

Novartis apparently seeks to control the market for this medicine in India. According to their own report, they have been distributing it for free to 95 per cent of all Glivec patients in India.[221] When they sell the drug, their price is about ten times that of the generic companies, that are now also fighting for market shares. The price of the generic medicine is however already much too high to be affordable for the poor.

What makes the case typical is Novartis' arguments. Regarding the case a matter of principle, they said prior to the Supreme Court decision that the ruling would show whether inventor companies, not only Novartis, can rely on patents in India: "The ruling is important for all innovators, national and global, with a presence or wanting to have a presence in India. This is about safeguarding incentives for better medicines so that patients' needs would be met in future."[222] The argument is utilitarian, following up the policy tool approach I separated from the trade perspective above. The message is that if the ruling goes against Novartis, the future presence in India of any kind of innovative company should not be counted upon. This is one current incident showing that the patent system India had to set up as a WTO member, now including product patent for pharmaceuticals,[223] is a tool that could be used to obtain monopoly privileges also in developing countries, as long as there is a market there.

Non-attainable standard of medical treatment

Even though Novartis alone reports to have reached 89 million people globally through their access-to-medicine programs, such initiatives, however commendable, cannot come close to meet the push towards poverty in low income markets where people who are initially not poor must stretch beyond their resources to access essential medicine.

It is estimated that one third of the world's population lack access to essential medicines.[224] Most of the drugs on the WHO's list of essential medicines are not patented, and there are many and complex reasons why poor people especially in rural areas in developing countries do not have access to them, not to mention their lack of access to clean

[221] Novartis website.

[222] Novartis executive to *The Economic Times* March 5, 2012; Rajagopal, D (2012)

[223] India did not offer product patents on pharmaceuticals before 2005, Cf.: WTO (2006b).

[224] Hogerzeil, HV & Mirza, Z (2011).

drinking water or mosquito nets to protect children from getting malaria. These are not all economic reasons, but the high price on medicines is nevertheless one very important reason, and this particular issue can be dealt with directly on the political level.

To the extent that it works, the TRIPS Agreement consistently contributes to the creation of situations where a medical treatment of a life-threatening disease actually exists, but many people are cut off from receiving such treatment due to monetary reasons. Thus the Agreement strongly needs a moral justification. TRIPS could directly create a situation where by giving protection in a market that has a sufficiently strong segment to support a price that is interesting for a brand name company, it will exclude many lower income people (as in India). It could also create this indirectly, as mentioned, by pushing more people below the poverty line just by being unfortunate enough to get a serious disease that is expensive to cure. In fact if TRIPS works as planned, which means that it will pave the way for costly (therefore patent protected) and needed (industrially applicable[225]) new medicines, it would seem that the circumstances calling for a moral justification are bound to occur regularly, and not only as a spurious effect. Even if a utilitarian justification might hold in the long term, I argue that the price it accepts in the form of non-access for vast numbers of people is a non-necessary cost.

Two questions regarding the utilitarian justification in the short term need to be discussed. First, if pharmaceutical research leads to good prospects of developing a considerably better medicine for a serious disease, is it acceptable that large patient groups must wait to have it, if the alternative is that no one gets it? From a utilitarian point of view it could, and probably should be argued that the wait is justified by the large number of future patients receiving treatment. If the waiting list is ten years, the effective time of selling monopoly,[226] or even if it is longer than that, it would be acceptable. In principle, there is no limit to the acceptable time frame as long as it does not exceed the time it takes to cover the cost of developing the medicine and earning a reasonable profit. The utilitarian answer to the

[225] Cf. the patentability criteria as given in TRIPS, art. 27.1

[226] I use numbers from the Centre for Medicines Research International Ltd, cited by WHO, showing a 10 year average development period for pharmaceutical products in WHO. 2006. *Public Health. Innovation and Intellectual Property Rights*. Geneva: WHO. The patent period is at least, and most often, 20 years from the day of application for patent. The application being submitted before the extensive and costly development and testing period means that an average of 10 years remain of selling monopoly. The Pharmaceutical Research and Manufacturers of America says the time spent on development of the new product is 10-15 years. See n.76

question of whether or not it is acceptable that large patient groups must wait would seem to be yes.[227]

If the general answer is yes, then the second and more troubling question needs to be answered. What if the large group is said to be comprised of only poor people, and the fact that they are poor, due to geopolitical contingencies, is precisely the reason for them being on the waiting list. Is this then a less acceptable reason for being on the waiting list than if the group members were randomly chosen, say for capacity reasons? Organizing inventor incentives this way (through agreements) leaves us with a sense of unfairness that is not easily captured by utilitarian reflection, as it focuses primarily on the number of people affected and the total amount of suffering. It is prominent, however, in the human rights perspective as formulated in the International Covenant on Economic, Social and Cultural Rights. From that perspective, it would be wrong systematically to let someone wait longer than others by reference to where they live or how their economic situation is.

Article 12 in the Covenant provides, as cited in the Introduction, everyone's right to the "highest attainable standard of physical and mental health." The universal right to health affirmed here, after initially having been set out in UDHR Article 25, is also reflected in the UN Millennium Development Goals where three out of eight of them (goals 4, 5 and 6) deal exclusively with health. Moreover goal 8 E reads: "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries". Taken together these documents make access to essential drugs a thoroughly affirmed human right.

From the rights perspective, lack of access to an essential medicine is morally unacceptable from the day it becomes an attainable standard of physical and mental health. From a utilitarian viewpoint, it might be said that the incentive created by IP protection is precisely what made the medicine an attainable standard in the first place. This objection, however, assumes what Thomas Pogge has pointed out to be a false dichotomy: it "asks us either to accept this emerging regime or else to renounce all hope for innovation."[228] Rejecting the utilitarian objection on these grounds, if not for the utilitarian idea, provides the opening to explore intermediate alternatives. An analytical opening that seems worth pursuing is to clarify what function patents on essential medicines has in poor countries. Here most patients cannot pay for the patent rent, and we have to see whether that function can be served without keeping the patent rent, or better still, if that very function, or the need to

[227] Rosenberg, A (2004)

[228] Pogge, T *op. cit*. note 7, *p.*230

protect the invention in this type of market, once brought out, could be consistent with affordable prices for patients.

The current state of affairs, that is partly unacceptable from a human rights perspective has also been criticized from within the utilitarian framework. Utilitarianism itself provides tools if circumstances occur where patent protection must be set aside in order to restore utility. This would be the type of situation which is the concern of Udo Schüklenk and Richard Ashcroft when they say that the consequential aim of intellectual property rights is to promote public interest, but if they fail to serve that purpose, their justification is removed.[229] In other words, if a normative defense of TRIPS rests upon utilitarian arguments, it also becomes especially vulnerable to utilitarian critique.

In view of this, a situation could well occur where a government in a developing country should assume it a utilitarian duty to issue a compulsory license or even to breach TRIPS altogether in order to meet the wider obligation for healthcare within the population. This would be their moral duty whenever the Agreement impedes efforts to meet short term, or present health related challenges. The duty could still be considered a utilitarian duty. Whenever current rules do not serve their purpose, which is to promote public interest, in any particular circumstance the legitimate authority could take measures, on an act-utilitarian basis to make up for lost utility.

The critical notion here is that of public interest, and the fragility of Schüklenk and Ashcroft's suggestion is, to my mind, that this notion is ambiguous regarding short- and long-term perspectives respectively. A utilitarian clarification could consist of counting the people affected in the two time-oriented perspectives and give as a result that the long-term gains, the concern for future patients, outweigh short-term losses. Following this line of utilitarian reasoning, the need for an alternative arrangement is not pressing. Again, it seems that present health concerns are better captured by the human rights perspective.

One utilitarian issue at stake in support of the TRIPS Agreement, asserts that the opportunity to seek patent protection in all WTO countries is necessary in order to secure recuperation of costs undertaken to develop a new product. The likelihood of recuperating the cost of hundreds of millions dollar for a new medicine in developing markets is however slight, to say the least.[230] Africa's combined global market share in pharmaceutical products

[229] Schüklenk, U & Ashcroft, RE (2002). See also Sterckx, S (2005:84).

[230] The average cost of developing a new medicine is hard to determine. WHO reports that *it is US$ 800 million, or even much more*, but notes that these figures are questionable because, among other things, the raw data are not made available for verification. WHO. *op. cit*. note 23, p.17

adds up to only 1,1%,[231] much of it is attributable to South Africa alone. An application for a patent in any other African country will give protection in only a fraction of 1.1% of the world market. The recuperation of costs therefore must take place elsewhere and is mainly accomplished by sales revenues from the markets in high cost countries.

Accordingly, when a medicine is patented in a low price market, where consumers are not able to pay the patent rent, it is not for the sake of earnings in that market, but for reasons well known to the TRIPS drafters when they included the precautionary measures regarding compulsory license. If a compulsory license is issued for the production and sale of a drug in a low cost market, the producer is instructed to mark products or packages in order to prevent diversion of medicines into other markets.[232] The products themselves should have special shape or form, and/or the packages must be given special labeling. Not least the quantities produced are not allowed to exceed the need of the state ordering the goods.

The measures demonstrate the concern for the interests of the brand name company, an interest that would not be served without a patent in place. If the brand name company had no patent protection, a generic drug could be produced in indefinite quantities and be re-exported to wealthier markets.

Patent protection following the TRIPS Agreement makes it possible to secure to a certain degree that generic medicines are not traded in these markets and then exported to wealthier markets to be sold there for a lower price compared to the brand name medicine. We see here a reason on the side of the brand name industry not to control the market inside a low cost setting, because there is no significant market for their products there, but rather to prevent diversion into priority markets. This concern, however, gives no reason to stop the drugs from being distributed locally in the low cost market. On the contrary, this is precisely what is achievable by the precautionary measures.

As mentioned above, compulsory licensing is intensely unpopular with the big pharmaceutical companies. Taking the Novartis case referred to as representative, pharmaceutical companies seem to prefer fairly large-scale donation programs over the perceived unpredictability of the compulsory licensing arrangement.[233] In making drug donations the brand name companies themselves are in control of the quantities and labeling

[231] Ibid: 15

[232] The concern is prominent in documents like WTO (2003), Also in EU (2006), Art. 10

[233] See also Rozec, RP (2000:912-3) who makes this argument from the industry perspective.

of the medicines and therefore are also largely in charge of stopping diversion into other markets.[234]

Reports from the International Federation of Pharmaceutical Manufacturers & Associations might support the indication that drug donations are preferred over compulsory licensing. Their member companies donated medicines, vaccines or diagnostics to nearly 600 million people in the year 2009 alone.[235] The number of donations is also increasing from one year to the next. In January 2012, the industry announced a donations program in cooperation with the Bill & Melinda Gates Foundation, the US and UK governments, receiving nations' governments and non-governmental organizations (NGOs) which will deliver no less than 14 billion treatments for neglected tropical diseases over the next ten years.[236] One other example from the same organization regards medicines for tropical diseases: "Research-based pharmaceutical companies are producing medicines free of charge and are donating unlimited supplies of medicines for many neglected tropical diseases. Notable examples include the case of lymphatic filariasis (elephantiasis). Through the Global Alliance to Eliminate Lymphatic Filariasis, GlaxoSmithKline, Merck & Co., Inc. and Eisai are ensuring that individuals infected with the disease get access to such medicines through mass administration of the medicines across subtropical regions of the world. Onchocerciasis (river blindness) is also being tackled by Merck's Mectizan® Donation Program, which has donated more than 1 billion treatments since 1987."[237]

The Novartis case and the two IFPMA reports combined amply indicate that extensive drug donations are less controversial in the pharmaceutical industry than compulsory licensing.

Some existing proposals for improved access to essential medicines

A number of proposals have been put forward to promote accessibility of medicines to the poorer regions of the world. For an overview I will list, but not systematically discuss, three

[234] Pogge, skeptically maintains that the difficulty in preventing diversion to wealthier markets speaks against the differential pricing option. op .cit. note 7, p.239

[235] IFPMA (2011)

[236] IFPMA (2012)

[237] IFPMA. *op. cit*. note 44, p.33

of them just in order to give a picture of how, and how diverse, the thinking on the issue has been so far.

1. Kevin Outterson has suggested that pharmaceutical companies sell essential medicines at marginal cost to patients in developing countries. He proposes a public buy-out program to cover assumed profit losses.[238]

Depending on how the marginal cost is calculated, it is not certain that people living in severe poverty actually are helped by his proposal. Generic medicines are already out of reach for them, many do not even have enough for sufficiently nourishing food. If the cost in research and development and the cost for marketing, which exceeds R&D costs,[239] are put into the price as well as transportation, administration, and market distribution, not to mention customs toll and local taxes, it is likely that far too many people still cannot access the medicine.

Other local factors than price also need to be taken into consideration. Many hold that inflated drug prices are not the problem at all. Pharmaceutical industry attorney Philip Grubb, speaking of AIDS medicine, thus holds that:

> In fact, patents are not the problem. Not only are there no patents for most of these AIDS drugs in most African countries, there are also no patents in any countries for most of the drugs on the WHO Essential Drugs List — so why then are these essential drugs not readily available to patients in poor countries? The answer is simply lack of money to buy even cheap medicines, and lack of social and medical infrastructure to deliver them. The terrible truth is that if AIDS could be cured by a glass of clean water, there would still be millions who would have no access to the cure. Unfortunately, patents and the 'greedy' pharmaceutical companies make a much easier target than the miserly rich country governments and the corrupt poor country governments who together make up the real problem.[240]

The infrastructure problem pointed out by Grubbs gives no argument to the effect that high prices are not an issue. Rather it highlights that solutions to the access problem must address these other factors as well, and not ignore them. Mechanisms for strengthening health infrastructure need to be included in a viable effort to improve access to drugs.

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[238] Outterson, K (2006)

[239] Stiglitz, JE (2006)

[240] Grubb, PW 2004. *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy*, 4th ed. Oxford: Oxford University Press, p .47. Citation and reference borrowed from Van Puymbroeck, RV (2010)

2. Another suggestion has been the Health Impact Fund, proposed as a complement to the emerging patent system.[241] The central idea is that efforts that reduce the total global burden of disease (GBD) are honored with payouts from a public fund. The thought is to promote pharmaceutical research into serious and widespread diseases by neutralizing any consideration of purchasing power.

The problem of insufficient health statistics or even non-existent data in several LDCs needs to be overcome in order to perform reliable GBD calculations and weightings, a task that is demanding in itself. The proposal implies an interest on the inventor's side even to work for improvement in local conditions such as lack of clean drinking water, low access to doctors and nurses and poor health infrastructure in general. Questions may be asked as to why health personnel, who are not receiving benefits from the Health Impact Fund, would cooperate and who is to pay their salaries. Furthermore, there is a cap on possible returns, and several actors might compete for them. Investors would need good reasons to prefer this prospect over the indefinite rewards in principle offered by the market. Last but not least, the fund must be financed, and donor states need to be found.[242]

3. India, with its powerful pharmaceutical generics industry, is following a judicial practice that sets a high bar on what inventions can be said to represent an inventive step (cf. above on requirements for patentability). The Supreme Court's recent ruling in the Glivec case has set the standard for the time to come. This practice can be followed by other countries too, to prevent so-called evergreening of patents,[243] which is the application for a new patent for only an incremental improvement of an existing medicine. The interpretation of the patentability criteria in TRIPS is largely left to member states and their legal institutions.[244] The UN High Commissioner for Human Rights, recommending this tool, said in 2001 about patentability requirements that she "encourages interpretations of these requirements that do not lose sight of the public interest in the wide dissemination of knowledge under article 15."[245]

[241] Hollis, A & Pogge, T (2008); Pogge, T. op. cit. note 7, pp. 244f

[242] For some of these critical points, and others, see Liddell, K (2010). Also Sonderholm, J (2010) and Pogge et. al's reply to Sonderholm in Peterson, M; Hollis, A. & Pogge, T (2009).

[243] Van Puymbroeck, R.V. *op. cit.* note 36, p. 526

[244] Correa, CM (2000:51)

[245] UNHCHR (2001), Art.62. The reference given is to Art. 15 of the International Covenant on Economic, Social and Cultural Rights. Art. 15 concerns the enjoyment, and also the protection, of scientific, cultural and artistic productions.

Incentive for governments of developing countries

A strategy that is not focused in the above proposals is to provide governments in developing countries, where the obligation to fulfill the human right to essential medicines indeed rests, with incentives to make stronger efforts to meet them. Incentives often seem to be associated with trade, not with the building of capacity to deliver necessary medical treatment to people. Respecting and promoting human rights in the Universal Declaration and the Covenants is an obligation of course for all the signatory parties, but as there is a lack of sanctions to enforce compliance, incentives to promote this are an option to consider.

Irrespective of the extent to which the TRIPS induced IP protection makes essential drugs unattainable to the poorest, solutions could be sought that utilize the patent system in creating such incentives to promote access, even in the short term. The opportunity to be explored is how an extension of the patent period in certain cases, beyond the time sufficient to recover the inventor company's expenses and to make for a decent profit, could create funding for free supplies of essential drugs to developing countries according to need and capacity. If such a step, which should be both technically and politically feasible, were to be taken, the developing countries themselves would have an incentive to look for solutions as to how the medicines and treatments could be distributed and delivered.

For reasons thoroughly discussed by others,[246] the flexibility provisions in TRIPS have not resulted in any significant improvement of access to drugs among poor populations. Parallel imports, one of the provisions, show no sign of taking on the proportions needed to accommodate the severely poor.[247] One other flexibility provision in TRIPS, that of compulsory licensing has proven not to be effective despite the fact that it was reiterated by the WTO ministers at the Doha meeting.[248] The voluntary donations made by the pharmaceutical industry are selective instead of comprehensive, thus these cannot secure the human right to basic health for the poor.[249] If the donations could be systematized, however, they might come closer to filling that function. Systematic donation of medicines, financed

[246] For example Hoekman, BM and Mavroidis, PC (2000); Kohler, Lexchim, Kuek and Orbinski (2010); and Matthews, D (2004)

[247] Correa, CM (2002:17-8)

[248] As explained in Kohler, J.C. et al. op.cit

[249] See Ashcroft, RE (2005:126) on why "dependence on charitable benevolence was a poor tool of public policy."

through time-extended patents, could be included in TRIPS, since the Agreement is so closely associated with the current situation of lack of access due to high prices.

As noted above, the recuperation of the investments in a new medicine is largely realized in high cost markets. It is estimated that between 80 and 90 per cent of the sales of patented medicine occur in the OECD countries.[250] This is where the recovery of costs in research and development takes place, and not in the developing countries. Jean O. Lanjouw and William Jack have pointed out that the developed countries already offered patents on pharmaceuticals before TRIPS, and that "the main result of the harmonization of standards required by TRIPS is to strengthen pharmaceutical patent rights in a group of poorer countries."[251]

Lanjouw and Jack comments on the effect of extending the patent period: "Lengthening patent protection for a couple of weeks in rich countries, for example, could provide returns equivalent to the introduction of 20-year patents in the developing world."[252] This concerns then the compensation for lost sales in developing countries. Another matter is the cost of producing the needed drugs for free supply. Here it is significant that the patent holder will already have its own, or they have out-licensed, ongoing production. The cost of R&D, marketing and testing for approval, as well as setting up production, will be covered by the ordinary patent period and should therefore be kept outside the calculation of cost for the added production. Details need to be worked out regarding the calculation of the cost and the length of the extended patent period, and the companies will most likely need to accept an authorized auditing instrument verifying the data necessary for the calculations.

The average effective sales protection is, as shown above, ten years. It is safe to assume that the extension needed for added production is a small fraction of that. Indeed it has been said by Harvey Bale, then the director general of the International Federation of Pharmaceutical Manufacturers Associations, that "Companies are able, through sales they make in developed countries, to offset the cost of donating drugs to poor countries."[253]

Here we see a strong reason to keep the patent institute in place instead of weakening it. If surplus values generated by extended patent protection could be used to make the donations programs comprehensive, then the patent system, instead of cutting people off from access to essential medicines, actually would be the arrangement that made them accessible

[250] Outterson, K *op. cit*, note 34

[251] Lanjouw, JO and Jack, W (2004:5)

[252] Ibid: 6

[253] Cited in Novak, K (2003:1271)

to people that could not even afford generic medicines. Lanjouw and Jack in fact concludes that certain medicines should be made available to the very poorest countries free of charge.[254]

An extended patent period would imply that the introduction of generic drugs and the price competition that follows from it would be slightly postponed. The cost for this, in that the price reduction is delayed in wealthier countries, would come as a result of expanded market protection through TRIPS and not from any new demands from patients in developing countries. They are cut off from generic medicines by the Agreement, a trait that needs to be addressed more actively by the Agreement itself.

The criteria for triggering donations of drugs would, taken together, look similar to the rational justification for a compulsory license. They would be i. public non-commercial use or ii. The widespread outbreak of a disease in a WTO country. iii. The country itself has no production capacity or purchasing capacity to meet the need. iv. The country can show plans for distributing the medicines and treatment of patients. v. The first four criteria are confirmed by an independent body like the WTO itself, or more suitably the WHO. Regarding the fourth point, an auditing instrument might be necessary at this end also, assuring the accuracy of the receiving capacity.

In TRIPS the compulsory licensing provision, which has not proven to be effective, should then be replaced by a requirement that patent protection is available in the WTO countries only under the condition that when the criteria are confirmed by WHO to prevail in any (WTO) country, the patentee is obliged to make the necessary drug donations.[255] To compensate for the cost, an extension of the patent period is offered.

The receiving country could not ask for more drugs than it can distribute and make effective use of. Focus would therefore shift to local conditions in the event that essential medicines do not reach where they are critically needed. Conditions that would need attention could be the host country's distributive capacity, its allocation of resources to meet an

[254] Lanjouw, JO and Jack, W *op. cit*, note 46, p.6

[255] I have not discussed the issue of moral responsibilities of corporations here. Instead I am concerned with the duty policymakers have to respect human rights when making agreements and other policy decisions taking account of the problem of perfect duties. Dan W Brock describes it, somewhat dramatically, this way: "[I]t is widely held that our moral obligations to benefit others in the absence of any special relations are sharply limited" (Brock, DW (2001:34)). See also Ashcroft, RE *op. cit*. note 44. He frames it in terms of legitimacy of power. If it is true that the drug companies do not have special relations to the poor patients, the same could not be said of their political representatives, signing international agreements, as pointed out by Cullet in Cullet, P (2003:140)

emergency and so forth.[256] This access of free medicines would serve as an incentive for governments to provide infrastructure like electricity and clean water as argued by Novak, citing Ellen 't Hoen from Doctors Without Borders: "We have seen that in countries like Cameroon, Mozambique and Kenya that as the cost of drugs comes down, governments start to talk about infrastructure, and patient access to the drugs goes up."[257]

The donated medicine would still be patented and adaptive measures should be built into the agreement to secure that such medicine will not flow into the wealthier markets. This would imply a revision of the parallel import article.[258]

In the event that the country where the emergency occurs is not capable or for other reasons is unready to receive donated medicine and distribute it, NGOs operating within its borders can act on behalf of national or regional authorities there. The NGOs could hand in documentation on the quantity of medicine they are able to deliver to patients and function as the partner of the donation authority (WHO for example) in cases where national health authorities fail their obligation.

The revised TRIPS would serve the interest of not only one party, i.e. society, but also the pharmaceutical industry, which would see a key reason for its poor reputation disappear. The main advantage for this industry would be the abolition of the threat of compulsory licenses and thereby the security and predictability of uninfringeable patents.

The concern for intellectual property rights to essential medicines and the concern for the human right to access such medicine would be better balanced through a revision of TRIPS implying systematized and patent funded drug donations. The biggest gain that would result from the revision, however, might be the shift of focus mentioned above. The attention which has up until now been given to the pharmaceutical industry and the patent law in the WTO would give way to renewed attention to all those other factors that are making medicines inaccessible to the poor, thus providing incentives to their governments, their neighbors and the international institutions to build competence, health institutions and distribution capacity.

[256] For more on this issue, see Gostin, LO (2007)

[257] Novak, K *op. cit*. note 48, p. 1272

[258] Matthews, D (2004:99-101)

The Distant Moral Agent

Introduction

In the debate on how to deal with problems occurring far away from home, much attention has been devoted to questions about the duties of moral agents. The agents in question are thought to be more affluent than the victims, and they are positioned at such a large geographical distance that few, if any, social connections seem to exist between agents and victims. Not even our current global communication structure has reduced the social distance between people to an extent that truly has the potential to close the economic gap (or the differences in access to education; healthcare; personal security and more).

Within the particular debate on the possible obligations towards needy people far away, the preoccupation with moral duties has overshadowed questions about their rights and particularly about the scope of these rights. The perspective adopted here does not belong to the moral agent or the duty holder. It is instead informed precisely by the right-holder perspective – the person at the other end, so to speak. I argue that the methodological shift involved in changing the focus from the moral agent to the holder of legitimate moral claims better enables the identification of duty holders in any given case.

Singer provides one such paradigmatic case to consider in his much-commented 1972 article "Famine, Affluence, and Morality," in which he introduced the imagined example of a man witnessing a child, a stranger to him, about to drown in a small pond. The pond is just deep enough to be life threatening to the child, but it is shallow enough for the man to be able to wade out and rescue the child, although it would ruin his suit in the process. The ethical principle Singer discusses through this case is this: "If it is in our power to prevent something bad from happening, without thereby sacrificing anything of comparable moral importance, we ought, morally, to do it."[259] Finally, he assumes that "suffering and death from lack of food, shelter, and medical care are bad."[260]

[259] Singer, P (1972:231)
[260] Singer, P (1972:231)

In his discussion he notes two crucial implications of the ethical principle. First, it is valid regardless of distances. Second, the principle does not distinguish between situations where the agent is the only one in a position to act and situations with millions of other agent candidates. It is the first of these two implications that most concerns us here. One would wish that Singer said more about its justification. However, he merely states that it must follow from any principle of impartiality, universalizability, or equality and that there is not much need to add to this.[261]

If we turn to his later work, we find justificatory arguments nevertheless. Leaving aside his preoccupation with biological development and his analogy (or even stronger connection) with the development of rationality, what he says about rationality itself is pertinent to his view on impartiality. Concerning equal consideration of interests between several persons, including oneself, he states that rationality enables us to take the broader perspective. This perspective informs us that "our own interests are no more important than the interests of others[.]."[262] Hence, rationality itself excludes the significance of distance between people.

If we acknowledge the duty to sacrifice the suit to save the child's life, then Singer invites us to consider what difference it would make, if any, were the pond situation to occur at a distance from the agent. The distance to consider is great enough to exclude witnessing the child in peril first hand. Thus the agent has only second-hand information of the child's situation, let us say from a radio report.

The configuration of Singer's initial case is quite basic but very effective. There are two agents: the man in a position to help – whom we may call the moral agent, and the child-in-pond, whom we can call the victim (of circumstance). This basic configuration, however, seems to include two key approaches, not only one. The first approach asks, as Singer does, about the scope of duties for the agent in question. Taking this approach, one could or should ask whether the scope of duties covers strangers and if so, if it also covers geographically distant strangers.

As noted above, the second approach investigates not the scope of duties, but the scope of the victim's moral claims. What morally valid claims could she make on the stranger? And what morally valid claims – if any – would apply if her stranger were located in some distant location?

[261] Singer, P (1972:232)
[262] Singer, P (1981:111)

We thus have two approaches corresponding to the basic configuration of Singer's example. They are quite different in method, and possibly in ethical orientation as well: the duty-based approach and the claim-based approach. An indication that the most common perspective chooses to focus on the duty bearer, and not the claim holder, can be found in the familiarity with which we speak of misery and victims of poverty that are far away.[263]

The other angle, explored here, implies the considerably less familiar perspective of distant moral agents. From a cosmopolitan perspective that has no privileged center of attention, however, this opposite angle should not be foreign.

In the first instance, the perspective clearly belongs to the duty bearer. From this perspective, the victim is in a distant position. The second, opposite angle views the moral agent from the victim's perspective. Instead of exploring duties independently of whether or not any misfortune exists, the victim-centered angle explores duties in relation to actual misfortune.[264] This perspective overlooks moral agents near and far. The aim of making this perspectival shift[265] is to see what implications it might have for ethical discussions of persons near and dear to the claim holder, and not necessarily to all duty bearers.

The argument presented here is methodological rather than normative, and it is not particularly directed against Singer. It is normatively neutral in the sense that it applies to separate normative theories irrespective of their divergences. Deontological and consequential theories – to take two broad outlooks – offer mutually conflicting foundations for moral duties. The question of assigning duties in particular circumstances to particular agents can be treated separately and regardless of what foundation they are based on.

[263] Singer's model is but one example of this. Others are Thomas Pogge's arguments for global negative duties in Pogge (2002:14f). The duties in question are justified with reference to causal factors, i.e. by placing responsibility with wrongdoers – people and peoples whose former behavior has negatively impacted people or peoples elswhere; Goodin (1988) on special duties to family, friends and compatriots, central in the debate on communitarianism vs. universalism preceding the more recent debate on global justice; Barry (2005) on ethical responsibility for poverty far away based on "our" contribution to it; Brock (2008) on commitments and obligations. These are all prominent names in the global justice debate, and the premises for it (Goodin). This is the debate I discuss, and my claim that the duty holder perspective overshadows the victim perspective is meant to apply to this debate in particular – not to ethics more generally.

[264] I do not differentiate between misfortunes that are caused by oneself or others and mere events, accidents, at this point. By misfortune I mean to refer to any situation where a person or a group of persons suffer from constant or sudden poverty, illness, oppression, lack of security or related deprivations. Below I take up the question of the moral significance, if any, of them being caused by oneself or not.

[265] Among prominent theorists that have opened the field I count Joel Feinberg and Ronald Dworkin (see literature references below).

Important to note is that the issue of assigning normative duties requires one to establish the scope of the duties, i.e. to determine how far an individual's responsibilities go, however they are justified. Assigning normative duties also concerns how to differentiate between duties within their scope, to prioritize between tasks whenever they cannot be dealt with concurrently. Both issues are ones that universalist normative ethics does not inherently address.

However, cosmopolitan ethics, inspired by universalist ideas, may still represent a standpoint on these issues. To consider this possibility, we should first distinguish between universalist and cosmopolitan ethics. Roughly, we can say that only the latter notion carries a geographical component. Universalism, on the other hand, is the position that stands in opposition to value relativism. It concerns the validity of arguments, rather than the number of persons subscribing to it. With this distinction in place, we may determine whether Singer's model of an expanding circle of moral concern falls under one of the two descriptions or both. Since it clearly concerns distance I treat Singer's example as a cosmopolitan model. A positive determination of cosmopolitanism, consistent with Singer's model, follows below.

Author-reader relations in the literature may to a large extent explain why we are so much more familiar with the concept of distant claim holders than distant moral agents. Authors tend to address a global north audience, and then their localization of the two agents in the basic configuration follows from this.

It is not the case, however, that cosmopolitans are alone in their preoccupation with the moral scope of duties as compared to the weight that is given to moral claims or rights and their scope. Their critics follow suit, as it turns out. Thus communitarian critics have also argued for stronger duties towards those persons near you than the duties we may also have toward distant strangers. The focus has largely been on the moral agent and his or her duties towards others when they are strangers, and not on the victim of poverty (or other misfortunes) or on individuals who are obliged to act on behalf of the victim.

At least methodologically, a shift of focus from duty bearers to claim holders is an underexplored option in this particular field of ethical investigation, and this is a good reason for choosing to explore further the claim-based view and to apply it in the global justice debate. The assumption of this essay is that central questions associated with the problem of distance in ethics will turn out to be more manageable in a methodological perspective from claim holders.

To be sure, an ethics grounded in claims or rights is not novel in itself for anyone acquainted with Kantian ethics or more recent human rights-based ethics. I should therefore stress again that it is in the particular debate on what Frances Kamm has framed the problem of distance in morality[266] that a claim-based perspective is rare to see. This also partly applies to discussions on global justice more generally, which has been distinctly influenced by cosmopolitan thought and predominantly concerned with negative (Thomas Pogge) or positive duties (Singer).[267]

It has been argued that Singer's child-in-pond example cannot deliver solid premises for the debate on problems far away, because it does not cover the contingencies involved in real-life situations of this sort. David Miller has objected that Singer says little about how obligations are to be assigned among many aidgiving candidates.[268] Miller states that a suggestion on how to differentiate between multiple candidates would have provided the necessary guidance in thinking about global poverty. Kamm has made similar arguments against Singer on this point.[269]

Their substantial critique of his example is not applicable to the reversed use of Singer's model. The criticism pertains to the expanding scope of an agent's moral duties. Expanding, alternatively, the scope of the validity of moral claims can proceed because it does not identify duties at all. Instead, it identifies agents one by one, or group by group, as the circle of legitimate moral claims expands. Even though the model is the same, we see here that the use is quite different. In Singer's initial use of it, the model adds instances of moral concern (people, surely) for one and the same moral agent. In the reversed use of the model, the number of agents increases with the expanding circle, but the instance of concern remains one and the same.

Singer regards his model as ecumenical, meaning that it does not determine the normative basis for duty. He presents it as a model that is applicable for consequence ethics and deontology alike. The same holds for the reversed use, whereby the model does not provide a normative solution to the foundation of obligation.

The configuration of the model works well for my case in highlighting the two key approaches, which address the duties of the moral agent and the claims of the victim,

[266] Kamm, FM (1999:177)
[267] Pogge, T (2002) and Singer, P (1981)
[268] Miller, D (2007:234-5)
[269] Kamm, FM (1999)

respectively. In short, the configuration deals with both parties, whether they involve one or many individuals on either side.

Singer's model is described in more detail in his work, *The Expanding Circle*.[270] Again, my use of the Singerian circle here has a methodological purpose. His model can be used to explore the claim-centered view. In doing this we replace the moral agent in the center, and into this center position we place the claim holder.

At least in some basic sense this seems a sound thing to do, given the condition that the concern for the victim in the basic configuration must, for any credible moral theory, outweigh the concern for the moral agent. The shift of perspective would imply that the moral agent asks what needs to be done and who should do it instead of asking what should I do about it – the latter being the self-centered question (cf. the expanding circle around the agent).[271]

I

Mass poverty as a result of inefficient or indifferent international policies, as well as poor domestic governance, are well-established drivers for widespread misery in various shapes and forms, including undernourishment, lack of access to essential medicines, and child mortality.[272] Global justice theorists, like Thomas Pogge, Peter Singer and several others rightly sound the alarm about the scope and perseverance of the misery and point to everyone's duty to eradicate it.

In order to discuss how the duty can be distributed among all, I first address the more general problem of what obligations, if any, individuals living in relatively affluent regions of the world have towards people living under much less favorable conditions, often in distant regions as seen from the affluent regions. More specifically, the article addresses the issue of basic rights, such as the right to basic healthcare, if there is such a right. My assumption is,

[270] Singer, P (1981)

[271] I realize that my phrasing of the moral agent as self-centered in Singer's original model might invite opposition. Still, I believe it is worthwhile pursuing this path to see if it works for a perspective from claim holders.

[272] For disturbing numbers, see Pogge, T (2010:11-12)

following Onora O'Neill,[273] that rights, in order to be effective in practical life and meaningful at the conceptual level, must be accompanied by obligations. This assumption points to the question of who bears the moral obligations that come with basic moral rights.

In the broad scope of deontological or utilitarian theories, guidance is provided on why every rational being has moral duties towards other rational and sentient beings and why any given moral agent has a duty to support rules or perform actions that promote the best outcome in terms of welfare for anyone affected. As pointed out by Richard Ashcroft, however: "'moral' theories (such as utilitarian theory, or natural rights theories such as Lockean theory or modern human rights theories) are less illuminating, in that they fail to construct compelling *perfect* obligations lying with *specific* agents."[274] By perfect obligations, Ashcroft connects to the Kantian notion of perfect duties and thus takes them to be non-contingent. Distance or personal ties do not influence their strength and relevance. A perfect obligation will imply, he holds, "a specific duty to assist"[275] for any particular agent. In Iris Young's treatment of the issue, she asks how we are to "conceptualize responsibility for producing and rectifying structural injustice."[276] Her case concerns the inhumane working conditions in many sweatshops in low-cost countries, where conditions are such that whenever we hear and read about them we think somebody ought to do something about them. She says her question on injustice and responsibility involves a puzzle "because standard models of responsibility in moral and legal theory do not supply a satisfactory answer".[277]

The types of moral theories Young discusses are the cosmopolitan view on the one hand and state-centered views on the other. The refusal to acknowledge any moral significance of geopolitical borders between people, central to the cosmopolitan view, seems a promising conceptual framework for taking responsibility for distant regions. This framework first of all includes people far away in its scope of moral concern, and thereby also makes it reasonable to investigate criteria for assigning obligations toward people, irrespective of where they live or how far away they are from the moral agent. A statist view seems to have a comparatively harder task in justifying such obligations, or indeed to recognize them at all.

[273] O'Neill, O (2005)
[274] Ashcroft, RE (2005:140), his italics.
[275] Ashcroft, RE (2005:126)
[276] Young, IM (2006:115)
[277] Young, IM (2006:115)

Granted, many situations exist where it is reasonable to see severe deprivation in one part of the world as a matter of moral concern, perhaps implying duties for comparable privileged people at safe distance. Even so, convincing criteria for identifying responsible agents are needed. Young discusses some such proposed criteria, and I shall present her position, but first I want to make a few remarks on what I will not include in this presentation.

I will not speak directly on distributive justice in the following, nor about distribution of goods like essential medicines or socio-economic distribution in general. The issue here is instead the distribution of duties, so to speak, or better, the identification of responsible agents at the foundational level, which should in turn, and ideally, inform theory on those other distributive issues. The methodological approach I consider is to investigate in moral and political detail what moral claims or corresponding political rights people might reasonably be said to have or be entitled to from distant moral agents.[278] These moral claims are assumed foundational and in fact not distributed. I will then proceed by making clear two distinctions that underlie the following discussion.

II

First, in taking up Young's discussion of cosmopolitanism I should make clear that I will be primarily concerned with moral cosmopolitanism, as distinct from legal or political cosmopolitanism. Adopting Pogge's distinction,[279] legal cosmopolitanism is the ideal that all persons have equal rights under a shared political and legal system. Moral cosmopolitanism, on the other hand, merely states that all persons are morally related whether or not they belong to the same political unity, and that the relationship commands equal moral concern among everyone. Political units, as well as geographical proximity and cultural affinities, are morally insignificant according to this view.

Second, moral cosmopolitanism has three characterizing dimensions, pointed out by Pogge (2002:175) and slightly reformulated here.

1) *Units of concern*. The ultimate unit of moral concern is the individual person.

[278] I separate moral claims from political rights here and in the following, seeing claims as holding between persons, and rights as regulating between persons and political institutions. I concern myself with moral claims in this essay.

[279] Pogge, T (2002:175)

2) *Unlimited scope.* All persons count equally irrespective of physical distance, rank, ethnicity, gender, religion or any other personal or cultural characteristic.

3) *Universal pertinence.* The concern is equally distributed among people. No one has reason to be less concerned.

The broad scope and pertinence central to the cosmopolitan outlook surely invites concern about how to identify particular agents for specific obligations, as expressed by Ashcroft and Young above.[280] I shall discuss these two dimensions here and take up the first one about the unit of concern by returning to Singer's model below.

Regarding unlimited scope of moral concern, even granting that concern is equally distributed among all (i.e. accepting universal pertinence), the moral agent still wants to know where to discharge his duties. Even when accepting personal moral duty towards fellow human beings without discriminating between them, he needs to know this. The moral agent's own material and financial resources, and influence on institutions, only allow him to attend to a miniscule number of individuals if the effort is going to be effective. He therefore must discriminate among the candidates somehow, even if refusing to do so along lines of physical proximity, personal ties, cultural dispositions and so forth.

The agent accepts that his duty reaches well beyond his local social environment comprising family, friends, neighbors, colleagues and co-nationals. Unless he finds a method of discriminating between them, duties towards everyone must be equally respected. The agent's efforts will not only fail to have the desired effect if he discharges his duty equally within the vast scope of concern, but at a practical level no one will benefit in a noteworthy manner.

At the conceptual level, if we consider the dictum often attributed to Kant that ought implies can, the aggregate duties cannot surpass the agent's capacity. Reminiscent of the Kantian dictum, Singer employs a principle of marginal utility within his argument of consequential ethics. It states that one is not required to contribute beyond the point at which one's own suffering surpasses the gains, or utility, received at the victim's end.[281] This is where Singer's principle sets the limit of capacity. In applying it however, one person's duty

[280] They are not alone, of course. Much has been written on the issue over the last three decades or so by theorists like Thomas Nagel, Bernard Williams, Samuel Scheffler, Michael Walzer and many others. Mostly the discussion has revolved around the observed failure of the broad outlook to accommodate the intuitive appeal, pointed out by particularists and communitarianists, of special obligations to people close to you. The more recent debate regarding John Rawls's statist view in The Law of Peoples has carried the focus over to the realm of political institutions and global justice.

[281] Singer, P (1972:234)

towards each and every person within the set scope surely dissolves into an indistinguishable proportion. Putting it in slightly different terms, if the contribution is to have significance at all for everyone involved, the agent's suffering already surpasses the perceived total gains immensely.

The pertinence of the duty to aid is balanced by the principle of marginal utility, which is introduced to tell a person when he or she has contributed enough morally, even if it is insufficient in practical terms. If the scope of concern does not include a theory of distribution within it, not only the contribution seems to dissolve as a consequence, but with it the duty itself. From a utilitarian standpoint at least, there can be no personal duty to contribute insignificantly.

If, on the other hand, the duty is made contingent upon others also complying, then new questions arise (which will not be dealt with here) as to how the individual should act in relation to concerted efforts. I leave out this contingency in order to follow Singer's reasoning a little further, as he dismisses this contingency as a concern for individual choice, stating that "this can make no real difference to our moral obligations."[282]

Utilitarian arguments applied by Singer and others that focus on the greatest gain in happiness or welfare, could point the moral agent toward people who are worst off. If the number of people falling under the agent's scope is limited, such as a local community, he might well be able to determine who is worst off. In this case, much of the conflict between utilitarian and communitarian theory would be resolved. And indeed, the communitarian could act from the utilitarian principle within the area of his concern. We should therefore take care to thoroughly distinguish between utilitarianism and cosmopolitanism in discussing moral scope.

But if the utilitarian also operates with a cosmopolitan scope, the advice to assist the worst off individual leads to an impractical task. The knowledge needed to identify the worst off individual or group of individuals in the global scope at any given time is beyond most agents.[283] Most likely it is beyond any personal agent both for practical reasons and also for theoretical reasons regarding problems of uniform comparisons between persons and their sense of wellbeing.

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[282] Singer, P (1972:233)

[283] Samuel Scheffler has referred to consequentialism's efforts to accommodate the information problem by "arguing back to a more conventional position" as its "well-known normative schizophrenia" in Scheffler, S (2001:42-3). His critique therefore presupposes that consequentialism comes with a (problematically) broad scope of moral concern, which might or might not be the case.

If the utilitarian instead takes a practical approach and concentrates on cases for which he has personal information, the scope of concern dramatically narrows. Any criticism that he could have looked further and should have known better, would come not from utilitarianism itself, but from any theory with a broader outlook. A true cosmopolitan, whether a consequentialist or not, would perhaps have to rely on the knowledge of NGOs, like Oxfam or Doctors Without Borders, and trust them with her or his donation instead of deciding the matter herself.

I will make one final note here to underline the distinction between utilitarianism and cosmopolitanism, and to emphasize that one can discuss the one without making statements about the other. The issue is cosmopolitanism as it is understood by Singer himself when he says: "[I]n writing about the obligation to assist the world's poorest people, I want to reach people who are not utilitarians, so I don't rely on utilitarian premises for that argument."[284]

In and of itself, cosmopolitanism merely defines the scope as global, and importantly, establishes that any one person within it might come to be one's responsibility. It establishes, as I understand it, that any reduction of this scope of concern is unreasonable. However, what I have tried to show is that cosmopolitanism is not a theory for assigning duties within the scope. The belief that it is such a theory might cause the confusion that one's aid effort should be distributed, pre-theoretically, to each and every victim of poverty or other misery within the scope. It confuses the scope of potential responsibility and actual responsibility.

My understanding of the cosmopolitan outlook then, allows that within it our duties are *in principle* of unlimited scope and universal pertinence, but that some legitimate criteria for discrimination exist in the scope dimension and that some division of moral labor must be tolerated on the pertinence dimension. In fact, several suggestions have been made, most of which connect duties with what might be summed up as causation of various degrees. I shall now look into how Young comments on this strategy.[285]

[284] See his journal debate with Andrew Kuper in Singer, P (2002b:127)

[285] For another critical, and more comprehensive, analysis of the relationship between causation and moral duty, see Miller, D (2007) ch.4.

III

In her treatment of a causation criterion for establishing duties within what she terms the 'cosmopolitan-utilitarian model', Young highlights its prominent feature, as she sees it, of being a liability model. The types of theories she addresses are, unlike Singer's, cosmopolitan-oriented theories that include discrimination criteria. They are often, according to Young, based on some form of causal liability. She holds that this criteria type derives from legal reasoning, where the function is to establish guilt or blame for a harm being done.[286] As an ethical model, she finds it insufficient for several reasons.

One reason is that in the current production and trade environment, the distance between the wrongdoer and the wronged party is often great. In a case like this, such as is exemplified by the sale of apparel in Western countries that is produced in lowcost Asian sweatshops, the causal connection from producer to consumer is so complex that the liability model becomes accordingly imprecise.[287] In clear cases with one perpetrator, where the causal connection to the harmful effects is evident, the model has applicability. However, the past decades' globalization of trade and finance has resulted in an increasing number of cases of a very different nature. The "clear rules of evidence" (Young 2006:118), which are central to a liability model based on causation, has escalated the need for a supplementary theory as conditions have evolved.

I shall take up two more points from Young's list of why the liability model is not sufficient for allocating duties and agents. One is that the model, in her view, is unduly backward looking. The other point is that the model fails to motivate by its insistence on blame, instead of more mobilizing pronouncements.

It follows from the very structure of a model based on causality that it looks to the past in order to find what produced harm or injustice. The causes are, by the very temporality of causal relations, prior to the resulting harm. Thus, Young says that "[u]sually the purpose of assigning responsibility in terms of blame, fault, or liability, then, is to seek retribution or compensation for this past action" (2006:121). When conceptualizing structural injustice, she convincingly maintains that the concern must be to reform practices in a forward-looking way in order to stop systematic injustice from happening in the future.

[286] See for example Barry, C (2005) for an example of this approach. My references to Young are throughout to Young, IM (2006).

[287] For a similar concern, see Scheffler, S (2001) chap. 2.

The point has also been stressed by O'Neill, who suggests distinguishing sharply between practical questions about what to do on the one hand and retrospective questions about the proper response to failure on the other.[288] O'Neill draws on Bernard Williams when she states: "Forward and backward looking ethical questions may seem inseparable if one takes a rather specific, complex and hostile view of obligations." The view she has in mind is one that Williams criticizes as "the morality system":

> [It] is a way of looking at ethical requirements that links them closely to issues about blame and other retrospective attitudes. This way of looking at ethics deliberately lumps together forward-looking practical questions –'what ought I, or we, or this institution do?' and judgmental, retrospective questions – 'what view should we take of those who fail to do what they ought'?[289]

O'Neill takes this to be a conflation of responsibility and obligation, and argues that obligations to act shall not be based on responsibility for past actions.

It should be noted at this point that things might look different if one foresees harm coming from ongoing activities now.[290] This would be precisely a forwardlooking perspective, and also a causal one. Cases in point are structural injustices where it is reasonable to expect that a certain activity produces harmful effects for people. Young acknowledges this and separates such cases from the model she criticizes. She does not give her reasons for this, but it is reasonable to assume that she views this forward-looking causation model as applicable only to fairly transparent cases where the causal events are evident and not of a complex nature, which often makes the model inapplicable in the retrospective cases. Young in fact embraces the forward-looking causation model, assuming a case is sufficiently transparent, and includes it in the model she herself suggests, the social connection model.

Since no harm is yet committed in the forward-looking perspective, guilt and blame aspects do not belong to it. This brings me to the last reason I want to include, that of motivation. Identification of agents based on blame might work counterproductively because, as Young observes, when people are assigned obligations in proportion to blame they tend to react defensively. This is not a moral argument, but a psychological one, and I take it that it

[288] O'Neill, O (2004:248)

[289] O'Neill, O (2004:248). She is quoting Williams (1985; ch. 10).

[290] Pogge, T (2002)

rests on a fair observation. The defensive reaction is likely to lead to excuses, and the more complex the causal situation is, the more candidates for blame are indeed to be found.

With her social connection model, Young proposes a different approach for allocating duties. Her positive account of this model is, however, not as radically different from a causation theory as one might expect. In a defining line she explains that "[t]he 'social connection model' of responsibility says that all agents who contribute by their actions to the structural processes that produce injustice have responsibilities to work to remedy these injustices" (2006: 102-3). Within her model, she replaces the causal criteria for assignment of duty with other relations: power, privilege, interest and collective ability. The structural processes here are not exclusive to nation-states or other institutions, but tend to be oriented to a more social level. Their scope is however cosmopolitan, with an emphasis on duties that range from the duties of victims themselves (for example factory workers in sweatshops) to improving working conditions, all the way to buyers in foreign markets.

I believe that what she accomplishes by her duty-oriented connection model could also, and with greater precision and more stringency, be achieved through a methodological focus on moral claims or rights. I shall now develop the argument to this effect through a return to Singer's theory of the expanding circle.

IV

Singer's historically and rationally expanding circle of moral concern starts its movement at the closest range seen from the agent:

> Ethical reasoning, once begun, pushes against our initially limited ethical horizons, leading us always toward a more universal point of view. Where does this process end? Taking the impartial element in ethical reasoning to its logical conclusion means, first, accepting that we ought to have equal concern for all human beings.[291]

And:

[291] Singer, P (2011:119)

> The circle of altruism has broadened from the family and tribe to the nation and race, and we are beginning to recognize that our obligations extend to all human beings.[292]

The circle thus starts at the family level. As it expands, it includes more and more people. We can fill in our own personal ties in a decreasing order of strength and see that friends, neighborhood people, colleagues and so forth are included in our circle of concern as the circle expands. Singer sees the expansion as driven by rationality itself, that the human capacity for reason prevails over time, and that the circle has just started its movement.[293] In the center of the circle is one agent and it is this agent's moral concern that is expanding through this rational process. As we can see, the expansion does not stop until the circle includes all human beings.

Singer's argument is that there is no reason to stop the expansion, that the expansion is reasonable. I shall not argue against this, because it is precisely what makes his model cosmopolitan. I have chosen his model as an example of the scope I want to discuss because, as already noted, it is effective and made transparent by the illustration of the child-in-pond-situation. In other words, I cannot criticize his model for being cosmopolitan, since this is the property needed for the present discussion.

Instead, I would like to point to a fact that he leaves out of his picture by the very agent-centeredness of the model, namely that other people have circles too. Audun Øfsti has noted that

> [T]he centeredness and perspectivity of human existence cannot be overcome through universality in the sense of expansion and size. In an important sense it cannot and should not be overcome at all. What we have to see is rather that a system of concentric circles of concern is built up around any human being. And we are obliged to respect the circles of others.[294]

I will argue, in line with Øfsti, that it is as reasonable to respect the narrower circles as it is to accept the expanding circle. This is the case when the narrower circles designate the recipient's scope of moral claims. I contend that Singer's agentcentered model cannot capture this, and therefore a method to find moral claims the basis for distribution of duties is lost. More precisely, I do not argue that expanding the agent's scope of moral concern is irrational,

[292] Singer, P (2011:120)
[293] Singer, P (2011:113)
[294] Øfsti, A (2002:280). Printed in Burckhart, H. und Gronke, H. (2002)

only that it is insufficient as a tool for assigning moral obligation, unless one also considers the recipient's social and institutional situation.

In the following section, I distinguish between moral concern and moral obligation by taking the sphere of moral concern to delimit the domain of possible moral obligations. The people included in the expanding sphere of concern are then the people to whom I can come to stand morally obligated, and we need to ask how I, as a moral agent, should deal with the social and institutional circle encompassing people. I would therefore argue that one must consider not only one, but two agent considerations. They correspond to Singer's basic configuration of two parties – the moral agent and the victim. One consideration is the moral agent's expanding circle of moral concern as viewed from inside, from the agent's own viewpoint. The other consideration also belongs to the agent. It regards the victim's circles, which are viewed from the outside. I shall try to determine their significance shortly.

In the introduction, the viewpoint from which I considered the basic ethical configuration belonged to neither the moral agent nor the victim. The issue there was how to theorize about their situation. It was observed that there are two parties involved and that many people choose to focus the theory on the moral agent. Now, in order to stay close to the duty-based theories coming out of this perspective, we shall stick with the moral agent's viewpoint.

Since the ultimate unit of moral concern within the cosmopolitan perspective is after all the individual person, it seems reasonable that the moral agent, also the cosmopolitan agent, takes the recipient's socio-political circles into consideration. The theoretical positions to which Singer's cosmopolitanism is an alternative (such as particularism and communitarianism) actually share Singer's agent-centered outlook. They differ mainly in that they draw the circles closer to the agent in order to allow preferential treatment of co-nationals, for example. The various positions essentially share the same perspective, where the vantage point is the agent.[295] Moral agents are in turn portrayed as self-centered, however, to the extent that they fix their attention on their own duties. Andrew Kuper therefore holds, in the journal debate with Singer referred to above, that the debate is "couched in terms of an unhelpful binary opposition of 'self-ish' against 'self-less.' The whole debate is too narcissistic in its preoccupation with conscience and sacrifice."[296]

[295] I take Scheffler's view on "associative duties" to be another instance of this, for example through its reference to identity-forming membership in social groups (Scheffler, S 2001:57)
[296] Kuper, A (2002:111)

To look at social and institutional circles from outside means that the relations in question are those of another person and not oneself. Two different ways of doing this appear to be available. First, one might approach the situation of another person through sympathy and empathy or second, through respect. The first method would imply trying to imagine what the recipient's social and institutional relations – circles, in Singer's terminology – look like from the inside. This is the familiar thought experiment of putting oneself in another person's shoes. Staying with the view from outside, however, we should not take this route but instead keep the outsider's position. From this viewpoint the circles present themselves as a matter to be respected or not. We may note that Young's theory of connectedness is not about sympathy, but of social connections established by interaction, with trade as a prominent example.

To take pause from the technical language of outside and inside considerations and social circles, let us consider two examples, one from the literature, the other from a possible neighborhood schoolyard situation. In writing about special obligations to family members, Williams has described an imagined case where several persons are in immediate danger and one of them is the agent's wife. There is also the premise familiar from such imagined cases that no possibility exists of rescuing more than one person. Williams makes the point that any plausible moral theory must accept the reason "it's my wife" for rescuing the wife.[297]

Paul Gomberg has commented that this answer is egoistic in contradistinction to an answer like "it's my group," which expresses a moral attitude – a parochial one.[298] Williams forcefully argues that the agent has "one thought too many" if he reasons: The woman in peril is my wife "and that in situations of this kind it is permissible to save one's wife."[299] Williams' argument is existential, calling attention to the role of deep attachments. Without such attachments to other people, he argues, "allegiance to life itself" is at risk. He also includes adherence to impartial morality systems among the things that gives life the necessary "substance or conviction".

By the very existential merit of his argument we see, however, that the focus of attention rests clearly, even here, with the agent. Considering the wider body of Williams' work, it is the agent's life projects that are threatened by the prospect that his spouse is in danger. The

[297] Williams, B (1981:18)

[298] I borrow this point from Øfsti, A (2002:274)

[299] Williams, B (1981:18)

moral issue is, according to Williams, that every person's life prospects have moral significance.

If we alternatively do not concentrate on the agent's duties and concerns but instead shift the attention toward the recipient, in this case the agent's wife, other moral issues surface. By shifting the perspective, the idea is accessed that she has more reason than the others at risk to think that she has been let down by the rescuer if he chooses some other person than her, say by flipping a coin. The circumstance that she has special claims on him is not captured by the agentcentered perspective evident in talk of preferential treatment of our own. It therefore also goes unobserved, as for Gomberg, that in rescuing his wife the agent acted on her moral claims towards him and that his act by that motivation was a moral act and not an egoistic one. If, hopefully, he also had strong feelings about his wife being in peril, they merely add affection to the deed. This affection hardly gives reason for moral frustration. On the contrary, it corresponds well with the existential qualities taken up by Williams.

By shifting the attention from the agent's duties and concerns to a consideration of the other parties' legitimate claims – and in the political realm, on their rights – the agent in the example could realize that he had a particular obligation in this case. He could recognize this without the awkward support from one thought too many and furthermore without support from his own life projects.

In our next example we observe an imagined instance of human suffering, a malnourished child in the schoolyard. I cannot help noticing this shorter, thinner and paler boy every time I pass him en route to my office. As weeks and months pass with no signs that the boy's appearance of health is catching up with the other kids, my concern grows that he is not being properly cared for. I make some initial inquiries about his situation. I soon learn that he rarely brings food to eat at school like the other kids do, and that the word among the other children is that he is poor.

In approaching a case like this, we would quite likely and very reasonably start cautiously. We might seek circumstantial information about the victim's family situation, whether relatives know about the boy's condition or have had a chance to help, and if they have failed, whether other people or institutions should be informed. It should be noted that the caution demonstrated in this situation is not exercised in order to escape moral obligation, but rather to avoid conflicting ones. Caution is observed to respect other people's or institutions' obligations, by accepting their first-hand information and acknowledging the complexity of the situation and issues of time and organizational matters. Institutions that acknowledge a

certain responsibility for their employees, students or others ask for just this kind of information to be reported on potential victims.

Every time we proceed cautiously in situations similar to this, our actions confirm our respect for other persons' social and institutional relations. The concerned attitude displayed here nevertheless testifies to the point that the scope of concern is not limited to family and friends, but can go further than that, indeed much further in cases where social and institutional relations break down.

Due to reasons of expansion, the moral agent's scope of concern is wide, and in principle unlimited. This is what Singer's model shows. How about the social circle around the recipient – can that circle be pushed outwards for the same reasons? The circles encompassing the recipient represent the social and institutional units towards which the person can direct legitimate moral claims. In this respect they are not actually "circles of concern" as Øfsti (pointedly) sees them in the context of the citation above. Here they are rather delimitations of legitimate moral claims.

Again, the moral agent is not at the epicenter of the social circles, but the recipient, or claim holder, is. This can be captured from outside, from the agent's position. The distinction to be made is one between the view from inside the Singerian circle of moral concern and the view from outside at other persons' circles. The first view, then, corresponds to the scope of concern and the second to the pertinence in my reformulation of Pogge's explication of the cosmopolitan outlook above. The moral agent is at the center of the view from inside, whereas the claim holder has this position in the agent's view from the outside. Even though we agree it is reasonable to expand the circle from the first perspective, as Singer holds, the other perspective finds that the social circle surrounding a person only expands when the original social surroundings fail, as in the schoolboy example.[300]

One might object at this point that a place for special obligations exists even within the agent-centered view, allowing for different roles as family member, neighbor, colleague and so forth. It might well be that such allowances could be admitted, without taking other persons' moral claims into view, but they would then come as exceptions to the general rule, or as in Robert Goodin's case, as derivatives of the general rule.[301]

[300] Even in a cosmopolitan "one polity" theory it would not be reasonable to assume that people have legitimate moral claims towards only one global institution. The necessary decentralization of functions and institutions could not ignore people's moral claims at various levels.

[301] Goodin, R (1988). In Williams' case they would come as "one thought too many," as we have seen.

What is worse is that a duty-based theory seems weaker than a theory grounded in claims or rights (corresponding to moral and legal cosmopolitanism, respectively).[302] This is due to duty-based theories' dependence on agent surveillance and initiative. In claim-based theories, agents are instead picked out simply by the quality of being next in line. The securing of moral rights then, is determined by the bystander's reaction to being first in line to act on them, or to acknowledge the personal duty activated by being in this position.

The view from outside other persons' protective social shields provides the agent with a map, where the assignment of obligations is at least sketched out and shows which person or institution is to take over the case whenever a social shield fails. The perspective from duties does not provide this information as clearly or directly, because it has to rely on oft-contested assertions of cause and blame.

The perspective from other people's legitimate moral claims deals with the problem of dissolving duties. It is a view from a particular position in the world where circles of moral claims are being monitored. Thus, it is not a view from nowhere, informed but not concerned.[303]

The problem of universal rights is well known: if all circles but the most distant are to be removed, not from the agent, but from the holder of the rights, the position of the holder is less secure.[304] The moral claims or legal rights meet with obligations in the nearest social or institutional body, respectively, as seen from the claim holder. Important to consider is that I might find myself repositioned by events from a position outside of the claim holder's social and legal situation to the innermost circle of a recipient far away. My repositioning might occur irrespective of any prior involvement in creating the circumstances that need to be addressed, as in the imagined case of the malnourished schoolboy above.

If the inquiry for circumstantial information about the child's social and institutional relations reveals that his family is dysfunctional, his relatives unaware, the kindergarten personnel not brave enough to report the case and the school's routines to deal with it deficient, we are likely to become more worried rather than less as we progressively uncover the facts. The sense of discomfort or alarm intensifies as we find that one social shield after

[302] In statist theories often based on Hobbes, like Thomas Nagel's in Nagel, T (2005), the argument is that there cannot be meaningful talk of rights unless there are duties in place to secure them. I assume the reversed statement is as reasonable, that unless there are people with rights there cannot be talk of duties. A logically related claim is made by Singer with regard to interests and equality: "If there are no beings with interests, the requirement that we treat all interests equally is entirely empty." See Singer, P (2011:106).

[303] Ref. Nagel, T (1986).

[304] This is the statist argument from Nagel and others.

another has failed. The sense and awareness of the stranger's unsupportable situation thus grows more personal for us instead of being peripheral within the general scope of concern. Short of developing a psychological argument for the case, I content myself with taking the imagined case to give intuitional support for the stringency of moral obligations outside the narrower scope of concern, even if there has been no prior involvement from the agent's side.

In the institutional realm, we might consider any case where agents create or contribute to an unlawful situation, through military operations for example, and thus fail to assume their responsibility for post-war security and (re)establishing institutions. The claim-based approach seems better equipped to identify agents for remedial responsibility, to borrow Miller's term, than the focus on duties alone can do. Bystander nations and regional organizations accepting the claim-based view would find that they could point to the perpetrator and his duties only for so long. They would then realize that the task falls upon them as neighbors, trading partners, allies, or co-members in regional organizations to meet – not out of good will but out of obligation – the moral claims for medicines, food and civilian security. The victims' claim cannot be derived from the duties of the perpetrator, because it has a wider reach. The order rather seems to be the opposite, that their claims activate obligations. When the first in line has failed in his obligation, the claim perspective would demand that the next in line is obligated to take over.

A person could also be positioned in the innermost circle of a recipient far away by being a member of an institution or corporation that has played a role in shaping the predicament of the remote person. An example of such involvement would be large-scale foreign aid, such as the aid delivered by many countries to Afghanistan in recent years. Another example would be Western states' responsibility after military operations, as in the security situation in Libya after the removal of the leadership there in 2011. Yet another example might be state-supported or state-operated foreign trade and commerce activities like oil production and mineral excavation. When an agent is repositioned to the inner circles of the claim holder by events of this sort, the stringency of the claims towards the relevant institution, in these cases my nation-state, will be of the highest order and thus far from dissolved.

A claim-based approach serves this end, I believe, by rejecting a system of different rationales for agency, where a rationale for the perpetrator will not be valid for the bystander. An altogether different rationale is required for the bystander, which is hard to accomplish without recourse to mere benevolence – an unsecure resource for the party who has been wronged or suffered a misfortune. A claim-based approach, rather than an exclusively agent-

centered duty-based approach, can activate obligations also for bystanders, and indeed for local authorities as well.

V

To reiterate, the topic of this essay is methodological issues regarding the allocation of duties. I have defended the position that the sorting out of obligations and, correspondingly, the identification of duty holders are better served, or perhaps even made possible, by concentrating more on the claims of those harmed than on the duties of any individual person or institution operating with a global scope as his or her principal tool.

The view on allocation of duties that follows from the proposed reorienting of outlook is that no claim on the moral agent exists before the inner circles of the recipient have been tested and failed. Hence there are no duties to discharge before the expansion by failure of the claim holder's social circles. The claim holder's circles expand as those most closely connected to her or him fail in their obligation. The direction of the expansion in my reoriented view is toward the agent, rather than away from the moral agent, as in the expanding circle of moral scope. The circle closing in on the agent, so to speak, is the circle of other people's legitimate moral claims already covered by his concern. The claim holder's circles do not threaten to dissolve when they are being pushed outwards and towards the agent. The duty to assist following from the universal scope is a principled duty, activated by certain circumstances.

The two agent-perspectives combined – the agent's own moral concern and his regard for other persons' claims – activate his agency, so to speak. They differ from Young's model in that the duties are not always activated, even if the agent possesses the qualities of power, privilege and so forth, which are the triggers in her model. This is because the recipient may have legitimate claims on other, closer social or political units.

In a claim-based perspective, the moral agent is the distant other instead of the needy claim holder holding this position. The validity of the claim does not follow only from the recipient being drawn into the circle of the agent, or according to Singer, by expansion of the agent's circle to include the recipient within its domain. Moreover, it is the agent who finds himself

within what has become the innermost circle of the recipient. This combined position of the agent is what validates the claim and correspondingly gives the duty its pertinence.

PART THREE

ON THE ARTICLES

Preliminary notes

The research questions of the thesis, the method applied, and my reasons for dividing the topic of patent rights in three separate articles were presented in Part I. Now, after presenting the articles in Part II, I shall give more detailed explications of concepts and arguments involved, and relate them to current debate on rights.

In general, one could argue that the topic of IP rights is fairly new. As a growing part of ownership interest in our time is directly connected to the realm of ideas, the philosophical discussion spans a wide area in terms of the great variety of inventions. In an area like biotechnology, the property-bestowing act in legal terms is one of acquisition through invention. The inventive step has taken up the function which traditionally was ascribed to labor in the realm of physical objects in John Locke's theory of property. Legal right to intellectual property is justified by this inventive step, together with a handful of other criteria presented above and to be commented further below. The person or commercial entity that performs the inventive step has the right to claim property privileges to the original idea and control over its commercial potential.

Apart from this theoretical discussion, for the most part dealt with in the article *Patent Funded Access to Medicines*, this thesis also has a more practical purpose. It falls in line with my host institution's focus on applied ethics, to discuss solutions in the domain of practical politics. Consequently, the thesis devotes a considerable amount of attention to the practical question of how to resolve conflicts between right-holders whether this is accomplished by seeing the rights of one party as ethically prior to the rights of the other party in circumstances of urgent need, or alternatively, by way of reconciling the conflict.

Being a work in philosophy and not in legal theory the thesis explores ethical arguments exclusively, also when they have close affinity with legal issues, as in the discussion of the TRIPS Agreement. The published articles are not concerned with legal discussions on how the Agreement is to be incorporated into national law in WTO member states or how its text should be interpreted within a law context.

The article, *Ethical Reasons for Narrowing the Scope of Biotech Patents*, is placed first in Part Two because it takes a more general outlook on patents than the two succeeding articles – which discuss patents on pharmaceutical inventions particularly. This first article expands the perspective on questions regarding intellectual property rights and research by discussing patent on gene material and information. Here I give a critical discussion of the broad scope on DNA patents provided for in c patent law. I argue that because the patent is granted for an entire product (in the normal case of product patents), the scope of protection for biotechnological inventions will often exceed the scope of the invention itself.

The excess protection, I contend, is unjustified. Even a justification of intellectual property rights within the scope of invention is problematic to work out from the classical sources of Locke's theory of property or from utilitarian reasoning. From being the classical sources for justification of rights to material property, it does not follow that they will serve that same purpose for intellectual property. Locke concerned himself with the acquisition of tangible property and thus met the demands of his time. Any transition of his justification into modern time-limited property right to intangible inventions is profoundly problematic.

The practical side of this discussion is one that was touched upon by the Nuffield Council of Bioethics, but not developed fully in their report from 2002.[305] The report raises the question whether DNA patents stimulate or impede further development and research, and whether patents unduly restrict access to products resulting from inventions.

[305] Nuffield Council on Bioethics (2002)

The US Supreme Court decision from 2013 in the so-called Myriad case is a recent case of practical (legal) implications of the more theoretical inquiry into the foundations of the right to exclude others from using your invention. The Court revoked the patent on the naturally occurring BRCA1 and BRCA2 genes, but confirmed the patent for the altered gene, where the protein coding exons where intact, but other and non-coding elements were removed.

I argue that in the case of the altered gene the patent is unjustifiably broad if it exceeds the inventive step involved in removing the non-coding introns from the gene and making a stable synthetic gene. The synthetically produced gene crucially includes the protein coding information, which is clearly not invented, being preserved from the original gene. In a product patent, the whole synthetic gene is being protected, making it harder if not impossible for other parties to use this information for other purposes without permission and compensation to the patent holder.

The case is an example of a contemporary and common instance where it is not the product in the form of a particular tissue sample that is the object for protection. Rather, what the inventing party wants protected is the use of a set of information, whether it is carried in an unaltered biological sample or a sample that has been altered in other, non-relevant qualities, or in an electronic datasheet for that matter.

The second article, *Patent Funded Access to Medicines*, discusses patents on medicines and introduces this project's proposal for patent reform for essential medicines. The third article, *The Distant Moral Agent*, takes up a point left mostly untouched in the preceding article. Even so, it is closely related to it. It concerns the fact that the dissertation work has been conducted in northern Europe and partly in the US, in other words at considerable distance from the least developed countries, the article's locus of concern. This article on access to medicines is about the situation in the LDCs, in the process of implementing TRIPS in their legal systems. An explanation therefore seems to be in order as to what audience the article addresses in its discussion of lack of access to essential medicines in the LDCs. If it is true what critics of the Agreement say, that it will lead to more limited access to essential medicines in the LDCs, then who should address the problem? Lack of access would clearly be a felt problem within these countries themselves. The tradition is however that philosophical articles in ethics written in the global north (Japan, Australia and New Zealand included), addressing a northern audience, also focuses on institutions and practices in the north and as a general rule not on institutions and practices in

the LDCs themselves. There are good reasons for this, as authors presumably have more influence in their home audience and institutions than can be expected in the institutions of an LDC country, in a remote position geopolitically and perhaps also in terms of distribution of the texts.

The ethical debate on global justice serves to demonstrate the fact that some authors tend to underplay the role of developing country institutions, directing their criticism to northern institutions and global organizations instead.[306] Northern institutions are the entities that might come under pressure from public opinion and election results in the countries where many authors exert their influence. With regard to the international agreement TRIPS, ethical questions present themselves, like who would be accountable for the foreseeable effects of the Agreement, who is responsible for remedying any adverse effects and not least, whose responsibility is it to balance the interests within it in order to make it work as a fair arrangement for the highly varied parties involved? These questions are discussed in the third article in a more general fashion than the second, on patents, allows.

The signatory parties, all the WTO member states, differ widely in terms of market size and industrial capability. At one end of the spectrum we have affluent countries, hosting much of the pharmaceutical industry. At the other, we find developing countries with no such capacities. In addition, the developing countries have weaker markets. To frame the topic of the third article shortly then, I borrow Frances Kamm's term and describe it as the problem of distance in morality.[307]

[306] One example is Thomas Pogge's view on negative duties towards the globally poor, that is the duty not to harm them, in Pogge, TW (2002; General Introduction). Here he rejects so-called explanatory nationalism: a comparison between poor nations and nations that have overcome poverty indicating that local factors – not the global order – are the main causes of poverty. Pogge highlights the role of rich countries' trade with dictators exporting national resources as the major source of poverty abroad. In placing causal blame here in the introduction of his book, he sets the tone for his treatment of these issues, even though he elsewhere shows he is aware of the role of local factors in creating poverty (cf. note 349 below). For criticism of Pogge's view, see Miller, D (2006) pointing out that governments in rich countries buy the stolen resources, implying that it is a diversion to indict the global order for this.

[307] Kamm, FM (1999)

Patent Funded Access to Medicines

The most practically aimed article in this IP rights project, in the sense that it discusses institutional reform, is the article on intellectual property rights to essential medicines. I will present and discuss it first, since doing so will bring out the whole project's practical objectives.

The conflict of interest regarding access to essential medicines for the poorest in the least developed countries is between poor patients in these countries and the property right-holders to the medicine they need. The patients' interests are protected, in principle, by the human right to health.[308] We need to make the reservation that they are so protected in principle, and not always in real fact if the state that should enforce the rights has not developed the means to do so. After having made that reservation, the conflict could in general terms be seen as a conflict between two rights, the human right to healthcare on one hand and intellectual property rights on the other. It might well be then, that the IP rights could come under pressure from the human right to healthcare, and particularly so if the right to healthcare is held to be more urgent than the right to intellectual property.

Urgency, however, is not the main concern for long term planners. For utilitarian planners for example, if their chosen time horizon is long enough, urgency might be outweighed by the concern for the possible infinite number of coming generations. I discuss the significance of horizons with regard to the arguments of Udo Schüklenk and Richard Ashcroft in the article. At this stage I want to emphasize that it is not only the utilitarian reasoning that is at stake, but also the time horizon.

As it turns out the time horizon can be more crucial to the outcome than the ethical orientation. Schüklenk and Ashcroft present the utilitarian point that intellectual property rights are justified by being beneficial to public interest. Therefore, intellectual property rights must be shown to contribute to public interest in order to be respected: "[I]ntellectual property rights are designed to promote innovation in the public interest. However, where they contravene the public interest, the justification for their enforcement in that context is removed."[309] The authors thereby stress the role of utilitarian justification of enforceable IP

[308] ICESCR (1966:Art.12). As mentioned in the article the right to health is singled out in several of the UN Millennium Goals. The inclusion of adequate healthcare (if not a right to good health per se) is also normally included among the basic rights by commentators operating with a shorter list than that of the UN and its institutions. Cf. Miller, D (2007: Ch.7); Rawls, J (1999:65)

[309] Schüklenk, U & Ashcroft, RE (2002:192)

rights, i.e. patent rights. In the article, I comment that the public interest notion central for utilitarian reasoning on well-being is ambiguous because it does not by itself differentiate between short term and long-term perspectives. The TRIPS justification belongs to the long-term perspective of having the protection of investment for a period of time to help recovering development costs, and then to have the new invention on the competitive market after the patent period has expired. A medicine, which is developed and produced under this arrangement, will possibly serve the coming generation, as long as the disease persists. This is therefore a long-term utilitarian justification argument for patent right to essential medicine.

Any given government may at any particular time regard it the public interest to fight a disease that has become widespread in the population. If the state is poor, the government might find that they lack financial capacity to import a sufficient quantity of the necessary, but patented medicine. Because of the high numbers of infected patients in combination with the patent holder's high price, the health budget simply does not allow for the necessary purchase. Thus, the utilitarian duty will be to do whatever is needed, even if it implies breaching TRIPS to get the treatment to the patients. This is the argument of Schüklenk and Ashcroft.

Their argument would seem to be valid in the short-term horizon, but it is questionable whether it holds true in the long term. As I have noted above, and also in the article, the urgent needs of the present generation stand the risk of being outweighed by the concern for the interest of the indefinite number of coming generations in a long-term perspective. If it can be shown that the utilitarian argument for patent right implies that the first generation of patients must bear the cost of financing the medicine so that the generations to come can access it to post-patent prices, then this is a public interest argument in the long-term threatening the urgency concern of Schüklenk and Ashcroft. Following the argument, their view on utilitarian justification would be unduly preoccupied with the short term. We therefore have two conflicting utilitarian arguments due to their diversity in assumed time horizons, the utilitarian justification argument for TRIPS and the utilitarian argument for resolving a current health crisis in the population.[310]

Add to this that not only different time horizons can bring conflict into utilitarian decision-making. Differing geographical horizons can have similar effect. A simple but quite realistic imagined situation should suffice to illustrate it. A producer of generic medicines in

[310] On the distinction between rule-utilitarianism and act-utilitarianism, see: Smart, JJC & Williams, B (1973:9)

for example India copies a drug that has been developed, say, in the United States. There is considerable demand for this particular drug in India, so the production of the copy drug creates new activity in the form of many jobs and demand for external services from surrounding enterprises ranging from, service industries to house builders through to restaurants. Let us imagine that a considerable number of local people are lifted out of poverty by this combined activity. Increased tax revenues is a welcome result for the local community, but even more importantly, the access to the much needed medicine is greatly improved all across the country.

Overall, if these positive effects are in the basket, the authorities should perhaps consider it a utilitarian duty not to respect the inventor's IP rights, manifested as patent rights – now also in India. However, the effects are on the negative side near the production site in the United States, but only to the extent that activity there is not able to increase to expand its business in India. The gains in India would vastly surpass the loss in the US, especially when the higher marginal utility[311] for poor people in India are taken into account – workers and patients alike. In this case, where the circumstances in the US are compared with the situation in India, the horizon is global and works against the protection of IP rights. Therefore, unlike the previous case, where the broadest perspective supported IP rights against the narrower urgency perspective, here we have the opposite. The broader geographical horizon provides strong utilitarian arguments against the protection of the inventor's IP rights. What this shows is that a utilitarian argument in support of IP rights generally is not easy to produce.

Both cases, the time horizon and also the geographical horizon case, speak against a cross-cutting utilitarian justification of the protection of IP rights as patents in a global organization. They both strengthen Schüklenk and Ashcroft's general position, as I understand it, that this particular consequential argument is not as solid a foundation of patents as one might think. But they also show that the defense for breaching TRIPS might depend on what time horizon is chosen, when public interest is the motive.

A better justification of patent rights, because it is robust against the arbitrariness involved in choosing horizons would read something like this:

[311] Increased marginal utility is determined by a proportional increase in utility units, relative to what one has already, as demonstrated in Deaton, A (2013:29-36) talking about the relation between life expectancy and increasing wealth. Instead of reference to absolute wealth, measured in hard currency money, he refers to additional income in percent of present income. This way he captures the higher value of an extra dollar for one person earning 365$ a year relative to one who earns 100 000$ (my example). The absolute utility of the dollar is the same in both cases, in the sense that the dollar buys the same. The marginal utility, however, is different, and measured by the proportional increase.

> If no market protection is available and generic medicine manufacturers can copy any invention and sell it in any market without having to bear the costs of developing it, then – by market failure – the endeavor of developing new medicines will in most cases be irrational.[312] Patent protection therefore needs to be in place in order to enable development of new and inventive medicines.

This is an argument to correct a market failure. If the development of a new medicine is not carried out because it would not be rational to do it, the result for the health authorities in India and other developing countries is that there will be no medicine to copy. There would, then, be no medical solution to the urgent crisis. The argument in effect allows for a time-period of high prices, 10 years is the norm.[313] Apparently, it conflicts with a principle of inalienable rights to essential healthcare for everyone. The article aims to show that the conflict is only apparent, and that the world's poorest patients need not be cut off from access to new inventive medicine under a patent regime, given some modifications of the present arrangement.

In the utilitarian argument as stated above we can see that the interest of two parties are being addressed, first the inventing company and in the last sentence, the public. Not included in this rendering of the argument, but also serving the public interest, is the disclosure function of the patent institute. Patent law, as promoted by TRIPS, includes the requirement that the patentee gives a detailed description of the new invention instead of keeping it a secret. This should in turn stimulate further research and possibly technological transfer, at least wherever there is sufficient technological capacity in place to assimilate new technologies when their patent protection expires.

Criticism has been raised regarding this last point on disclosure. Holger Hestermeyer, for example, holds that the disclosure clause provides no convincing argument for patents because of the possibility of reverse engineering. If an invention could be studied and copied,

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[312] In the article I have adopted the use of the term *incentives for inventions*, much used in the literature. Now I invoke the notion of repairing a market failure instead. The two quite different labels for the same phenomenon together reflect the rather differing takes on market protection through patent rights. Even the term *market protection* is not innocent in this regard. Depending on context, it could indicate that an innovator needs protection from a market failure. It could also indicate a need to be shielded from free market competition.

[313] Patent Funded Access to Medicines, n.226

society has no need to grant a patent to obtain the description of how to make it. Indeed, countries like Japan, South Korea and Taiwan benefited tremendously from lax IP protection laws during their period of development.[314]

If, on the contrary, the invention is not open to inspection and copying, then the inventor might prefer the trade secret to patent, still according to Hestermeyer. The disclosure argument is thus not likely to convince the inventor who sees a realistic option in keeping his invention a trade secret. He will have his market advantage as long as he is able to keep the secret, whereas if he chooses the patent option, he will be sure to lose the advantage at the time the patent expires.

In this choice situation the disclosure argument promotes dissemination of knowledge. The patent is an offer to relieve the inventor of the risk inherent to the trade secret. If the inventor chooses to apply for patent, he will give up his secret and have his invention protected. It means he would need to guard his secret no longer.

In the former cases, where it is an option, technically, to study and copy an invention, the disclosure argument would at first view seem to have no force. Cell-phone screens, car propulsion and medical pills provide cases. If anyone skilled in the art performs a detailed inspection to study the mechanics, physics, materials and chemicals involved in the product, and is able to make a perfect copy based on what he learns, then the invention is fully disclosed. This is called reverse engineering.

The need for protection on the inventor's part may be present, and even to a greater extent, if the product can be copied. The non-rivalrous nature of intellectual property allows for wide distribution of the product with no exhaustion of the source. If anyone skilled in the technology should be able to reproduce the product without consulting its description, the value of the description as exchange for protection is highly questionable. This is the objection.

The disclosure document is however not without merit, even with regard to products of this category. An additional function of disclosure persists, and it is better described in economic rather than ethical terms. The economic argument is that patents correct a known market failure and the disclosure clause has a function in that regard. Generally, a market failure has occurred when a free market is proven not efficient in a sector or for a class of goods. The pertinent market failure is one of suboptimal dissemination of a social good. A free market will not provide the sufficient amount of a social good because it leads to a

[314] Hestermeyer, H (2007:27f)

collapse in the price in the near time horizon, even before the developer has recouped the investments in research and development. A free competition market in copy-products will bring prices down to little above cost of production for the copier.[315] For copy-products the cost is negligible compared to the cost of developing the original product. The anticipation of a price-drop in a free market could therefore stop invention. The resulting social cost of missed inventions is greater than the cost related to time-limited patent protection. Therefore, and with no view to rights, market intervention in the form of patents, is introduced to correct the market failure.[316]

By the introduction of patent, making or using the protected product without a license agreement is made illegal. Reverse engineering is thus stopped, and this route to disclosure of the invention is closed. To ensure that the knowledge behind the invention is distributed in the absence of ingenious copiers, a full disclosure is provided.

This argument for correcting a market failure does not imply that society offers the patent in exchange for information. It is not an argument against trade secrets. The economic argument for correction of market failure is that the description is required in exchange for banning reverse engineering. The invention, once let out on the market, cannot be kept a secret. It is reverse engineering, in the free market, that poses a threat to investment in costly innovative products. Society thus promotes innovation that is threatened in a free market and it obtains the knowledge behind the innovation from the inventor's description rather than through reverse engineering.

The argument for correcting a market failure therefore withstands the objection, conveyed by Hestermeyer, that the disclosure is worthless for products that can be reversely engineered. If the objection is expanded to imply that no market failure in fact exists (free market fundamentalism being the position that does not acknowledge failure in the market), we enter a cross-section between idealism and empirical questions which I do not discuss. Conclusions are hard to get to and would have to involve empirical study and also counterfactual arguments (like what if patents were not introduced?).[317]

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[315] Sonderholm, J (2010:3-4)

[316] Rosenberg, A (2004:81). Cf. also the thesis article *Patent Funded Access to Medicines*, the introduction, where the ethical side of this problem is attended to.

[317] Sterckx, S (2006:261): "[E]mpirical research on the economic effects of the patent system remains scarce and inconclusive." Maskus, KE (2000:44) on patents' role for the undertaking of risky investment in research and development: *While there is little empirical evidence on the role of patents in this process, largely due to the difficulty of constructing counterfactual cases to study, practitioners suggest that patent protection plays an important role.*

I noted above that economic perspectives on the question whether patents stimulates innovation have been inconclusive.[318] Economist Angus Deaton demonstrates that empirical evidence in economics are often challenged on ideological grounds.[319] He refers to a heated debate on the minimum wage in the US where empirical findings are refuted by economists opposing a raise in the minimum wage. Deaton quotes another economist and Nobel laureate,[320] James Buchanan, who once said in a newspaper comment, discussing the relation between evidence and theory in economics, that "there is no minimum scientific content in economics" – meaning that "economists can do nothing but write as advocates for ideological interests."[321]

Regarding the question whether patents fulfill their purpose, it is clearly an empirical issue and as such hard to settle by anyone, economists or others – not forgetting philosophers. I have, nonetheless, included arguments from a few economists in the thesis, aware that they might be ideologically invested. An observation relevant regarding patents in particular is that their rejection can be argued from politically opposite sides. From a left leaning side patents can be seen as giving undue advantages to big corporations like the pharmaceutical industry. Numbers from their financial reports, quoted in this thesis, can be taken to support the view. At the opposite side, patents will serve as a first-rate example of undue intervention in the free market. Even though the conclusion may be the same for both sides, to abolish or reduce the use of patents, the ideological platform from where they are advanced are very different, for example on willingness to regulate markets.

Despite this broad resource of resistance, patents have persisted. In lack of empirical evidence, the historical overview provided above might serve as the better source of evidence why patents on inventive products are still in use.

What is crucial to normative arguments, however, is not whether patents in fact stimulate invention, but whether they are sufficiently justified if they do. In the chapter Critics of WTO's TRIPS agreement above, I assume that patents can stimulate invention of new products. It does not matter, however, what I assume in this respect. What matters is rather that TRIPS assumes that patents fulfil this function. The ethical question to ask, then, is: if patents work as prescribed, are they then sufficiently justified?

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[318] Cf. The opening paragraph of the chapter Critics of STO's TRIPS agreement.

[319] Deaton, A (2013:197). See also DeCamp, MW (2007:87-90) above (Cf. note 317)

[320] Deaton was awarded his Nobel Prize in economics a couple of years after the publication of the work I quote from.

[321] Ib. Deaton cites Wall Street Journal, April 25, p. A20.

Whenever a patent is issued for a particular idea for medication, the assumption is made by patent authorities that the patent protection is a positive, even critical, step in the developing of the inventive idea through to an effective drug. The assumption of the function of patents made by legislators carries a responsibility. The state might be called upon for remedy if negative effects are not dealt with.

If state legislators on the contrary are not convinced about the net positive effects of patents for innovation of costly and useful products, they might instead be motivated by a threat of trade sanctions, and in the last instance by their interest in maintaining the WTO membership. If they fail to address local negative effects of a drug patent for such considerations, the circle of moral claims from patients expands to comprise the WTO itself and its TRIPS agreement.

One further point related to this, but regarding the function of disclosure should be noted. It has to do with the patent function that the disclosure protects not only the inventor, but also competing producers from false claims of patent infringement. This flip side of the disclosure requirement applies equally to products whether they are easy to copy or not.

Once a patent is granted, any moral disputes over theft of ideas or other inappropriate acquisition of intellectual property, are reduced to matters of patent infringement. The disclosure document will be the resource to consult. The legal dispute is manageable because the patent description provides a tool for ascertaining whether the competing product is an infringement or not.

To mount a defense against a big corporation might certainly prove a difficult task due to asymmetry in resources. We should not forget, however, that the court offers protection not only to patent holders, but also to other actors, unduly accused of stealing intellectual property.

There is one point I should like to make for the argument that patents serve to correct a market failure against any objection that it depends on empirical assumptions on market behavior. In circumstances where a competitor exists in an unregulated market, competition for market shares will mostly be fought over price. The producer with the lowest development costs could offer the product at a lower price and is therefore likely to win the largest market share. This enterprise is however, like the previous one, as exposed to the risk of copiers as the competitor was. The market failure argument is that no developer of original brand pharmaceuticals can meet the competition from producers of generic drugs. The assumption being made by the argument is then merely that developing a mature product

from an initial invention, testing it, and having it approved for market release has a cost. This is a fair assumption, empirical or not, and represents no critical qualification that should make the argument dependent on shifting circumstance.

The issue raised in this thesis is therefore not whether the utilitarian argument for IP rights is strong when it comes to regulate competition among medicine providers. I think it is. The issue is rather whether the argument discards rights to healthcare in the least developed countries. In the article *Patent Funded Access to Medicines* I try to show that the utilitarian argument for patents does not stand in the way for fulfilling rights to healthcare in the short term. I suggest one more reason to go through with implementation of a revised TRIPS. The Agreement should be refitted not only to protect the IP rights of the inventive enterprises, but also to work as an instrument to finance the provision of essential medicines to the least developed countries. The thesis does not see the apparent conflict between IP rights on the one hand and human rights to life and health on the other as an irresoluble conflict where a choice needs to be made on the ranking of rights.

Laurence Helfer and Graeme Austin have presented two ways of seeing the framework between human rights to health and intellectual property rights.[322] One way of conceiving the relation is as a conflict between the two types of rights, to be resolved by respecting the human rights' primacy over other international agreements by reference to the UN Charter. The other is a coexistence framework, holding them to be "compatible but as in tension" asking "how existing intellectual property protection rules should be modified in light of human rights concerns." The position of the thesis, seeing IP protection of essential medicines compatible with affordable prices for patients everywhere falls under their coexistence framework. This position is neutral with regard to varied conceptions of human rights. Whether they are defined by the UN Charter, or arrived at otherwise is not the point here. The view on rights at work in this thesis is discussed in *The Distant Moral Agent* as well as in the concluding section Human Rights, Legitimacy, and Moral Claims.

[322] Helfer LR & Austin GW (2011:65f). Also Haugen, HM (2007)

The feasibility of systematic donations

As stated above, the article on TRIPS is the most practically aimed chapter of the project, in political terms. The justification for IP rights on essential medicines argued here involves a revision of the present arrangement of patents in exchange for new inventions. A justification that preserves what is achieved by patents and meets the moral right to healthcare where a healthcare system is in place is a stronger justification. A note should be added however, as to the practicality of the suggestion made in the article.

The inclusion in TRIPS of a requirement of systematic donations of medicines, argued for in the article, could provide the stronger justification. In the article, I present ethical arguments for donations. Here I shall comment on the question that presents itself, but is not developed in the article, whether or not systematic donations of medicines is a feasible revision of present IP protection. In a legal text such as TRIPS, the revision would be inserted as mandatory provisions for patent on vital goods.

A judicial examination of TRIPS might conclude that the provision is not required and that WTO member countries have the opportunity to add the provision into their respective patent laws without coming into conflict with TRIPS as it is. Article 27 of the Agreement prohibits differential treatment of product categories. It states that any inventions, in all fields of technology shall be treated equally. Exceptions are inventions which threaten *ordre public* or morality. The patent regulation treated by art. 27 is however restricted to patentable subject matter, i.e. what kinds of products and processes are eligible for patent. The minimum standard of 20 years of protection must therefore be available for inventions irrespective of technological field. Art. 27 does not prohibit an extended period of protection, beyond the minimum standard, for selected categories of invention. If it is a reasonable interpretation of TRIPS that an extension of the patent period is available for life-saving medicines, no mandatory provision is strictly needed to enable member states to introduce such a provision in their own patent law.

There are other reasons, though, to make the amendment to article 27. A mandatory provision does not merely state that members are free to add the provision without coming

into conflict with TRIPS. It goes further and includes it in the standard patent law agreement for all member states. Moreover, the introduction of a mandatory provision in TRIPS works against pressure that might otherwise be exerted against one member country in singular cases not to apply the provision, whenever a corporation resists the extra production.[323]

I divide the question whether or not systematic donations of medicines is a feasible revision of present IP protection in two parts: i. Are systematic industry contributions of vital goods, as required by a mandatory provision in TRIPS practically feasible? And ii. Is it reasonable to require from the industry that they comply with the mandatory provision?

If systematic industry contributions were not practically feasible, it would certainly be unreasonable to demand them from industry. Let us therefore look into this part of the question first. Since the argument is that contributions end at the border of the receiving country,[324] any complexities concerning the distribution of the medicine inside the country should be put aside. What remains, therefore, is first the cost of production and delivery. Second, the presumed loss from giving up sales revenues from patented essential medicines in the LDCs must be addressed. Regarding the cost of the increased production, if it turns out to be so high that the extended period of market protection in developed countries expands unjustifiably, then questions arise whether it is at all reasonable to ask the public to finance it. The pharmaceutical company is at any rate not directly affected since it will have the extra cost covered. The buyers of medicines in wealthier countries carry the costs for the compensatory contributions. Given that health authorities (and in the US, also insurance companies) are in effect the largest buyers of pharmaceutical products, tax payers and insurance policy holders would carry the burden of funding the donated drugs. Health authorities are moreover a major funder of pharmaceutical research, thus also in that respect deeply involved in financially supporting the protected inventions.

[323] There are technicalities associated with the proposal which need to be addressed. One such technicality is how to determine the extent of the prolonged patent period. A number of detailed considerations go into it, such as what country in particular shall be addressed by the patent on a given drug in any particular country. Also, if both Norway and the UK for example are to occasion industry contribution of drugs, how do the two parties share the responsibility? Some international coordination must be set up, for example in the form of a priority list. The principle behind the proposal, its urgency and its justification is the topic of this work, the practical side needs to be taken care of separately. In the article *Patent Funded Access to Medicines* I have suggested that WHO is a good candidate for overseeing this. They would have an overview of the needs already through studies they collect and perform.

[324] Cf. The point on incentives to build capacity for distribution in the article's concluding section: Incentive for Governments of Developing Countries

Let us recall that the contributions in question are introduced as a response to the ban on generic medicine in poor countries where a patent on the brand name drug is pursued. In this capacity the contributions are compensatory. The situation created by a mandatory provision in TRIPS in fact is much to prefer over previous times, when generic drugs were offered for sale in the market but many could not afford to buy even this less expensive treatment. Now, that the brand-name drug would be accessible for all, the argument is that an improvement would have been accomplished. It would be effective through the period of the duration of the patent.

The justification for letting people in developed countries share the burden of this compensatory measure, is the topic of the article on the problem of distance in morality: *The Distant Moral Agent*. This part of the feasibility problem is then best understood as a question of whether the financing through extended patent periods, varying from case to case according to demand, is at all feasible, not whether it is feasible for the industry.

In the article, I cite the former director general of the International Federation of Pharmaceutical Manufacturers Associations, Harvey Bale, who maintains that the companies could cover the loss involved in donating medicine to poor countries even by present sales in the developed countries.[325] His statement is one clear indication that the burden imposed on the taxpayers in the developed countries is negotiable.

Regarding the second aspect, the possible loss of sales in the LDCs, I have cited Jean Lanjouw and William Jack claiming that this loss could be recovered by a couple of weeks of lengthened patent in the developed countries.[326] In their article, they further refer to one study by Lanjouw, which estimates that "countries with half the world's population represent less than two percent of spending on cardiovascular drugs. In fact, firms often find it unprofitable to exercise their option to patent in poor countries."

Another study, from Michael A Friedman, Henk den Besten and Amir Attaran concludes that "Africa, the Indian subcontinent, and the poorer countries of Asia total only 1·2%, 1·3%, and 2·6% of the global pharmaceutical market, respectively, and the proportions are even smaller for the sales of patented medicines (calculations based on data from http://www.imshealth.com). Accordingly, most companies agree that provision of certain

[325] Andreassen, T (2014:9)
[326] Ib.

patented medicines at a discount or for free in poor countries is a humanitarian imperative, the value of which exceeds the minor revenues that are forfeited."[327]

To counter any objections that the industry comes out of the proposed reform of TRIPS even better than before, in terms of net income and profits, I should emphasize that the corporations would not increase their sales as a consequence. All revenue from a prolonged sales period at high prices in an industrialized country, is spent to cover the cost in producing and shipping compensatory contributions to poor markets. It is performed in complying with a mandatory provision for patents on vital goods. Therefore, it is not an applicable point in the corporation's report on initiatives in social responsibilities. The pharmaceutical corporations, then, neither earn on the reform nor do they build reputation for philanthropy through it. They do however not suffer financial loss. But then, I do not believe it would strengthen the proposal if they did.

In the article Patent Funded Access to Medicine, I made the case that even extensive drug donations are less controversial in the pharmaceutical industry than compulsory licensing. The concern expressed there should now, hopefully, be clearer. The proposal, which aims for funding supplies through patents, makes sure that patents are still in demand by corporations. It does this not for fear of crossing the interests of the corporations, nor from a wish to please them, but rather out of concern for the funding of medicines to these regions. The systematic contributions of medicine to poorer regions is financed by extended patent periods. The medicine is thus patent-funded, not tax-funded, and it is essential that patents are kept attractive in order to accomplish the objective.

In dealing with the second part of the question of feasibility, whether it is reasonable to require systematic contributions or donations from industry, the broader perspective should be brought in that weighs the reasonable expectations from the sides of the lawmaker and the side of industry respectively.

Economists Robert Cooter and Thomas Ulen have pointedly described what is involved in a patent:

> A valuable invention creates a new product or a cheaper way to produce an old product. If the invention has no close substitute, granting a patent creates monopoly power. [..] As we know, monopolists earn profits that exceed the ordinary rate of return on investment. Specifically, a patent enables an

[327] Friedman, MA; Besten, HD & Attaran, A. (2003:341)

> inventor of something valuable to earn profits that exceed the ordinary rate of return on investment. However, monopolies impose social costs in that too little of the monopolized good is produced and the price is too high.[328]

It is nevertheless the case that a patent does not remove risk altogether. It does not protect from competitors working on other solutions to meet the same demand. Neither does it grant a monopoly on treatment for a particular disease, nor does it give protection from already existing competing medicines. Besides, the substantial risk remains that the new product will not be approved by health authorities. Further, a patent does not guarantee market access, and it cannot promise sufficient sales to return the investment. Still the patent removes any competition on the same product or process, and thus eliminates the risk that might tip the balance.

The corporations taking advantage of the patent institute are offered a considerable privilege by this very function. As it is, not much is expected in direct exchange for the advantage. Society assumes they will come up with more new medicines (which should of course also be profitable for the companies) than they would have if they did not enjoy market protection, and it hopes for a resulting transfer of technology through the disclosure requirement. The granting of a patent might crucially reduce the risk in going through with capital-intensive inventions. It therefore seems extraordinary already to expect the same rate of return as an investment would have that was not risk protected – the ordinary rate of return on investment in Cooter and Ulen's terms. To expect an even higher return than this as a result of market exclusivity from a protected investment, is quite unreasonable.

If it is unreasonable to make the unprotected investment, the point could be made that it is equally unreasonable to expect profits from competition shielded investments in excess of the ordinary rate of return on investment.

A final point on the feasibility of funneling essential medicines to poorer global regions through (systematic) contributions should be included. It regards price sensitivity. If the financing governments were to buy the needed amount of medicines locally instead, at a lower price than in their home markets, they might, through higher demand, contribute to drive prices higher. This alternative could even create a market for patented medicines where

[328] Cooter, R and Ulen, T (2004:122). The reference is taken from Bird R & Cahoy DR (2008) which deals with a topic I have not taken up, namely the negative effect compulsory licensing has on foreign direct investments in developing countries. For indications of this effect, see Rozek, RP (2000).

no such market existed previously, thereby restricting access in the longer term rather than promoting it.[329]

To conclude the argument on feasibility, I have argued that the expectation that the pharmaceutical industry should accept that a systematic contributions arrangement is reasonable. The argument refers to the expectations of the industry on their part, of extraordinary rates of return on risk-protected investments. In light of these industry expectations, society's demand for contributions of vital drugs in non-yielding markets are modest. This answers the second part of the feasibility question as I divided it above.

The first part concerned the practicality side, whether the drug contributions are practically feasible. The argument is that the medicine producer is not asked to distribute the medicine, only to deliver it at the border. The cost is fully compensated for by an extended period of patent protection, meaning here that drug contributions will not stop due to financial reasons.

Rather than pertaining to the industry, the financial issue pertains to those who will bear the costs. These are taxpayers and insurance buyers in the strong markets. Above, I briefly noted the question of whether or not it is reasonable to expect patients or the public in the developed countries to pay higher prices for an extended period of time to finance access in other parts of the world. The issue is discussed in the article *The Distant Moral Agent*. This is the more acute question when it comes to reasonable expectations, as I see it. Therefore, I deal with it in a separate article on moral claims across distances.

The Distant Moral Agent

The topic of discussion in *The Distant Moral Agent* is, as mentioned, the problem of distance in ethics. To give a broader background of the discussion than the article itself allows space for I shall divide it here in two sub-sections: i. the assigning of perfect duties with specific agents, and ii. the problem of non-transparency of cause-based duties in ethics. The two sub-sections are intimately connected as is evident in cases where a particular agent is identified

[329] Attaran, A & Gillespie-White, L (2001:1891)

as the perpetrator of some harm to others. A cause-based ethical theory will assign responsibility to this particular agent for the harm being done. The harm-doer is identified as the one with the strongest obligation to compensate for the harm, or to remedy the circumstances. The two issues are therefore often treated together. Only if the causal history is unknown or the causal theory is rejected altogether does there seem to be a need to establish independent criteria for assigning perfect duties with specific agents.

In the article, I have treated the issue of non-transparency of causes by reference to Marion Young and Onora O'Neill. Here I will expand by including the discussion between Thomas Pogge and Debra Satz and between Pogge and Joshua Cohen on the role of global institutions in causing poverty. Pogge advocates the view that developed states and global institutions cause poverty in the poorer regions of the world, and that if this cause was removed, poverty would end. The functions of the global order Pogge refers to as important in producing global poverty are the international resource privilege and the international borrowing privilege. The first privilege acknowledges the right of an autocrat to sell a country's oil, minerals or other natural resources even if he did not acquire power through legitimate procedures. From the revenues of the sales he is able to build up military force to stay in power. The buyer of the resources is in turn acknowledged as the legitimate owner of the goods by international institutions, financial and legal.

The international borrowing principle resembles this in the sense that it also acknowledges the illegitimate ruler of an autocracy a right to borrow from international or foreign banks on behalf of the country, and on security in national resources. A whole nation thus faces debts for many years to come, even if the ruler resigns to live on the funds once obtained in power. This way, according to Pogge, the developed world and the organizations they control severely contribute to harm the poor states. He builds a theory of justice that is not based on positive duties to aid, but rather on the presumed stronger negative duty not to harm others. In choosing the principle of negative duties, most commonly associated with the libertarian tradition, he aims for an ecumenical theory, able to draw support from many corners.

Satz and Cohen oppose Pogge's cause-based view from different angles. The first sub-section, on assigning perfect duties with specific agents relates to Satz' criticism of Pogge's view. In the next chapter, on non-transparency of cause-based duties I take up Cohen's arguments.

Assigning perfect duties with specific agents

Satz states the problem in a way that corresponds with the division of the two sub-sections above. She calls one empirical, the other philosophical.[330] The empirical matter concerns the task of determining "the main causes of global poverty."[331] She finds it dubious "that most world poverty is the effect of global institutions."[332] The philosophical issue is, she says, that 'the extent of "our" responsibility for global poverty is complicated by our diverse agency relationships to institutions.'[333] Thus, she questions the meaning of the pronoun "our" when used in abstract statements on responsibility for world poverty.

There is also another, closely related, issue she could have discussed. It is the question how to understand the widely used expression "world poverty." If it stands for (i.) all instances of poverty in the world, it would be some coincidence that their origin was one and the same. If by the expression "world poverty" something more is indicated, that is if (ii.) "world" is to be taken as a predicate, and not as a mere geographical indicator, then there is talk of a particular kind of poverty that can be traced back to some function of the world for its origin. The expression then, that world poverty can be explained with reference to global institutions would be analytically true. A third option might be (iii.) that "world poverty" signifies a standard well below some given world reference. This meaning of the expression is often used in statistical presentations of poverty. Using purchasing power parity for currency conversion the World Bank sets the poverty line at 1.9 US dollars' worth of a basket of necessary goods. This way they manage to establish who is locally poor according to a world standard. To more fully appreciate these numbers however, one should also take into account the inequality between nations and make a new ranking of how poor a person is relative to her/his national average.[334] In any event, the assertion that a definite set of specific global causes is common to all or most of these instances of poverty is a very strong statement indeed. I will not pursue this matter any further, restricting myself to indicate that the expression "world poverty," widely used in the literature on global justice is a complex

[330] Satz, D (2005:48).
[331] Ib.
[332] Ib.
[333] Ib.
[334] One useful source of information and explication of the economic terms involved is Milanovic, B (2011)

concept and that it is often not clear what is meant by it. The ambiguity of the expression, whenever it is not defined, often muddles discussions on how to fight poverty.

I will discuss the empirical issue of determining causes for poverty around the globe with regard to Cohen shortly. The notion Satz points to as a less than clear concept, still playing a crucial role in Pogge's arguments is the concept of "our," as used in "our responsibility for world poverty" in his book *World Poverty and Human Rights*.[335] Satz comments, using decision procedures in the International Monetary Fund (IMF) as an example:

> Because IMF policies are most often debated in secret, most people are unaware of the policies they debate. There is little accountability for international institutions and even less information about their policies than about domestic ones. What exactly is our responsibility here? To what extent do the unfair (indeed sometimes ruinous) policies of the IMF render us responsible *participants* in an unjust global order? And how is "our" responsibility different from the responsibility of others?[336]

Her chosen example is an international institution, the IMF, where citizens or persons anywhere have no word in the debate. Domestic institutions are, on the other hand, much closer to the agent. Even regarding these, she points out that people have different opinions about their policies. Our most direct influence on domestic institutions as citizens is through our vote in the local and national elections every fourth year or so. Here we can sensibly talk about "our" influence. But among us, and in democratic societies, we vote differently, i.e. we do not all vote for the same candidate, but choose from a list of candidates each of which stands for different policies. Therefore it becomes more problematic after the fact so to speak, when decisions are made of a government you voted against to take responsibility for a policy you voted to prevent from being carried out. Any talk of "our" responsibility then will not correspond to how "our" influence was referred to before the fact.

Pogge's point is that in a democracy we always have influence on our own institutions. The government always risks protest if it makes hugely unpopular decisions. Theoretically, there is perhaps nothing wrong with this argument. Practically, though, something seems to have been lost along the way from the argument to the conclusion that

[335] Pogge, TW (2002)

[336] Satz, D (2005:50-1). Italics in the original

"we" are responsible for world poverty. Causal issues are one important component, so is a lack of appreciation of democratic dynamics like people's sense of handing over responsibility for foreign policy to trusted leaders, issues of critical mass for effective communication with the government and so on and so forth. I do not pursue these issues. The philosophical case Satz raises is the question who are we that are responsible for our country's vote in international organizations, provided it has one.

If the people referred to by "we" and "our" comprises supporters and protesters of the policy alike, the assertion "we did it!" seems to be off the mark if it is supposed to express the carrying out of the promised, and contested, policies. The assertion had abstracted away the difference. The abstract "we" used by Pogge, thus deserves the scrutiny Satz calls for. The all-encompassing "we" purportedly designating a definite number of people (and excluding others) sometimes takes the form of an abstraction that can have only limited political purpose. There might nevertheless be a rhetorical quality to the abstract notion of the all-encompassing "we." This might probably be the effect in the introductory presentation of his book:

> Chapters 6-9 propose modest and feasible, but significant, global institutional reforms that would better align *our* international order with *our* moral values.[337]

To the degree that it actually singles out people or peoples, the pronoun should mean that it designates some, not all. Then we assume that those who are responsible for national neglect to end poverty abroad for example, are the ones voting for the closing of home markets against imports. The other party, endorsing imports of meat from developing countries, are not responsible. If there is no more to it, then what is implied by "our" failure to fight global poverty is that those who have publicly argued for poverty eradication are not included, the rest (the majority I suppose) is.

The distinction Satz invokes, between civic and personal responsibility could possibly account for the different referrals to "we" and "our."[338] The civic responsibility is the one that makes sense of a responsibility for acts committed of a country of which you are a member, even though you did not endorse the act yourself. Instances of "our politicians and

[337] Pogge, TW (2002:1-2). My italics.
[338] Satz, D (2005:50)

negotiators"[339] as well as others, like "we elected the parliament" and "we are at war" will fit within the realm of civic responsibility. The self-referral that comes out of it is due to membership. You identify with it through your sharing of obligations and benefits, not by choice. Most of us do not choose our nationality but stick to the citizenship that was handed to us at birth. We see no ethical demand in the literature on global justice or cosmopolitanism of individuals that we change citizenship in order to strengthen the influence of, say, a country promoting human rights internationally. We therefore assume that responsibility for belonging to a specific nation is not to be considered even if civic responsibility is acknowledged.

Thomas Nagel has famously argued that since state membership is not chosen, citizens' obligations cannot legitimately have a larger extension than the benefits.[340] The benefits and the burdens should be shared by the same people. This is how rights and obligations are constituted, he argues. Satz holds that when we are responsible for our given nation's acts and omissions we are so by virtue of civic responsibility, not by personal responsibility.

In drawing the line between the two types of responsibility, Satz suggests that neither, not the individual's civic responsibility nor personal responsibility, pertains to acts of international organizations like the International Monetary Fund and the World Bank. Here, she says, the "agency relationships are more indirect".[341] By rejecting either type of responsibility for the policies of institutions at this level, she distances herself from the notion of responsibility for which Pogge argues.

Taking no account of the distinction, Pogge must include personal responsibility when speaking of responsibility for world poverty/poverty in the world.[342] Anyone who does acknowledge the distinction would object to the import of the political concept of responsibility into the realm of personal morality. The article in this thesis *The Distant Moral Agent* starts out from difficulties with abstract notions like the first person plural indicators just discussed.

[339] Pogge, TW (2005:79).
[340] Nagel, T (2005)
[341] Satz, D (2005:50)
[342] Indication that he does is evident in his reply to Satz, where he calculates that "the typical affluent person, by the time of his or her death, bears responsibility for roughly one poverty-related death, for about 200 human life-years spent in severe poverty, and for about 20,000 hours of children suffering intense pain from hunger or diarrhea." (Ib.)

The conclusion of the article is that agents who ignore moral claims can be identified by empirical inquiry. In this particular sense, I have found the moral approach from claim-based theory to be methodologically stronger than cause-based deontological theory. Its strength draws from the fact that even if a causal role for poverty far away is not recognized at the individual level, a moral imperative to contribute to alleviate it can nevertheless be acknowledged. Cause-based deontological theory, on the other hand, depends on a contested claim of the moral agent's individual role in creating poverty far away, and it builds individual duty on this premise. This dependence, sometimes involving the abstract *we* to establish personal responsibility, is a weak point not shared by claims theory.[343]

To give an illustration of the claim-based approach we can stay with the case of negotiations for revision of the TRIPS agreement and make two observations. First, here was a case of an international arrangement that turned out to have significant deficiencies and therefore came under pressure. Among the states pressing for reform was the African Group, a group of all the African member states in the WTO.[344] The fact that the problems were brought to the table by the parties responsible for providing the healthcare in poor countries demonstrates their accepting responsibility for the affected people. By taking that action they demonstrated that they acknowledged a perfect responsibility in this matter, not equally shared at any moment by every party around the table, each of them present to promote their national interest, at best with secondary concern about welfare abroad as well.

Second, the case illustrates the fact that the distance between states and the distance between persons is not of equal measure. State representatives meet in organizations and negotiations. In several fora they will meet regularly, and the delegates will often know each other personally. There is a "we" among states that is well defined and could qualify for moral considerations.[345] International governmental organizations work against the state of nature-like condition where the most powerful state dictates the rules. The organizations provide the rationale and opportunity for agreeing on fair terms of cooperation in trade, for example.

[343] On the other hand, Claim theory must show how to separate moral claims from other claims - for example claims from interest in luxury goods. I do not address this normative question here, as the article is about the claim to existing essential medicine, a human right that is denied them by the political power in charge.

[344] WTO (2006a)

[345] Thomas Hobbes' social contract theory established moral rights and obligations by creating state institutions, Hobbes, T (1651). The rights created applied inside the state. On the outside the state-of-nature still prevailed. Our day's global institutions might call for an expansion of this classical theory. John Rawls theory on international cooperation in Rawls, J (1999) is a recent proposal about how to avoid the state of nature-like conditions of international relations.

What the African states accomplished at the ministerial meeting in Doha in 2001 was that important clarifications and extensions were made and reform of the compulsory license provision was initiated.[346] Ironically, they were helped by the anthrax threat occurring in North America just the month before the meeting. Canada had threatened to issue compulsory licenses for anthrax medicine and the United States had threatened Bayer, the producer of the medicine, to buy cheaper generic medicine if Bayer did not reduce the price. The US got the price reduction in embarrassing contrast to the country's policy on AIDS medicine in South Africa where it had protected its pharmaceutical industry.[347]

The Doha clarification addressed the issue of determining the occurrence of national emergencies. It is an important matter as it has consequences for the legality of issuing a compulsory license. The ministers made it clear that the country in question had the undisputable authority in this matter, and added that the outspread of illnesses like HIV/AIDS, tuberculosis and malaria can represent national emergencies.[348] Clarifications were further made on the exhaustion principle, with consequences for parallel import options. Finally, extension was decided for the LDC's deadline to implement the Agreement.

A claim-oriented theory assigning responsibility to each of the states for the healthcare of their respective populations needs to say something on what is the next step in cases where a state does not take its responsibility. In such events responsibility might be passed on to the group of states represented at the table. The organization might even, conceivably, end up assigning responsibility for a particular case to the whole community of states. The difference is that it does not start at the global level for any case. It is not bound by conceptions of causes for poverty, and further by all of them being global causes.[349] Because it is not so invested in global notions it does not call on everyone at every occasion.

[346] WTO Doha Declaration (2001)

[347] Singer, P (2002:72f)

[348] WTO Doha Declaration (2001:art.5c)

[349] Here it should be added that Pogge for his own part does not regard global institutions as the only causes of poverty. He accepts the view that local factors like tax evasion and illegitimate and abusive state power contribute to poverty and if removed sufficiently could eradicate a state's poverty. He holds that global and local factors are not additive, they do not add up to a combined cause of poverty. On the contrary, if one of them is removed, most or all of global poverty would be eradicated. See Pogge, TW (2005:77). In holding this view it might be rational to address the global aspect instead of addressing the local issues one by one. Cohen's criticism, which is discussed in the following section, is that a causal theory of justice cannot merely assume that removing global factors, keeping local factors intact, eradicates poverty.

Non-transparency of cause-based duties in ethics

Cohen reformulates Pogge's general position on causes and responsibility for world poverty and presents it as "the strong thesis:"

> Most of the global poverty problem could be eliminated through minor modifications in the global order that would entail at most slight reductions in the incomes of the affluent.[350]

Cohen highlights, through the reformulation of the thesis, its strong assumptions on matters that need to be empirically investigated. He sees no empirical case for it and bases his vigorous criticism largely on this purported deficiency. What qualifies as minor modifications? What is the global order? Will the strong thesis hold true even if domestic institutions and arrangements in the poor countries were held fixed? What is the evidence for this? These are questions the strong thesis must address, precisely because it relies on causal assumptions. Cohen argues that it takes quite a lot to complete the task: "Global rules might explain the bad institutions, but then again, they might not. We want to know if they *do.*"[351]

A challenge to Pogge's view on the global order would be to ask for empirical evidence that if the two privileges, the international resource principle and the international borrowing privilege were abolished, but not the autocratic rule nor the corrupt institutions in these countries, that eradication of most of the poverty would follow in these autocracies. Pogge's reply is that the unjust global order sponsors corruption and autocracies, that developing world corruption is created and upheld by international institutions. One of his examples is Nigeria. He points to the enormous advantages that follow from taking power in such an oil-rich country: "Corruption in Nigeria is not just a local phenomenon rooted in tribal culture and traditions, but encouraged and sustained by the international resource privilege."[352]

We can add an example from Angola. In a news article about the advantages for trade over aid, two Norwegian government ministers were interviewed on their travels to

[350] Cohen, J (2010:19). My references to Cohen in the following pages are to this article.
[351] (p.25, Cohen's italics)
[352] Pogge, TW (2002:120)

Luanda.[353] One of them informed that over a ten year period the Norwegian oil extraction company Equinor alone paid NOK 90 billion (≈ USD 10 bill.) in taxes to Angola from its operations there. For comparison he cited the sum of foreign aid money (official development aid) going from Norway to the whole of Africa in the same time period. This number is NOK 40-50 billion, about half the amount paid in tax to Angola alone.

The news report further tells us that of Luanda's five million inhabitants only nine per cent have water supply to their homes. The country is listed as one of the least developed countries by the United Nations.[354] Equinor is not the only oil extraction company operating on the Angolan coast, and according to a 2004 report by Global Witness cited by Terry Lynn Karl, about a quarter of the country's oil revenues disappear, and: "President Dos Santos keeps large sums of money in secret bank accounts while 70 percent of Angolans live on less than a dollar a day."[355]

The two privileges Pogge holds up for review are indeed worth discussing, as this example shows. The point here, though, in line with Cohen's remarks is, however, how can we know what will be the effect in the developing world of removing the privileges? Will corruption and poverty disappear? Instead of "sweeping preconceptions" we need local knowledge, says Cohen.[356]

Pogge's reply is that he claims the global order is unjust if it foreseeably contributes to poverty with ensuing suffering and death. He also claims that the imposition of a severely unjust global institutional design "harms those who avoidably suffer the effects of poverty as a result."[357] The claims as such are true, he says, and they are also effective in motivating people for taking responsibility.

We should not underestimate this last point on motivation brought up here at a stage where it was requested of him to address the evidence challenge. Pogge says, prior to the quoted passage, that what he needs is not "a precise distinction between global and domestic causal factors."[358] What he does need is a "distinction between causal factors that are shaped, controlled, and imposed by our countries and governments in our name and those that are not."[359]

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[353] Melgård, M (2011)

[354] Cf. note 10 above for a reference to the full list.

[355] Humphreys, M: Sachs, JD & Stigliz, JE eds. (2007:268). President Dos Santos has since retired.

[356] Ib. p. 21

[357] Pogge, TW (2010a:179)

[358] Ib. p. 178

[359] Ib.

To appreciate the difference between what he does not need and what he indeed needs we should pay attention to his focusing here on the in-our-name condition. This is where he establishes the connection to everyone as harm-doers in his reply to Cohen. It is a statement of the connection which enables him to build a theory of negative duties (the duty not to harm) from our causal role in the events. He regards the argument of not violating negative duties as stronger than arguments for positive duties, in the sense that it is more compelling and not least more motivating. Theoretically, if we assume that the people causing an unjust trade regime are the ones that benefit from it, the argument that these agents will be most motivated to end it is not convincing. On the contrary, they will be the ones who have the most to lose from changing it and therefore be the least motivated.

As regards the evidence requirement, Pogge himself realizes it would not be fulfilled in "certain scientific contexts."[360] His strong thesis on the causal connection between poverty in the world, or global poverty on the one hand, and the global make-up, the institutions on the other, still is, he argues, supported by a "preponderance of existing evidence"[361]. This notion should then be taken to mean something other than scientific evidence, but it is still compelling according to Pogge. The preponderance of evidence is so strong that to reject the strong thesis, in practical contexts, is "gravely immoral."[362]

The evidence Pogge has in mind is selected estimates on the effect for developing countries of the removal of trade barriers. He also provides other statistical evidence. Whether the effect on poverty, and not only national income, in the LDCs is evidenced is a matter of dispute between Cohen and Pogge. I make no conclusive assessment of it as my aim in including their discussion is merely to point to some major challenges facing theories of distributive justice within a cosmopolitan outlook, the sort of theories discussed under the heading of Global Justice. In *The Distant Moral Agent* I have discussed a version of it, namely Singer's account of a positive duty to eradicate all poverty in the world. That account is an example of a theory which is not based on causes because it seeks to work independently of how poverty was produced. Singer himself is otherwise a well-known consequentialist, but in his cosmopolitan take on distributive justice he is ecumenical, arguing for the duty to assist even for non-consequentialists. My article centers systematically on three defining characteristics of cosmopolitanism, its acknowledged ultimate units of concern (the individual person); the scope (global) and pertinence (everybody's duty to help).

[360] Ib. p. 182

[361] Pogge, TW (2010a:182)

[362] Ib.

In the broader background commented here, with regard to the two debates on Pogge's version of a cosmopolitan outlook, I have elaborated further on the pertinence issue and included a discussion of the dependency of causal explanations of poverty, relevant as a supplement to the comments made in the article on Iris Young's criticism of cause-based views. The alternative view I explore in the article is the method for assigning obligations to end poverty based on moral claims between individuals, and moral rights towards the home state. I point to some advantages of this approach in that it does not have to wrestle with problems characteristic of causal theories like the ones described here. I argue that a moral claim-based outlook redefines the scope without diminishing it, and it has resources to cope with the problem of assigning perfect duties.

Ethical Reasons for Narrowing the Scope of Biotech Patents

The type of intellectual property I discuss in the first article is restricted by the focus of the thesis in general. Whereas the second article discusses patents on essential medicines, the consumer product, this article deals with research that is geared towards treatment of human diseases. It takes patents on gene sequence information as its case of concern. Much of what has been said above about justification of IP rights and why it is a concern for everyone applies in general to the third article as well, so I shall not add much in this regard. There are some particular problems though, regarding product patents on gene sequences that are presented in the article and I will consider this problem in more detail using a few analogies. It concerns the content, not the form, of gene sequences, in other words it concerns the molecules coding for proteins. The molecules themselves or their combination is not invented, so when a product patent is issued for a gene sequence the normative questions to ask are, first, what is it exactly that qualifies for intellectual property and second, how are product patents in this field justified.

The Myriad patent case discussed in the article invites analogies from copyright protection by being a case where the idea itself is not protected, only its new carrier so to

speak.[363] The "idea" with reference to DNA can be described as the information conveyed by the gene sequence.[364] The carrier is the synthetically made DNA containing the exons in their original number and order, but is unlike the natural DNA in other respects not significant for the protein-coding function of the gene. This manufactured DNA, called cDNA, can be viewed as a new carrier or a vehicle for the information of the gene. This carrier represents a new thing, something not existing naturally. The cDNA is the result of an inventive step and it is this carrier which is patented. This is the premise and background for the article.

The analogy with copyright protection holds by reference to the copyright not being extended to the idea itself, only to its expression.[365] Thus an expression of a scientific discovery in the form of a journal article for example can be protected, but not the ideas conveyed by the article.[366] In the arts, an idea can be expressed graphically or in literary works but not copyrighted. Only the work itself, the artistic expression, can be given this protection. A key difference in legal terms between copyright and patent is that only the latter requires an inventive step relative to prior art.

For a synthetic DNA, like BRCA1 and BRCA2 in the Myriad case, the contested protection was that of a patent. If the information carrier were a database instead of a cDNA substance, the eligible intellectual property protection would be copyright. Of the two available patent categories, the process and the product patent, the first gives no protection if other inventors were to produce the same or a similar product through a different method or process. Only the product patent protects the final, and commercially interesting, product. With these key differentiations of the alternatives for intellectual property protection in mind, we can look at some analogies and disanalogies between product patent on gene sequences on the one hand and copyright on the other.

We can take as an analogy a topographic map showing footpaths, vegetation, contour lines showing elevation; geographical position and all the information that is presented on a topographic map. All this information is given a scaled-down visual expression on the map.

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[363] Resnik, DB (2004:47): *[T]o obtain a copyright there must be no merger between the idea and the expression. If the tangible expression is virtually the only way of representing an idea, then the expression merges with the idea and one is barred from obtaining a copyright. The rationale for this doctrine is that copyrights protect forms of expression but not ideas (..). For example, the U.S. Supreme Court held that one may copyright a document describing a system of accounting, but that one may not copyright the system of accounting itself.*; Parry B (2005); Helfer LR & Austin GW (2011:22-3); WTO TRIPS. Section 1, Article 9:2.

[364] Ib. p. 51, and chap.5

[365] WTO TRIPS, Article 9, pt.2.

[366] Resnik, DB (2004:47)

The topographic information stands in a relation to the actual landscape it describes that is as true as possible in terms of an accurate representation, more true the better the map. This relation resembles the relation that also holds between the cDNA and the actual DNA sampled from a human body. An analogy between the cases is to be found in the legal fact that the landscape itself and likewise the natural DNA from a patient cannot be appropriated and made a personal property. The landscape belongs in one sense to everybody, or to nobody but is most likely divided in personal property parcels already, and the sample tissue from a patient cannot be sold or used without her or his consent.

Further, regarding intellectual property, the "ideal" content of the map cannot be candidate for IP rights. This content is determined by the actual landscape and is surely no part of the expression. Similarly, the ideal content of the cDNA corresponds to the information coded by the exons. This content is separable from the form of presentation, or the carrier as I call the synthetic product. Accordingly, a new and original form of the information, as separated from the information itself, can be protected.

A disanalogy is to be found in the cDNA being more true to the original than the map. The scale is unaltered and materials are the same as in the original. In fact, as far as the essential qualities go, there is no difference between the copy and the original.[367] This is part of the rationale for applying for patent instead of copyright protection in the case. The cDNA is not a new expression of the original, it is exactly similar. For this reason alone it would not qualify for copyright even if it otherwise did. However, by representing a non-obvious useful product (US law) or an inventive step (EU law),[368] it qualifies for patent protection. This was decided by the US Supreme Court. The originality of the product lies in the inventiveness in creating the carrier.

A patentable invention might also have been, and has in fact been made of the map. When it was digitalized for the first time we can assume, true or not, that every possible use of it was not anticipated by the patent holder.[369] Let us say that the inventor just digitalized the map and made names of locations searchable and that was the end of it. Only later it so happened that an independent party added the function of showing the user's geographical position on the map at any time through a GPS connection. A product patent of the electronic

[367] Hence the often used name cloned DNA for cDNA.

[368] References are made in the article, page 56 above.

[369] I present this as an imagined situation, for illustration. I need little information on the actual historical event to make the case.

map, held by its inventor, now entitles him to license fees from use of the new invention on top of his own.

Later still, we imagine that a third party enters the field with his/her new tool for routing on the map. A starting point and the destination are fed the software and the shortest route is calculated from the net of footpaths displayed. If this inventor wants access to electronic maps on the market, (s)he needs to come to an agreement on price with the holder of the map patent, which is a product patent covering all uses of the product. The agreement is needed even if the original inventor had no knowledge of, or no expectation at all about the new ways of using the invention and making it more popular than it would have been without the additional functions from the later inventions.

The article discusses the justification issues arising from this far-reaching scope of the original product patent and its consequences for research in vital goods. In this it takes up the issue that has been described this way by Correa:

> Broad claims may have a negative impact on research and unduly block competition. They are also likely to lead to a great number of legal conflicts, ultimately increasing the costs for companies and consumers. Narrowing the scope of patents through strict claim description and coverage requirements creates more room for innovation and competition. From a health policy perspective, an appropriate balance needs to be found. The TRIPs Agreement is absolutely silent on these matters.[370]

I explore a relaxing of the product-binding of the patent and a correspondingly stronger connection to the description of the product's specific use, as it appears in the application for patent. Transferred to the domain of intellectual property, this is necessary to be able to justify the property right. The tool for delimiting the property is the description of how the invention can be used. This then, forms the horizon of the inventive step and sets the limit for the expectations of the market potential of the product. Arguments for a scope of protection wider than this have accordingly no strong support in a reference to incentives for innovation.

The rationale of IP rights is that they serve as a tool for promoting new and needed innovations for people and society. The expectation of the innovating enterprise arguably sets the horizon for this rationale. The reasonable revenue prospect of the product is determined

[370] Correa, C (2000b:33)

by the foreseeable value the innovative enterprise's finished product will have to consumers. The market demand that can be expected from it in budgets and prospects and presentations for the board of directors sets the expectations. Once the patent covers the description of the new product's utility, the developer's expectations are met. From the law-maker's side there should therefore be no need to extend patent scope beyond this point.

All risk is not removed. The risk of failure in the market, as noted above, still persists. But this risk is no different than the risk of any investment in commodities or consumer goods to be tried in the markets. If the patent applicant seeks to have investment risk removed altogether, he asks for a surplus protection which goes beyond the incentive function of the institute. The current broad scope of patents invites this surplus protection.

For the innovative enterprises that have their fully described expectations reflected in the application, their loss is the revenues from fees they would have harvested if, by chance, other inventors enhanced the utility of their product. This premium from chance might materialize or it might not, but I have yet to see arguments to the effect that the legal protection of this premium is part of the incentive to develop useful products.

HUMAN RIGHTS, LEGITIMACY, AND MORAL CLAIMS

Human rights – a political conception

I have presented arguments for the view that justification of property rights in the form of patents on essential medicine is problematic on two counts. Accordingly, I have treated the issues in two separate articles. First, I argued that restrictions on development of new inventions due to patent on existing products, to a large extent are connected to an unwarranted patent scope.

Second, even if patents stimulate invention of new medicines in the long run, they might block dissemination of these essential goods in the shorter term. I suggest a reform of current patent practice. The reform seeks to amend the short-term problem of limited access to essential medicine without removing the overall benefit.

Third, the last article, on the problem of distance in morality, relates to the article preceding it, in which I propose mandatory provisions of drugs to patients in low-cost markets. Human rights were central to the discussion in the preceding article. Here, however, I distinguish between human rights and moral claims and attend to the latter.[371] Hence, it would seem that two different theoretical frameworks are in play, to the detriment of the internal coherence of the project as a whole. In the following, I explain why this is merely an apparent incoherence, and that the corresponding distinction between institutional justice and morality sheds some light onto the scope and pertinence of moral claims.

To be clear, the theoretical outlook underlying the articles is a political conception on human rights. It assumes that human rights are political rights and as such they meet with obligations in the political body securing them. It is central to the political notion of human rights that the duty to respect and fulfill them rests with the state.

In the political view of human rights, they do not extend beyond the political unity in charge. The rights of individuals, to healthcare for example, is the responsibility of domestic authorities. Therefore, an appeal to human rights must be directed to political authorities

[371] Cf. The last paragraph of chapter I

collecting taxes and exercising power where human rights are violated. When it happens that local authorities are non-responsive to appeals of human rights responsibilities, and concern is raised elsewhere (i.e. outside the area where the political unity is in charge), this is the concern to be explored. An example of such concern would be the apprehension following from learning that severe persecution towards an ethnic minority takes place in a neighboring country. The concern underlies the question Simon Caney raises when talking about duties to prevent poverty: *One particularly pressing issue in this context is how the duty [to prevent poverty] should be distributed when some do not do what is required of them*.[372]

In *The Distant Moral Agent* I argue that moral claims meet with respondents in a social circle expanding from the claim holder. Inverting a model proposed by Singer, the argument is that if a social circle fails in fulfilling its duties, the claim is not exhausted. Instead, the circle expands to comprise other respondents. Failure to respond is what occasions its expansion.

In the article, I see claims expanding from the claim holder not as appeals for sympathy, but rather for respect in a Feinbergian sense, which I will comment on later. The nation-state is a crucial station on the expanding circle because there human rights apply. In the event that the state does not respond to human rights appeals the expansion of the circle continues by directing moral claims to outsiders.

Yet another reason, and my last one, to be clear about rights is the connection between human rights and legitimacy of states. The connection has been much discussed at least since the publication of Rawls' works on the society of peoples, starting with A Theory of Justice in 1971. I have announced this connection above, and now there is occasion to explore it a bit further. The following survey is meant to explain the notion and role of human rights in this project, even if it does not set out to present in a comprehensive manner current debates in the field. I shall attend, first, to a presentation of the political conception on human rights, then proceed to legitimacy of states and its relation to the respect for human rights.

In a first approximation, I turn to the distinction between morality and legality as it is worked out by Jürgen Habermas. Whereas the realm or morality ("the moral universe") is unlimited, socially and in historical time,[373] by contrast, legality is not. Legality protects members of a legal community, located in space and history. Its members enjoy the artificial status as right-holders. Accepting the distinction, our question is which category human rights

[372] Caney, S (2010:294)
[373] Habermas, J (1998:158)

belongs to: morality, legality or perhaps both. Habermas sees an apparent (but only apparent) ambiguity of human rights:

> Human rights are Janus-faced, looking simultaneously toward morality and the law. Their moral content notwithstanding, they have the form of legal rights. *Like* moral norms, they refer to every creature 'that bears a human countenance', but *as* legal norms they protect individual persons only insofar as the latter belong to a particular legal community – normally the citizens of a nation-state.[374]

The puzzle seems to consist in not only that they have the form of legal rights, but that they actually are legal rights (when referred to "as legal rights"), and valid for all humans.

As legal norms, human rights presuppose legal community. This is the position Habermas takes and he grounds it in the argument that human rights are not discoveries. They are not prepolitical rights, and not moral truths. Rather, they are constructions.[375] Being individual rights, their nature is "inherently juridical" and they are "oriented toward positive enactment by legislative bodies".[376]

Noting that he refers to human rights as legal rights, not political rights, that distinction is not crucial. It can be explicated like this, if human rights are not legislated in a jurisdiction, they simply are not legal rights yet. They are political rights because respect for rights come with political power, and they should be legislated in order to qualify political power. This describes the "peculiar tension between the universal meaning of human rights and the local conditions of their realization."[377]

Habermas further sides with the tradition going back to Locke seeing human rights not only as protected by nation-states but indeed as a protective measure from power abuse by the nation-state itself. The rights are therefore not only subject to positive enactment, but they also place restrictions on state authority.

Thomas H Marshall's categorization of rights into civil, political and social rights[378] was originally presented as a historical development related to the specialization of the various functions of the state. Thus, all three rights categories can be claimed by the person as a citizen. It is this very idea of citizenship that is unacceptable to libertarian ideology, as

[374] Habermas, J (1998:161). Italics in the original.
[375] Ib. p. 164
[376] Ib.
[377] Ib. p. 161
[378] Marshall, TH (1950:8)

pointed out by Robert Moore in his preface to the 1996 edition of Marshall's essay: "[Citizenship] leads subjects to cease thinking of themselves as subjects and to believe themselves to be persons endowed with rights, rather than under the obligation to be governed."[379]

His criticism of libertarianism could be expanded, I think, to have implications for commercial enterprises. In a hypothetical pre-citizen condition the public is not organized as such and are powerless consumers in the markets and unprotected laborers in the labor market. Citizenship empowers people to legislate workplace standards and agree on conditions for the activities of the enterprises. This implication of citizenship tends to conflict with laissez-faire libertarianism taking advantage of an unorganized workforce.

The empowering effect of citizenship is underexplored in literature on global justice, perhaps because citizen status is unclear in many disadvantaged states, and perhaps also because the version of cosmopolitanism often adhered to rejects the significance of state borders, and hence the significance of citizenship.

Marshall locates the establishment of the historically first of the categories, civil rights, to Eighteenth-Century England – where, as I have shown in the chapter above on the history of patents, rights had an ethical-political history already. Marshall includes among civil rights the right to property; to freedom of speech, of thought and of faith; and equality before the law ("the right to justice"). Prominent among civil rights is also the right to work, which is a right to pursue one's occupation of choice, wherever one chooses to follow it, irrespective of class.[380] Political rights are rights to "participate in the exercise of political power", either by taking office or by voting among candidates for local councils or parliament. Social rights are welfare rights most typically provided by systems for education, health and social security.

In the forming of the UDHR, civil rights where promoted particularly by the UK and the United States based on their long traditions, reflecting ideas from the US Bill of Rights as well as the French Revolution, designed to protect the individual from power abuse from the state. The Soviet Union advocated social and economic rights. India pressed for the right to freedom from discrimination of religion and race.[381] The point could therefore be made that perspectives from different global regions were represented.

[379] Moore on the libertarian view in Marshall, TH (1950:vi)

[380] Marshall, TH (1950:10-11)

[381] Risse, M (2012b:9-10); Hestermeyer, H (2007:81)

The political conception of human rights is more abstract than the categories of Marshall as it applies to all three of them. Civil rights, like the right to property, generally determine restrictions on states in their dealings with individuals and are clear examples of the political conception of human rights. Marshall's political rights are, naturally, good examples. Take for instance the right to vote, which is quite inconceivable if not adjoined by the notion of a social institution. A social right, as the right to education, also illustrates the point. The political conception on human rights simply sees all three types of rights as sharing the property of presenting restrictions on, or obligations to, those in power. The political conception of human rights sees significance in not confounding the human rights obligations with individual duties. This significance is not least connected with the determination of state and government legitimacy.

Pogge illustrates the difference with an imagined example of a person who has just got his car stolen.[382] Pogge thinks, rightly I believe, that we will not sort the event under UDHR Art. 17.2: *No one shall be arbitrarily deprived of his property*, and that we would, more likely, regard it as an instance of ordinary theft. Unless, that is, the government has arbitrarily confiscated the car. In both cases the car is arbitrarily gone, but only the last case would qualify as a human rights violation. This is because, says Pogge, petty criminals cannot violate human rights, only governments, armies – perhaps large corporations can: It is "implicit in the concept of human rights that human-right postulates are addressed [..] to those who occupy positions of authority within a society [..].[383]

The other view, that human rights obligations apply to individuals and not only states, we find in global justice theories applying a cosmopolitan perspective. Central to this outlook is, as I have already pointed out, that national borders carry no ethical significance. In order to maintain a notion of human rights, the responsibility of their fulfillment must consequently find some other agent than the state. It is perhaps not surprising therefore, that cosmopolitan theorists tend to ascribe human rights obligations to individual persons.

Caney takes a middle ground position arguing that the duty to "ensure that people can enjoy their human rights" is a duty on everyone who can help.[384] The right he refers to as an example is the right not to suffer from poverty. The opponent theory he addresses is that of

[382] Pogge, TW (2002:63-4)

[383] Ib. Pogge's position is not clear, though. He makes his own distinction between institutional and interactional human rights obligations, both types applicable to governments as well as individuals (Pogge, TW. 2002:71).

[384] Caney, S (2010:287)

O'Neill who has claimed that no such positive rights exist precisely because agents with obligations to meet them cannot be identified.[385] O'Neill regrets the Universal Declaration's reluctance to allocate duties corresponding to the rights it prescribes because, she says, "in the end obligations rather than rights are the active aspects of justice."[386]

Surely large institutions, the state being the most prominent example, occupy a privileged position to help fulfill welfare rights for all. Caney's argument is that even if there were no institutions, the duty to create institutions to fulfill the positive rights would fall on everyone. In that sense, everyone has an obligation to help fulfill human rights, according to Caney.

Joseph Raz observes that theorists and political activists alike point to the importance of human rights but neglect to establish a good case for assigning the corresponding obligations to particular agents.[387] This is due to the difficulties facing anyone who tries, one of which is procedural.[388] He reminds us that there are indeed moral rights which should not be enforced by law. Instead of being enforced, they are left to the discretion of people, and decided in interactions among them. In fact, it might be added to Raz's argument that it is doubtful whether coercion would even create moral conviction. To the extent that conviction is a premise for a certain act to be moral (as in Kantian deontology) coercion is ruled out as an appropriate tool.

In any event, moral rights which are established in unforced interaction between people, Raz holds, "should [ideally] be respected voluntarily, independently of any institutional involvement. But of all our moral rights only rights that should be respected and enforced by law are identified as human rights."[389] Regarding any unforced right, he makes clear that: "It is important here to remember that the conclusion is not that the right does not exist. It just is not a human right. The contemporary practice of human rights identifies as human rights only those that should be enforced by law."[390]

The political conception of rights, then, does not deny individual morality, it only separates human rights obligations of institutions from moral duties of individuals. What regards familiar moral basic principles, be it human flourishing, capabilities, interest, other

[385] O'Neill, O (2001:185)

[386] Ib.

[387] Raz, J (2009:43)

[388] Others are difficulties regarding content. I do not pursue Raz's argument on this point.

[389] Ib.

[390] Ib. p. 44. We note that contemporary here refers to around 2009, the year of publication of the article, i.e. quite recent.

properties of being human, even universal rights, they are all available principles for theorists of individual rights, but not human rights unless they are meant to be enforced.

John Tasioulas argues against what he takes to be a recent (and American) view of political – not universal - rights as fundamental.[391] His view on human rights is, in his own words, orthodox because he grounds them in natural rights. Rights are natural, he holds, not because they can be derived from an imagined natural condition. The qualification natural instead means that they are accessed and derived from "natural reason" as "opposed to the artificial reason of some institution."[392]

Natural reason is truth-seeking, whereas institutional reason, even when found in institutions of law, is less so and prone to promoting political or religious ideas, according to Tasioulas. Further, human rights are universal, and they are positively given in the form of a list. Any theory of human rights must provide "justificatory materials to ground anything like the full complement of human rights in the Universal Declaration."[393] Against the orthodox view, Tasioulas sees a recent threat coming from the "radical development" emanating from "John Rawls and members of his school."[394]

Tasioulas' critique of the political conception of human rights is based on his rejecting the separateness of human rights and general moral rights. Tasioulas' imagined case is that of a violent husband and father, habitually inflicting serious violence towards spouse and children. The applicable right is the right to physical security. As regards the victims, he asks: "Is it plausible to think that a human rights dimension enters into such a case only if his pattern of abusive behavior can be interpreted as the object of official disregard within a coercively imposed institutional scheme?"[395] Tasioulas rejects the separation of rights because both types spring from the same source, which is universal human interest. If this is indeed the case, he asks, rhetorically: "what is gained by introducing a bifurcated system of universal moral rights, and why reserve the title 'human right' for those universal moral rights that fit the specifications of the institutional account?"

I have already indicated an answer by reference to Habermas and Raz. Seeing this debate as important and still not concluded, as well as decisive for my own observance of the principle of separation of human rights from moral claims, I shall proceed further with other

[391] Tasioulas, J (2013). Thomas Nagel, seeing rights as dependent on designated communities, is the most prominent fundamentalist, according to Tasioulas.
[392] Ib. p. 2
[393] Ib. p. 6
[394] Ib. p. 3. Rawls' notion of public reason (Rawls, J 1993, Part four) would be a point in case.
[395] Tasioulas, J (2007:97)

justifications for the political conception of rights. James Griffin sees an inflation in the use of the term "human rights" in political debates and among theorists: "Philosophers too, rather in the manner of magicians, pull rights out of nowhere."[396] Following up his view, it would seem that every human interest above a certain threshold of importance qualifies, although the threshold is not defined. He warns that "[i]t is a great, but now common, mistake to think that, because we see rights as especially important in morality, we must make everything especially important in morality into a right."[397] Raz shares the same general idea claiming that "scant attention is paid to the difference between something being valuable, and having a right to it."[398]

According to Griffin, what we need is a substantive account of human rights, one that is grounded in natural facts of human beings and that defines human rights against rights generally. He finds them in the status as human beings, that is, in personhood. Central to the notion of personhood is that we are agents, which implies, crucially, that we are not dominated by someone else.[399] From this notion he generates a list of human right, at least the first entries of it. In it, we find the right to life, to freedom of expression and other familiar civil rights. What we do not find is distributive rights like equal distribution of material goods, because they "do not bear on our personhood."[400] Even if Griffin acknowledges the importance of distributive goods, his point is that "human rights are quite particular moral considerations. They do not exhaust the whole moral domain; they do not exhaust even the whole domain of justice and fairness."[401]

HLA Hart takes the political view on human rights one step further, making the case that they are not at all moral considerations, that they are legal rights. To recall what I said about Habermas' view on human rights early in this chapter, he sees them as constructions, not discoveries of prepolitical morality. My interpretation was that human rights are part of the construction of political power. Hart is a prominent defender of this view going back to

[396] Griffin, J (2001b:306)

[397] Ib. p. 318

[398] Raz, J (2007:3)

[399] Griffin, J (2001b:311); Griffin, J (2001a:7). See also Pettit, P (2017) on non-domination, condemning it even when it is "well-disposed."; Williams, B (2005:chap. 6) argues that unmediated coercion and might rather than right lies at the bottom of human rights, holding that: "The charge that a practice violates fundamental human rights is ultimate, the most serious of political accusations." (p.72). The weight of human rights as a political concept and their bearing on state legitimacy is clearly indicated here.

[400] Griffin, J (2001b:317-18)

[401] Ib.; Griffin, J (2001a:17) on Kant's concept of dignity as not singling out human rights.

the legal positivism of John Austin and further to Jeremy Bentham insisting on separating between law as it is and law as it ought to be.[402]

Hart points to a paragraph of John Chipman Grey saying, in 1909, that "[t]he great gain in its fundamental conceptions which Jurisprudence made during the last century was the recognition of the truth that the Law of a State or other organized body is not an ideal, but something which actually exists. It is not that which is in accordance with religion, or nature, or morality; it is not that which ought to be, but that which is. To fix this definitely in the Jurisprudence of the Common Law, is the feat that Austin accomplished."[403] We see the reformatory thinking of the early utilitarians in their views on punishment as well. In Bentham's case, notions of retributions or blame is largely absent from his penal theory.[404]

Hart sees two dangers threatening by not observing the distinction between law as it is and law as it ought to be.[405] One is that authority of law might dissolve into discussions of what it ought to be. The other is "the danger that the existing law may supplant morality as a final test of conduct and so escape criticism."[406] Hart's arguments are for a large part referring to bad laws, his examples are mostly from Germany in the 1930s, whereas I discuss the current human rights system. I shall therefore contend myself with merely including his position that laws are what they are until they are replaced by other laws. They are not derived from interest, human dignity or values. They are rather decided upon following legal procedures, and in the case of human rights legislation they are regulating political power in a postwar reality of states. Human rights legislation came to be in the aftermath of World War II as a code of conduct for states.[407] And the UN human rights conventions have been successful to the extent that many states have ratified them and included them into domestic law. They were not introduced as a normative code for individual persons.

I conclude this chapter with a short presentation on Judith Shklar who gives a particularly clear expression of the political conception of human rights. She presents a perspective which I have only indirectly touched upon so far, at best. It has to do with a coupling between moral authority and physical force (from having disposal over military

[402] Hart, HLA (1958:596)

[403] Ib. p. 600, includes reference to Grey. Hart discusses and rejects the strict separation of law and ethics by the pioneering utilitarians. I shall refer to Dworkin below to support the view that legitimacy of government is at the intersection of law and ethics. Hart is another relevant reference on this point.

[404] Draper, AJ (2002:13-4)

[405] Ib. p. 598

[406] Ib.

[407] Griffin, J (2001a:19)

force and police capacities). Her warnings against confounding human rights and moral rights applies to liberal as well as oppressive regimes.

Her concern is the avoidance of cruelty and fear, and from a historical perspective she sees states as the biggest threat to the exercise of political freedom.[408] Her Liberalism of fear "does not, to be sure, offer a *summum bonum* toward which all political agents should strive, but it c e r t a i n l y does begin with a *summum malum*, which all of us know and would avoid if only we could. That evil is cruelty and the fear it inspires, and the very fear of fear itself."[409]

The overriding aim of liberalism is to secure personal freedom, and that is secured by complying with rights (she sometimes refers to them as "natural rights"). The state has however also great potential to repress it. This repression can come disguised as good intentions, noble causes and even solidarity.[410] A liberal state does not depend on philosophical thought and does not favor or reject any such system (apart from rejecting intolerant ones): "No theory that gives public authorities the unconditional right to impose beliefs and even a vocabulary as they may see fit upon the citizenry can be described as even remotely liberal."[411] The separation of rights and morals is here thoroughly affirmed.

Shklar is in line with Rawls, who also argues that a liberal state cannot take up a comprehensive moral or religious doctrine. He points this out very clearly when discussing the case of forming the society of peoples:

> There is also a serious question in the present case. Why do we suppose that the representatives of liberal peoples ignore any knowledge of the people's comprehension conception of the good? The answer is that a liberal society with a constitutional regime does not, *as a liberal society*, have a *comprehensive* conception of the good. Only the citizens and associations within the civic society in the domestic case have such conceptions.[412]

Rawls thus warns against official comprehensive doctrine, that is doctrine (in the form of a list) from religious or moral foundations whether they are applied internally or they are directed outwards. Regimes which dictate moral imperatives to be respected by local

[408] Shklar, J (1989)
[409] Ib. p. 10-11, text enhancements in the original.
[410] Ib. p. 13-15
[411] Ib. p. 6
[412] Rawls, J (1999:34). Italics in the original.

communities or businesses or individuals fail to qualify as liberal states. Rawls's position, which universal rights theorists must grapple with, is that states have laws, and not comprehensive doctrines.

From these reminders of the threat from unchecked political power, I proceed to comment on legitimacy of political power, to highlight the role of the state in producing essential medicines for its citizens.

What this survey of a political perspective on human rights amounts to can be given the following conclusive statements. Human rights are not discovered as moral universal rights, but are rather decided upon, to be a code of conduct for states, given the form of individual rights. The rights set limits to the exercise of political power and define a minimum welfare standard for legitimate states. The human rights of individuals are, according to the political perception underlying this thesis, not derived from interests, values or dignity of the person, but from the obligations of legitimate states. Stated human rights obligations are not decisions on personal conduct but part of what authorizes political power.[413]

The notion of moral claims, on the other hand, pertains to individual morality. I shall attend to moral claims shortly, but first follow up on the notion of legitimacy of states, just referred to in a mere implicit manner, as the relation to human rights is closely connected to theories of legitimacy.

[413] This last point on personal conduct would be equivalent to what Kant says about duty in his The Doctrine of Right (Kant, I 1797:6:239)*: All duties are either* duties of right *[..], that is, duties for which external lawgiving is possible, or* duties of virtue *[..], for which external lawgiving is not possible. – Duties of virtue cannot be subject to external lawgiving simply because they have to do with an end which [..] is also a duty. No external lawgiving can bring about someone's setting an end for himself (because this is an internal act of the mind)*[.] (text enhancements in the original).

Legitimacy

Since the drafting of the human rights conventions Western states have given priority to civil and political rights over economic, social, and cultural rights not only for ideological reasons, but also due to practical reasons to do with their immediate introduction as well as budgetary reasons.[414] Civil rights merely require state abstention from interference. They demand no action on the part of the state, and are therefore purely negative rights.[415] Social rights on the other hand are demanding and commit the state to financial expenses, as for example the right to healthcare. They are, typically, positive rights requiring action from the state.

If any given state consistently violates basic human rights, the question of accountability arises. One way to address accountability, in grave cases, is to question the legitimacy of the state. This is the perspective of the thesis, seeing the negligence of basic rights obligations as disqualifying for political power. The power license is no longer valid if basic human rights are not respected. A moral statement of this would be that grave human rights violations remove the right to rule. The importance for the case of essential medicines, discussed in this thesis, is that lack of access to available lifesaving medicine is a government failure. This effect of human rights neglect is peculiar to the one institution that bears responsibility to fulfill basic rights, and this is the state or its government.

According to Hestermeyer, a main reason why many theorists regard civil and political rights as justiciable whereas economic, social, and cultural rights are not, is the budgetary side of the latter group. State action to secure them has a high price, and the ability to carry the cost varies considerably between states.

Hestermeyer's main concern being access to lifesaving medicines, which is a social right, he challenges the view that social rights are not justiciable. His argument, as a legal theorist, is that the economic, social, and cultural rights in fact are the subject matter of a binding legal treaty, the ICESR. It has become part of international law, and states are bound by it because they have ratified it: "Any argument that these rights are not of a legal nature

[414] Hestermeyer, H (2007:82-3 and 89)

[415] The defining line between civil and political rights on the one hand and social, economic and cultural rights on the other is not totally clear as it depends on whether we see the negative/positive rights division as the criterion or if the separation is sought by reference to the subject matter of the rights groups (Hestermeyer 2007:81n30).

has to overcome the simple truism that a legally binding document is legally binding."[416] He grounds his conclusion by reference to a ruling by the International Court of Justice.[417]

My proposal of mandatory provisions of essential medicines is not in conflict with a legal approach as far as every member state of the WTO is concerned. From outside, however, personal concern (acceptance by taxpayers) for poor or non-existent human rights legislation in other jurisdictions than one's own, i.e. the concern for people elsewhere who are not protected by human rights, is treated not as a legal concern, but as a moral case. I shall proceed to clarify the Feinbergian notion of moral claims applicable to that case shortly. But first I shall attend to the relation between human rights and legitimacy of state and government.

Legitimacy and justification

The chapter on human rights as political rights above provides the background for the notion of legitimacy applied in the thesis. Protection of the rights, although their content is being constantly discussed, form the basis of the legitimacy of states. For one definition, we can return to Habermas:

> In the transition from nation-states to a cosmopolitan order, it is hard to say which poses the greater danger: the disappearing world of sovereign subjects of international law, who lost their innocence long ago, or the ambiguous mish-mash of supranational institutions and conferences, which can grant a dubious legitimation but which depend as always on the good will of powerful states and alliances. In this volatile situation, human rights provide the sole recognized basis of legitimation for the politics of the international community; nearly every state has by now accepted, at least on paper, the United Nations Declaration of Human Rights. Nevertheless, the general validity, content and ranking of human rights are as contested as ever.[418]

[416] Hestermeyer, H (2007:93)
[417] Ib.
[418] Habermas, J (1998:161-2)

Habermas here refers to a volatile "international community" which has, in spite of its different interests and despite giving priority to the most powerful players, still managed to unite on human rights as the basis of legitimation for politics. Importantly, the institutions bound by rights are states.

The relation of legitimacy and human rights stated here implies a liberal view, in that the view on human rights is political and not tied to a particular worldview, it is not supported by any particular religion or metaphysical (moral) justification.[419] And it establishes individuals as citizens. To this definition I shall add just one complication that Habermas does not address in his discussion here, which is the question whether it applies to the state as such or to its government. To do so, and work out an opening to hold government to be illegitimate – not the state as such – I turn to A. John Simmons. This distinction is significant in order to establish government responsibility for upholding human rights in the state.

Simmons sorts out what he takes to be a common conflation in theories on legitimacy. He separates strictly between the justification of the state and its legitimacy in the moral evaluation of states, although he finds that the two qualities are very often, confounded.[420] He argues that a distinction between justification and legitimacy is necessary, because without it we have no notion of a state being just and illegitimate, which is conceivable. And this is only one of the possible combinations relying on his distinction. Absent the distinction between justification and legitimacy one other option would also be lost, namely to discuss whether a state is legitimate but nonetheless unjust. This is Rawls' combination in talking of non-liberal decent peoples. They are not "perfectly just" – only "decent".[421] They are tolerated in the society of peoples even though they are hierarchically, not democratically, organized. In Rawls then, the distinction is already established, although not with the same rigidity as in Simmons.

The conflation occurs when justification arguments serve as arguments for legitimacy. Whenever a state is found to be just, it is by the same token, but erroneously, also believed to be legitimate. To hold that the state which has issued my passport is justified, could typically mean that it is "consistent with God's commands, passes the ''consistent willing'' test of the

[419] Ib. p. 168
[420] Simmons, AJ (1999)
[421] Rawls, J (1999:78)

Categorical Imperative, or avoids infringing anyone's rights."[422] The fact that the state is just, is not what gives it the right to rule in a designated territory, Simmons argues. If justification settled the matter, then nothing would stop the state from expanding its territory into territories on the globe that are ruled by less just states. Surely, questions must be asked as to its legitimacy in taking power in those other places.

Simmons' definition of legitimacy, as isolated from justification, reads: "A state's (or government's) legitimacy is the complex moral right it possesses to be the exclusive imposer of binding duties on its subjects, to have its subjects comply with these duties, and to use coercion to enforce the duties."[423]

If my own state is a just state, I have not chosen it for this reason, because there are other just states too. No one requires of me, or even allows me, to contribute citizen support toward all just states.[424] Difficulties concerning political voluntarism, how individuals can ever be said to have consented to belonging to a particular state prompts Simmons to reject that there are any legitimate states. For Rawls and others, support from a sufficient number of people establishes legitimacy. The threshold itself, setting the minimum standard of popular support, will be a matter for discussion, although not here.

Legitimacy of state and of government

In his definition, Simmons makes himself guilty of confounding two conceptually separate entities, namely that of the state as an organization on the one hand and its government on the other. Hence, his definition applies for both. Whether he holds that the differentiation which concerns him, between justification and legitimacy, applies for government as well as for states is not made clear. In the article *Patent Funded Access to Medicines*, when there is question of legitimacy, it concerns legitimacy of government, not states. The question whether a state, which is responsible for lack of access to medicines, is or is not legitimate in itself, apart from its government, is therefore not discussed.

[422] Simmons, AJ (1999:741)
[423] Ib. p. 746
[424] Ib. p. 753

Here is how Allen Buchanan presents the differing characteristics between state and government. Speaking about obedience to political authority, he gives the distinction the following statement:

> Those who employ the term 'political authority' [..] are sometimes unclear as to whether the entity that is said to have the right to be obeyed is the state or the government; indeed one suspects that they use these terms interchangeably in some cases. However, there is a distinction and it is significant. The state is a persisting structure of institutions for the wielding of political power. Within this structure there are roles that empower their occupants to exercise power in various ways, and the government consists of the occupants of these roles or at least the more important of them. Governments can come and go while states remain. Given this distinction, the more coherent view is that obedience is owed to the government, not the state, since the idea of owing anything to an institutional structure, as opposed to those persons who occupy roles in it, is problematic.[425]

The premise concluding the quote is not entirely convincing, as I can imagine times and circumstances where I would prefer owing something to the state rather than to the people temporarily governing it. An illegitimate occupation government might, for example, inspire stronger loyalty to stately institutions, suspended by occupational forces, than before. A more trivial case would be when I voted for the political alternative which lost the previous election. Loyalty to the constitution and democratic procedures, *the institutional structure*, is precisely what makes me prepared to obey the new authority, even if I happen to disagree with its politics in certain areas.

Buchanan sees legitimacy as built upon the respect for basic human rights.[426] Applying his distinction between state and government on Simmons' we may ask which is it that needs no justification, state or government? By state we mean here the constitution and organization of the state – hereunder whether or not human rights are integrated in its laws.

It would appear that the definition of Simmons is made mostly with government in mind. A closer look at the sheer choice of word might support the assumption when the definition says not that the state allows for the use of force, but rather that "the state (or

[425] Buchanan, A (2002:691)
[426] Ib. p. 703

government)" possess the right to use coercion to enforce the duties.[427] The indication is that government is identified with the state.

Simmons wants to show that a just state not necessarily makes a legitimate state. With the distinction between state and government in mind, this conception of a just and illegitimate state is available. It is just because its constitution prescribes freedom of opinion and expression and other civil rights allowing for public debate and reform of laws and institutions. If government acts unconstitutionally, the government is illegitimate, not the state as such. The only requirement applies that government rules according to law and procedure in its assigned territory. No separate moral requirement applies that government be just beyond what is required by law. In turn human rights are built into law for the legitimate state. The implication is significant, namely that government does not possess the right to use arbitrary coercion of citizens.

Implications regarding dealings with an illegitimate government (not state) follows and must be considered by other states in a re-evaluation of contracts of trade, membership of treaties, the right to export natural resources etc.. The pertinence of the question of legitimacy intensify by the proposal to provide essential medicines to countries that do not make them available to citizens. In the event that these medicines are received but not distributed, the government's legitimacy must be questioned.

In the article *The Distant Moral Agent*, I argue that a claim-based approach works better in assigning duties to particular agents, and that the problem of distance in ethics turns out to be more manageable in a methodological perspective from claimholders compared to a cosmopolitan theory of duty of the individual agent. In our case, lack of access to essential medicines, we can observe that a moral claim directed at the political level is ignored. Here the claim, because it is lifted to this level, invokes a human rights obligation, as described in the UDHR and the International Covenant on Economic, Social and Cultural Rights. A claim-based method for identifying eligible moral respondents will pick out governmental agencies first of all, and by their default find the next in line to respond to the claim, in our case surrounding states or even distant states and tax-payers.

By contrast, a theory of individual duty must always single out the same agent – oneself. This agent is Singer's individual in the center of the expanding circle of moral concern. If human rights obligations are included in individual duties, instead of being seen as a necessary part of the license for political power, government seems to be relieved of its

[427] Simmons, AJ (1999:746)

sole responsibility to respect and protect human rights. Based on these considerations, the argument is that as individuals step in to take responsibility for human rights the picture of state legitimacy is blurred.

Uneven influence in international organizations

Quite recently, in historical terms, organizations above state level have emerged, carrying significant influence on the conduct of states and the life conditions of their citizens.

How do we proceed if we want to show that the WTO, through its TRIPS agreement on minimum standards of IP rights to essential medicines, is illegitimate? Is the question itself is too narrow, perhaps? The exclusive reference to legitimacy might not be the best option to show what is, sometimes, troubling with obligations decided by international member organizations. There might be other and better alternatives.[428]

If a state enters an agreement through an international organization and it turns out that the agreement conflicts with some basic human rights obligations of the state, which political entity, then, is in breach with human rights, the member state or the international organization? The problem with pointing to the international organization is that it has not taken over the human rights obligations of the member states.

As already indicated,[429] the statutes and proceedings of the institutions can be heavily influenced by uneven bargaining power between members, favoring members with the largest economy.

If international organizations are used as vehicles for big market states to coordinate pressure on less powerful trade partners, in order to dictate terms on IP protection for example, it nonetheless seems to make sense to describe the practice as illegitimate. But the sense is imported from the domestic level, now with states in the position as subjects, or equal partners. This fact, that the subjects to a treaty are not individual human beings but states, complicates matters as human rights regulate the relation towards humans, as their title more than suggests.

Still, as noted by Tasioulas, "All states face problems—epidemics, economic instability, environmental degradation, the proliferation of weapons of mass destruction,

[428] One such alternative is fairness in international negotiations. Tasioulas, J. 2002.

[429] In the concluding paragraphs of the section *Flexibilities in TRIPS II: compulsory licensing* above. There I pointed to the unevenly distributed sanctioning tools of WTO members, benefiting large importers.

refugee movements, etc.—that cannot be adequately addressed by individual states acting alone but only through a framework for co-operation and co-ordination."[430] The international co-operation is however, as Habermas commented in a citation above, often (or always) dependent on "the good will of powerful states and alliances."

To sort issues of international co-operation under the heading of legitimacy with a reference to human rights is not at all a straightforward task. For the same reasons it is hard to import the concept of the legitimate state to the realm of international organizations giving it application for organizations. Buchanan provides a short-definition of legitimacy, namely the right to rule.[431] We talk here (as do Buchanan) not of the legitimacy according to international law, but the moral right to rule. Using this definition, we must first see the organization as a ruler, which in itself is complicated if it is compared to state authority and state enforcement mechanisms like police and military force, not available to international organizations.[432] Next, the subjects are not human beings but states. Hence, the civil, political, economic and social rights of persons vis à vis their state must be translated into rights of member states and obligations of international organizations, if it can be done.

Still, if an international organization would decide rules or procedures, which contradict a membership state's human rights obligations, can we not make the point that the legitimacy of the organization itself is weakened? If the organization moreover applies pressure towards member states as an enforcement mechanism it seems to make sense to question the legitimacy of the organization. One such form of pressure would be a bundling of obligations for example. Such bundling of obligation could be to tie the obligation of the member state to introduce patent on essential medicines to non-related rights, for example trade in commodities or the threat of no market access for textile products.[433] Another

[430] Tasioulas, J (2010:102)

[431] Buchanan, A (2011:7)

[432] Buchanan, A (2009:250): "International law claims legitimacy and does not qualify this claim by acknowledging any superior legal authority, even where it purports to regulate the internal affairs of states." Keohane, RO (2011:4100): "It almost goes without saying that liberal democratic theory does not match well with the actual practices of global governance. There is no coherent global public engaged in discussions over issues, little shared sense of fate, and no common political culture of democracy, much less one that people regard as global in scope."

[433] Buchanan, A and Keohane, RO (2006:414): "From the standpoint of a particular weak democratic state, participation in global governance institutions such as the WTO is hardly voluntary, since the state would suffer serious costs by not participating."

pressure mechanism is the availability to insist on market size as a measure of trade bargaining power (Steinberg, RH (2002:348).[434]

An alternative to the question of the moral legitimacy of international organizations like WTO is, suggests Buchanan, to review the fairness of the procedures of the organizations: "Even if an institution does not violate human rights, its operations may be disproportionately controlled by more powerful states, without any justification for this asymmetry of power consistent with the institution's publicly avowed goals and principles. An institution can exhibit unfairness, yet still be legitimate; in that sense, fairness or, more generally, justice are more demanding standards than legitimacy. But in extreme cases, unfairness can deprive an institution of legitimacy, especially if unfairness is, as it were, built into its very structure, as opposed to being an occasional consequence of aberrant policies."[435]

When I have been more interested in the legitimacy of the state than that of international institutions, it is for two reasons. First the state is the one institution with direct responsibilities for its citizens, including their healthcare system. Second, I have given sufficient reason to call for reform of the TRIPS Agreement, not arguing to abolish it. Indeed my proposal takes advantage of a patent system that could be more well-functioning than it currently is.

Moral claims

Having given an explanation of the conception of human rights as institutional rights, derived from obligations of political power, I now turn to moral claims. Even if the political view on human rights does not acknowledge the corresponding duties as binding for individuals, this does not imply that individuals have no moral imperative to engage in combatting poverty, unfairness and human rights violations elsewhere. It only implies that they have other reasons, or other moral imperatives to do so. A further elaboration of the concept of moral claims, from my article *The Distant Moral Agent*, will make this clearer.

[434] Steinberg, RH (2002:348)
[435] Buchanan, A (2011:10)

Unlike human rights, moral claims are, ideally, met with moral response by individuals. Claims may or may not coincide with human rights. Their reach is however not limited by political boundaries and are universal in that sense, whereas human rights are universal in that they apply to all states and all citizens within each state.

To get a better sense of the distinction between human rights and moral claims, we can consider an imaginary example given by Simon Caney, who presents it to argue against a political conception of human rights:

> An isolated island is run with ruthless cruelty by a tyrant who, because of his possession of weaponry far superior to the other islanders, is able to persecute them, slaughtering enemies, torturing suspects, and so on. Suppose, further, that we are aware of this island and could easily assist the persecuted and bring about a more tolerant peaceful society.[436]

According to Caney, a political view on rights would imply that from a distance we have no duty of justice to protect the rights on the island: Those who take this view on duties "must not only conclude that we have no duty of justice to protect the welfare rights of remote individuals: they must also abandon any idea that we have a duty of justice to protect the fundamental civil and political human rights of remote individuals. And this, I think, casts a wholly institutional perspective in an even more unattractive light.[437] The institutional perspective on rights and duties implies that "persons' most basic civil and political rights would also be sacrificed."[438]

The objection from the political view on human rights would be, however, not that the human rights of the islanders have been violated, but rather that no rights exist in the community. Rainer Forst argues from the difference of social contexts to which justification of social and political arrangements apply.[439] His fundamental principle of justice is non-domination, and from it he draws the most basic right, as he sees it, the right to justification. Domination means "the arbitrary rule of some over others."[440] It follows that his concept of justice is valid in social systems, where arbitrary rule by some indeed can occur, and that

[436] Caney, S (2010:286)
[437] Ib.
[438] Ib.
[439] Forst, R (2014)
[440] Ib. p. 7

where there is no political power, there cannot be talk of justice: "Justice requires that those involved in a context of (positive or negative) cooperation should be respected as equals. That means that they should enjoy equal rights to take part in the social and political order of justification in which the conditions under which goods are produced and distributed are determined."[441]

The islanders' claim to have rights in Caney's example would be a claim for justice and would, as such, not be directed at individuals outside the context of cooperation but to the eligible authority, the ruler. A tyrant would, typically, be non-responsive to civil rights claims. Therefore, if the islanders' claim to rights were directed at their tyrant, it would fail.

If we apply Forst's context theory here, a claim for justice directed at people in a neighboring or faraway community must be held to be a plea that this other community act towards them no different than they would towards other communities. This would be the eligible context once their community on the island had broken down.

The sense of alarm in the neighboring or faraway community therefore originates, not from a justice concern, but from a moral concern. This point, captured by Forst, is missed by Caney. The particular moral concern here is expressed by Hannah Arendt and others, as the concern for the right of individuals to have rights.[442] Volker Heins thus speaks of a claim to have rights: "In asserting claims, individuals do not address official dutyholders but rather the world – or the moral public – upon which they obtrude their claim to have a right."[443]

Singer's argument is that the domain of duties expands as the moral agent realizes that there are no reasons for singling out a limiting distance where to halt the expansion. In my adaption of his model the argument is similar, but applied to moral claims. There is no reasonable limiting threshold where the claims lose their validity. The circle expands outwards from the claim-holder (not the moral agent) whenever agents fail to act on their obligations, or when the claims in question are of the sort that only institutions can respond to them, in which case I have referred to them as rights (hence the institutional, or political, view on rights). In the distinction I make between moral claims and human rights, claims do not come with the promise of a set of universally valid claims. What is universal is rather the capacity to make claims.

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[441] Forst, R (2014:11)

[442] Heins, V (2008:223). I borrow his reference to Arendt: Hannah Arendt, *The Origins of Totalitarianism*, 2nd ed. (Cleveland: Meridian, 1958), 296–7.

[443] Ib. p. 223

To continue this final clarification of the concept of moral claims I turn, once again, to legal rights, for comparison. Legal rights stand in a complex relation to morality in that they should not breach with widely held moral norms or *ordre public*. For intellectual property rights the principle is stated in TRIPS article 27 point 2. Other than that, legal rights are not necessarily derived from moral conviction. Positive legal rights can be, and often are, the product of legislation based on public interest, with no particular regard to individual claims or human rights (cf. Hare's position above).

When patent rights are viewed, as I have done, as public interest legislation, and not as a manifestation of natural property rights, the rights conferred on inventor companies are enforced as long as public interest in the matter persists. If public interest at some point in time shifts, and if, moreover, the old statute as a result stands in the way of public interest, a revision of the legal right might well result. Moral claims, on the other hand, are conceived of here as not written down but raised spontaneously from case to case. Therefore, they cannot be held to shift or not to shift with interest. To be clearer about this property of moral claims it might be instructive to bring in a notion from virtue ethics and see claims as inspiring response from prudence, or moral judgement, which is knowledge of particular facts and not of definitions (Aristotelian *phronesis* in his Nicomachean Ethics, Book VI).[444]

This differentiating property regarding the justification of legal rights and moral rights is central in Dworkin's treatment of the relation between the two kinds of right. His arguments for the priority of moral rights over rules of law is another much referred case of showing how legal adjudication is not performed in isolation from preconceptions of moral rights. He argues from jurisprudence in common law, and so-called hard cases – when a lawsuit is not subsumable under existing clear rules of law. Judges are authorized with discretional powers to decide such cases and Dworkin discusses what might guide their adjudication.

The main legal resource in hard cases is earlier court decisions.[445] The rationale for this is, Dworkin argues, that the precedent is a "piece of political history" presenting a fact. The guiding principle for the judge is, however, not the wisdom of the previous decision, this is not up for new treatment. Rather the principle at work is "the fairness of treating like cases alike."[446]

[444] Aristoteles (1973)
[445] Dworkin, R (1977:112)
[446] Ib. p. 113

It is quite possible to see his concept of fairness as being in line with Feinberg's conception of self-respect, its relation to respect for others and consequently a notion of equal respect for all. The question, in for example a case concerning payment of damage, is whether the government is bound to require a contractor to repair economic damage by the fact that it did so in an earlier, similar case. The political situation might have changed during the time that has passed so that welfare priorities are not necessarily the same as before. Dworkin argues that the duty to follow up the earlier decision is not derived from earlier legal decisions, nor political priorities, nor the judge's own philosophical convictions, but the moral conception of fairness. The historical fact of an earlier political decision coupled with the fairness requirement to treat like cases alike creates a moral right.

Feinberg's and Dworkin's writings on moral claims and rights respectively, provide a rationale for moral claims that are attributable to persons, relate them to public interest arguments and to legal rights. My presentation of them is hardly sufficient to fill the gap and establish independent moral rights in order to inquire about their scope. It is rather intended as a clarification of the concept of moral claims and their relation to moral duties, and not least, how they are related to other concepts of rights brought up in the articles.

If rights were not to be established politically from public interest, or by judges, through their interpretation of positive law, then there is question about their alternative source. One source is the Kantian notion of a fundamental right that no one should be subjected to the arbitrary will of others.[447] Kant grounds the notion in the free will of rational beings, understood as a characteristic of rational beings and not a contingent trait that might vary between individuals. To clarify the underlying conceptions of claims and rights, I shall now fill this gap, not by pursuing Kant's notion of freedom, but by including the rights arguments of Feinberg and Dworkin. As I see it, they both stand in a Kantian tradition. Both argue for the independence of moral rights, Feinberg from an ethical standpoint, referring to moral claims, and Dworkin from the judicial practice of Anglo-American common law.

In *The Distant Moral Agent* (n. 302) I made the assumption that unless a concept of rights is established there cannot be meaningful talk of duties. Feinberg discusses whether there is a symmetry between duties and rights in questioning what he refers to as the "doctrine of the logical correlativity of rights and duties."[448] He gives it the following expression:

[447] Kant, I (1797:238)
[448] Feinberg, J (1980:143)

> This is the doctrine that (i) all duties entail other people's rights and (ii) all rights entail other people's duties.[449]

He sees no need to defend (ii), but explains and defends the first part, the one I assume in the article, through his example of the imagined community Nowheresville. Feinberg sees duties, understood as "required actions" to comply with the regulations of various social institutions, as logically independent from any individual's rights. Duties are required "by law, or higher authority, or by conscience" for example. In these various classes of duties, the notion that a duty is something owed to someone else is not part of the picture. Indeed, we can imagine a whole society (his Nowheresville) where numerous duties are in place, regulating citizen's behavior, but where no one has any rights relation to other people. The notion of right is instead directed at various social authorities. In this situation the duties in place are likewise to be seen in relation to the requirements of authority figures or institutions, and not to persons.

This imagined social order allows for promises and contracts, marriages and partnerships and all the duties associated with such arrangements. These social arrangements are, however, perfectly possible without the notion of rights between people. As an illustration, Feinberg gives the example of two children fighting.[450] Billy kicks Bobby and is punished by his father. At his stage in moral development, Billy might well regret his performance out of his feeling of being estranged from his father and even be willing to apologize to him. But when his father instructs him to apologize to the wronged party, his brother, he is not prepared to do so. A direct apology to his brother would imply his recognition of his brother's "status as a right-holder against him." This he hesitates to do because it would imply a respect for his brother that he does not possess.

Feinberg complements this illustration with another, also from close personal relations. In his "three-to-marry" model, which he ascribes to religious teachings on marriage, the marital vows are made between each spouse and God, not between the spouses themselves. If it ever comes to a break of the vow, God is the wronged party. The relation between the spouses resembles, Feinberg argues, that between the brothers. "Respect for the other spouse as an independent claimant would not even be necessary," Feinberg observes. If

[449] Feinberg, J (1980:143)

[450] For this, and the following illustration, see Feinberg, J (1980:147)

the duty entails a right at all, it is not one that need to be ascribed to the other spouse. It is therefore questionable if it deserves the name of a right in its ordinary meaning.

He explains the applicable notion of respect by reference to self-respect and sees it as part of our human dignity that we can claim rights.[451] It is our own capacity to "assert claims" that commands respect for persons.[452] To lose sight of oneself as a maker of claims is to lack "that minimal self-respect that is necessary to be worthy of the love and esteem of others."[453] The relation of respect for others and self-respect apparent here is important, even though it is not as explicit as one would wish in his conclusion, namely that self-respect gives epistemological access to the dignity of other people and their moral claims.

It is not a straightforward task to sort out the relation between claims and rights. Feinberg admits this and my thesis, I realize, reflects this difficulty. The discussion here benefits, though, from Feinberg's discussion when he argues that having rights makes claiming possible, and then: "it is claiming that gives rights their special moral significance."[454]

The issue Feinberg raises in his Nowheresville example concerns the moral status of duties which are independent from any person's claims. Rights are well suited to be claimed, he notes, but only when they are claimed, is duty established, not before. Still, what is claimed must be a right, in order for a duty to be established. The relation between rights and claims is therefore an intimate one. Feinberg concludes that something is wrong in Nowheresville because the notion of the individual as holder of rights – i.e. as the one who can claim rights, is missing. Nowheresville deserves its name by representing a system of rights and duties that is different from the actual state of affairs. Feinberg thus explains why he endorses the doctrine of the logical correlativity of rights and duties.

In my use of the term duty above, conscience duties correspond to duties of benevolence (Rawls). Duties to comply with government regulations are seen as civic duties (Satz) or legal duties. As far as Williams' example of rescuing the wife in peril is concerned, he discusses it with no reference to rights. I interpret him as presenting it as an existential matter of virtue ethics, where (characteristically) no rights can be derived. The questions discussed in *The Distant Moral Agent* are whether individuals in affluent northern countries have duties to provide existing medicines to patients in weak markets, if these patients have

[451] Feinberg, J (1980:142;151;155;156)
[452] Ib. p. 151
[453] Ib.
[454] Ib.

rights to these medicines, and if any rights they have creates duties in faraway affluent countries, for our governments or individuals here. These questions are interrelated, and the correlativity doctrine is illuminating in this regard.

The correlativity doctrine is controversial to the extent that moral theory allows for imperfect duties.[455] These are duties of charity and benevolence towards others in cases where those others have no rights corresponding to the duty, they cannot claim the charitable donation or the benevolent act. The duty to act in these cases is therefore not a perfect duty, but still a duty in this terminology – it is required in some other sense than the fulfillment of a claim.

O'Neill has drawn the line between perfect and imperfect duties precisely by reference to whether the duty has a corresponding right or not. Rights thus create perfect duties, whereas there are also imperfect duties, "not matched by rights".[456] There is a "close link" between imperfect duties and virtues according to O'Neill. Many of the required (but non-claimable) acts are virtuous acts and have traditionally been classified as such.

To state in the shortest form how I position my concept of moral claims, I have made references to Feinberg's notion of self-respect as a basis for the respect of the claims of others. At the second level, which is where personal claims meet with institutions, like the city or the state, I point to Dworkin's moral principle that like cases should be treated alike.

There are two reasons to include Dworkin here. The first, and most apparent, is his assertion of equality as fairness described above. The second, and less apparent but not less important, is his implicit reference to someone or some entity treating the cases. Dworkin's own concern is, as laid out above, the duty of a judge to regard earlier court decisions, or positive law, as pieces of political history and decide accordingly. My point is simply that the handling authority cannot be left out of the equation.

Questions whether like cases are treated alike or not, must be settled by reference to an identified institution in charge of administering benefits, duties, and compensations. When the institution does, its rules and sanctions bind a designated number of people falling under its responsibility. I take Dworkin's fundamental fairness principle to be part of what authorizes political power, critical for the legitimacy of state government. The notion of

[455] Hinsch, W & Stepanians, M (2006). See notes 11 and 12 above where the distinction between perfect and imperfect duties is introduced.
[456] O'Neill, O (1993:120)

moral claims towards institutions used in *The Distant Moral Agent*, should be understood in light of this.

In *The Distant Moral Agent* I borrow the example from Bernard Williams of several persons in peril, one of whom is the wife of the only person who can rescue them. Time is limited, and so too is this agent's capacity. He therefore desperately figures that he can rescue no more than one of them. I argued that the wife in peril has more reason than the others to feel let down by her husband if he flips a coin, decides not to rescue her, and instead turns to some other person to save this person's life. The argument is that her reason for feeling let down is a moral reason (her claim has been rejected).

I do not use the example to make allowance for partiality on the side of the agent. Methodologically, at least, I make the more compelling argument, in my view, that if there are such obligations they derive from the moral claims of persons, not from rights. These claims are wholly external to the agent, even if they are his wife's claims. His moral response to her is determined not by his own needs and interests but by her claims.

Mathias Risse has made this point by reference to treating somebody as a means to one's own ends. I include his explication of it here:

> Suppose I am treating somebody merely as a means. The person whom I am so treating must rationally understand herself as a source of value. However, the capacity in virtue of which she must do so is the same one in virtue of which I too am rationally compelled to understand myself as a source of value. Disregarding the other person's capacity (by treating her as a mere means to my ends) amounts to disregarding a capacity I find in myself and must value if I am to see value in my own goals (which after all could get their own value only from my capacity to bestow, and thus be a source of, such value). To disregard another person is to draw a distinction between myself and that person that on rational grounds is un-acceptable.[457]

[457] Risse, M (2012b:22)

THE CLAIM-BASED APPROACH AND DONATIONS OF MEDICINES

The discussion in *Patent Funded Access to Medicines* concerns the situation in developing countries where lack of access to medicine is endemic. I therefore refer to state obligations already in place through international commitments.

Human rights are universal. They derive universality from being equally applicable to all whichever state they live in, whatever gender, race, religious conviction, economic standing people have.[458] What universality does not mean, however, is that rights could be claimed by anyone to any state. An example would be the right to equality before the law, which could not be secured by a foreign state. To press this right, the request must be made to the treating authority, the agency treating the case, and therefore responsible for treating it well. Another example can be taken from political rights, the right to vote (Art. 21 in the UDHR). It need not be understood as a right to vote everywhere, but must be understood as a right everywhere to vote.

According to the political conception applied in the thesis, the universality of human rights simply means that they shall apply everywhere. *The Distant Moral Agent* addresses the question why states which for a large part conduct their policies in compliance with human rights, or citizens of such states, should be concerned about human rights violations elsewhere.

This understanding of the universality of human rights gives one reason why I believe a clarification of the conceptions of rights and claims in the project is important. There are a couple more. After a workshop[459] presentation I made of the article *The Distant Moral Agent*,

[458] The United Nations (1948) Art. 1: "All human beings are born free and equal in dignity and rights."

[459] Bergen Twin Workshop June 2013 joint hosted by University of Bergen, Department of Philosophy and NTNU, Programme for Applied Ethics, sponsored by The Research Council of Norway.

I was challenged[460] to justify why people in well-off regions of the world, already paying high prices for medicines, should accept to finance the reform of mandatory provisions – which certainly has a cost side, albeit a small one. The extension of the patent period in high cost markets, however briefly, means added weeks or months of high price for medicines for patients and public budgets in these regions. Why would that be acceptable?

In the absence of a world state as provider of global civil, political or social rights, and in a case where rights are not uphold by any given state government, there is no candidate to take over the obligations towards people suffering rights deprivation. At the practical-political level neighboring states could not take over responsibilities to provide healthcare, education, freedom of press and religious beliefs as well as collecting taxes to finance the social rights, without risk of aggressive counter-measures from the illegitimate government in place. At the moral level, the neighboring states do not answer for human rights there.

What this means is, however, not that neighboring states and people there have no moral imperative to make efforts to have the rights restored. It merely means they do not have to take on human rights responsibilities to acknowledge this. Moral claims from the rights-deprived people carry weight across the border even if human rights do not. Indeed if they, by ignoring the separateness of human rights and moral claims, ventured to take over human rights responsibilities, they would need political authority amounting to something like full sovereignty to accomplish it. Assuming the overtaking of the state was not part of the claim, an alternative approach is indeed called for.

Tasioulas' viewpoint has been included above in order to position a claim-based view relative to a human rights perspective. Despite the differences in perspectives on the foundation of rights, the claim-based position is nonetheless consistent with the promotion of human rights to legal systems at home or elsewhere. The claim-based view, as I have presented it, involves no condition that the work being invested and the progress that has been achieved in post-war Europe should be halted or reconsidered.

Feinberg's analysis of the concept of a claim includes a verbal approach. He observes that the semantic weight of the noun "a claim" is carried by the verb form "to claim." And that the noun "a right" has no parallel. Feinberg's position is that within this "claiming vocabulary" we can ask what it is to have a claim and further: "[h]ow is this related to rights? I would like to suggest that *having a claim consists in being in a position to claim, that is, to*

[460] By Reidar Lie at the University of Bergen

make claim to or *claim that*. If this suggestion is correct it shows the primacy of the verbal over the nominative forms."[461] The notion of claim at work in Feinberg, and largely adopted in my treatment of moral rights here, is not to be confused with the ordinary notion of human rights in the form of a list. The verbal primacy of the concept suggests the procedural approach taken here and the close connection with legitimacy suggests further the possibility of changing claims, relative to geographical region.

Griffin takes his departure from stated human rights like minimum provision and liberty, from the UNDHR list. He grounds them in personhood and practicalities[462] and asks:

> Would we not have a right unless the correlative duty-bearers were identifiable? Must rights be, in this sense, claimable? Some writers think so [note pointing to Onora O'Neill]. Some of them use this requirement of claimability to argue that welfare rights cannot be human rights. The duties correlative to a right to welfare, they say, fall upon what we can describe no more specifically than '*some agents*', thus failing to identify any actual agents against whom to make the claim. A right to welfare therefore will not meet the requirement of claimability until certain social institutions, such as governments, are on the scene to decide on both the content and the bearers of such duties.[463]

Not embracing skepticism of rights in areas where correspondent duty-bearers are hard to identify, Griffin points out that if there is no institution in place to secure the rights, this gives no occasion to give it up. The way we manage it is that we simply do our best. By calling together people and institutions, individuals and commercial enterprises if need be, that are willing to help in forming an ad-hoc group. This way we make the rights claimable.[464]

Griffin clearly takes the list of human rights, imagining a perfected one, to signify moral rights between agents other than those comprised by the state-citizenship relation. Human rights thereby command duties for all. A distinction between human rights and other moral rights is absent from this setup.

Griffin arrives at his position by starting with stated human rights, as already noted, and proceeding to claims from there. To position the notion of moral claims at work in this

[461] Feinberg, J (1980:151), italics in the original.
[462] Griffin, J (2008:44). For details, see ch. 2.4 and 2.5.
[463] Ib. p. 107, Griffin's italics.
[464] Griffin, J (2008:108)

thesis relative to Griffin's rights, the claims themselves are seen as fundamental. Their universality is tied to the capacity to make moral claims, not to interest, nor to human dignity as such, but to the person making a claim. For a person who is deprived of his human rights by the local authority his appeal to have the rights restored is not an appeal to human rights elsewhere, but a moral claim "to the world" (cf. Heins above).

The scope of moral claims

At this point I leave the distinction between moral claims and human rights in order to concentrate once again on the scope of moral claims, this time at the broadest limits of it. To follow up the previous point, the question now is to whom the claim can be directed. I have already given an indication of a party that falls outside of the domain of eligible candidates, like someone without the capacity to meet the claim. Here we meet the same criteria that are discussed in theories of moral duties.[465] Unlike an inquiry of duties or responsibilities, the opposite route taken here asks not the question what constitutes a duty, but rather what makes a claim apply morally to a particular agent, at a distance from the claimholder.

It is in the discussion of this question I evoke, methodologically, Singer's cosmopolitan model of an expanding circle of moral concern. But instead of using it as a model for establishing cosmopolitan duties for the moral agent, as Singer does, I apply it to determine the scope of moral claims of the other party, in particular patients with no access to otherwise available medication. The methodological shift I propose is to replace the person in the center of the circles, Singer's moral agent, with the holder of moral claims.

I shall not repeat Singer's argument here. A brief reminder is however in order to demonstrate how I use his model as a methodological tool to support an argument of a wide scope of legitimate claims. According to Singer the driving force of the expansion of moral concern is rationality. There is no reasonable argument, he argues, to stop the expansion of moral concern from the inner circle of the family outwards through local communities all the way to the global level. This is how Singer demonstrates the rationality of the widening concern.

[465] Miller, D (2007; ch. 4) discusses several forms of moral responsibility

In taking up his model, I suggest that his argument is valid for moral claims expanding from victims of poverty and/or political repression. As local individuals or institutions, like their state, fail to meet the claims directed at them, even if they have the capacity to meet them, there is no reason to delimit the area of duty at this level. The expectation that moral claims are not exhausted at the level of a mismanaged state for example, but expands further is not unreasonable. One consequence to be drawn at a distance would be to reconsider the legitimacy of the state.

Pressure could build on my state not to harbor the mismanaged state's funds, deriving from natural resources extraction for example. Alternatively, harboring the funds and locking them in anticipation of a legitimate regime could be an option if the outlook for regime change is optimistic. When for instance several governments failed to accept free donations of the drug nevirapine from Boehringer Ingelheim, against HIV/AIDS infection of inborn babies,[466] the women's claims to the drug were not necessarily invalidated. In fact, I have argued that it is due to the mismanagement or negligence at one eligible level that the scope of legitimate claims expands. With it, the area of respondents expands accordingly, identifying other agents at similar or higher social or political levels.

The agents thus identified need not be persons. In the case of a mismanaged state, the candidate with a capacity to address the case would not be one person but more likely another state or even association of states. The practical solution explored in *Patent Funded Access to Medicines* implies shipments of essential medicine to countries with no capacity to produce and no resources to import them. The country in question receives the drugs in exchange for introducing and enforcing patents on medicines, which means that they could not export them for profit.

The chosen method is a reconstruction of Singer's model to establish that moral claims can have validity far away. This version of the model can thus provide the justification needed for citizens in well-off countries to accept a short extension of the patent period at home in order to finance shipments of medicines to countries where access is severely limited. This is not to say that there might not be other practical, or even more practical solutions to the access problem. It suffices, though, to establish the moral imperative to assist in this matter.

[466] Matthews, D (2004:98)

DEFINITIONS AND KEY TERMS

LITERATURE

35 U.S. Code § 101-3	Available here: http://www.gpo.gov/fdsys/granule/USCODE-2011-title35/USCODE-2011-title35-partII-chap10-sec101/content-detail.html. Accessed March 13, 2014.
Andreassen, T (2014)	Patent Funded Access to Medicines. *Developing World Bioethics*. http://onlinelibrary.wiley.com/doi/10.1111/dewb.12058/abstract. Accessed Oktober 10, 2014.
Aristoteles (1973)	*Etikk.* Oslo: Gyldendal. The 1996 edition. Stigen, A (transl.)
Ashcroft, RE (2005)	Access to Essential Medicines: A Hobbesian Social Contract Approach. *Developing World Bioethics* vol 5, No 2.
Attaran, A & Gillespie-White, L (2001)	Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa? *JAMA*, October 17, Vol 286, No 15
Barry, C (2005)	Applying the Contribution Principle. *Metaphilosophy* Vol. 36, Nos. 1/2.
Beitz, CR (1975)	Justice and International Relations. In Pogge, TW & Moellendorf, D (2008). First published in *Philosophy and Public Affairs* 4:4 (summer): 360-89.
Bird, R & Cahoy, DR (2008)	The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach. *American Business Law Journal*. Volume 45, Issue 2, 283–330.
Brock, DW (2001)	Some Questions About the Moral Responsibilities of Drug Companies in Developing Countries. *Developing World Bioethics* Volume 1 Number 1.
Brody, B (2006)	Intellectual Property and Biotechnology: The U.S. Internal Experience-Part II. *Kennedy Institute of Ethics Journal*; Jun 2006; 16, 2.
Buchanan, A & Keohane, RO (2006)	The Legitimacy of Global Governance Institutions. *Ethics & International Affairs*; 2006; 20,4
Buchanan, A (2002)	Political Legitimacy and Democracy. *Ethics* 112. July.
Bundesministerium der Justiz und für Verbraucherschutz (2013)	Patent Act. Available, together with the Original text at: http://www.gesetze-im-internet.de/patg/. Accessed March 13, 2015.
Burckhart, H und Gronke, H (2002)	*Philosophieren aus dem Diskurs. Beiträge zur Diskurspragmatik*. Würzburg: Königshausen & Neumann.
Burley, J and Harris, J, eds. 2002	*A Companion to Genethics*. Malden: Blackwell, 2004.

Calabresi, SG and Leibowitz LC (2013)	Monopolies and the Constitution: A History of Crony Capitalism. *Harvard Journal of Law & Public Policy* Vol. 36
Caney, S (2010) Chatterjee, DK (2004)	Global Poverty and Human Rights: The Case for Positive Duties. Pogge, T ed. (2007) *The Ethics of Assistance. Morality and the Distant Needy*. Cambridge: Cambridge University Press
Cockburn, IM; Lanjouw, JO; Schankerman, M (2016)	Patents and the Global Diffusion of New Drugs. *American Economic Review* 106 (1). Available at: https://www.aeaweb.org/articles?id=10.1257/aer.20141482. Accessed June 5, 2021
Cohen, J (2010)	Philosophy, Social Science, Global Poverty. In Jaggar (2010).
Coke, E (1602)	The Case of Monopolies. *Selected Writings of Sir Edward Coke*, 3 vols. Steve Shepherd ed. Vol 1. Indianapolis: Liberty Fund, 2003. available at: https://web.archive.org/web/20091223070111/http://oll.libertyfund.org/?option=com_staticxt&staticfile=show.php%3Ftitle%3D911&chapter=106358&layout=html&Itemid=27. Last accessed 26. April 2018
Cooter, R & Ulen, T (2004)	*Law and Economics*. Pearson Education. 4th edition.
Correa, CM (2000a)	*Intellectual Property Rights, the WTO and Developing Countries.* London: Zed Books.
Correa, CM (2000b)	*Integrating Public Health Concerns into Patent Legislation*. Geneva: South Centre
Correa, CM (2002)	*Implications of the Doha Declaration on the TRIPS Agreement and Public Health*. Geneva: WHO.
Cullet, P (2003)	Patents and Medicines: The Relationship between TRIPS and the Human Right to Health. *International Affairs* Vol. 79, No. 1, pp. 139-160. Available at http://www.jstor.org/stable/3095545. Accessed Januray 2, 2015.
Cullet, P (2007)	Human Rights and Intellectual Property Protection in the TRIPS Era. *Human Rights Quarterly*, Volume 29, Number 2, pp. 403-430.
Deaton, A (2013)	*The Great Escape*. Princeton: Princeton University Press
DeCamp, MW (2007)	Global Health: A Normative Analysis of Intellectual Property Rights and Global Distributive Justice. Doctoral thesis. *Duke University*
Deutscher Bundestag (2003)	Drucksache 15/1709. Entwurf eines Gesetzes zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen. Available at: http://dip21.bundestag.de/dip21/btd/15/017/1501709.pdf. Accessed March 5, 2015.
Devaiah, Vishwas	A History of Patent Law. Alternative Law Forum. Available from: http://altlawforum.org/publications/a-history-of-patent-law/. Accessed 14. August 2017.
Doll, JJ (1998)	The Patenting of DNA. Science Vol. 280 no. 5364 pp. 689-690. Available at: http://www.sciencemag.org/content/280/5364/689.full. Accessed March 6, 2015.

Drahos, P (1996)	*A Philosophy of Intellectual Property*. Surrey: Ashgate Publishing Limited.
Draper, AJ (2002)	An Introduction to Jeremy Bentham's Theory of Punishment. *Journal of Bentham Studies*, 2002, 5(1): 1. Available at: https://www.scienceopen.com/document?vid=c274a9bf-ce42-4076-b751-f6327157f266. Last accessed June 28, 2019.
Duggan, M; Garthwaite, C; Goyal, A (2016).	The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India. *American Economic Review* 106 (1): Available at https://www.aeaweb.org/articles?id=10.1257/aer.20141301. Accsessed June 5, 2021
Dworkin, R (1977)	*Taking Rights Seriously*. Cambridge: Harvard University Press.
Eisenberg, RS (2002)	How Can You Patent Genes? In Magnus, D; Caplan, A; and McGee, G, eds. (2002).
EU (2006)	Regulation (EC) No 816/2006 of the European Parliament and of the Council. 17. May
EU (2010)	SEC(2010) 380 final. Brussels: European Commission. Available t: http://ec.europa.eu/transparency/regdoc/?coteId=2&year=2010&number=380&language=EN.&CFID=4263562&CFTOKEN=fa3474e704a3d440-88ED0818-AB7C-FA5E-35673364235AAA48&version=ALL&fuseaction=list. Accessed January 14, 2016.
EU directive 98/44/EC	Directive on the legal protection of biotechnological inventions. July 6, 1998. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0044&from=EN. Accessed October 16, 2014.
Federal Register (2001)	Vol. 66, No. 4 / Friday, January 5, Notices
Feinberg, J (1980)	*Rights, Justice and the Bounds of Liberty*. Princeton: Princeton University Press.
Finnie, I and Liberto, M (2014)	USPTO Guidance for Examiners Takes Expansive View of Myriad and Prometheus Decisions. Global IP Matters. Available at: http://www.globalipmatters.com/2014/03/07/uspto-guidance-for-examiners-takes-expansive-view-of-myriad-and-prometheus-decisions. Accessed October 16, 2014.
Fisher, WW (1999)	The Growth of Intellectual Property: A History of the Ownership of Ideas in the United States. A translation of Geistiges Eigentum – ein ausufernder Rechtsbereich: Die Geschichte des Ideenschutzes in den Vereinigten Staaten in *Eigentum im internationalen Vergleich*, p. 265-91. Vandenhoeck & Ruprecht. Available at http://cyber.law.harvard.edu/people/tfisher/iphistory.pdf. Accessed 26. Sept. 2012.
Forst, R (2014)	Two Pictures of Justice in *Justice, Democracy and the Right to Justification: Rainer Forst in Dialogue*. Ed. Rainer Forst. Bloomsbury Academic, 2014. 3–26. Bloomsbury Collections. Available at: http://dx.doi.org/10.5040/9781472544735.ch-001. Accessed July 10, 2021.
Friedman MA, Besten HD & Attaran A (2003)	Out-licensing: a Practical Approach for Improvement of Access to Medicines in Poor Countries. *The Lancet*, Vol 361 January 25.

Goodin, RE (1988)	What is So Special about Our Fellow Countrymen? *Ethics*, Vol. 98, No. 4. (Jul., 1988).
Gostin, LO (2007)	Meeting the Survival Needs of the World's Least Healthy People. *JAMA* July 11 Vol 298, No 2.
Goswami, R (undated)	Compliance of Trips in Indian Patent Law. *Legal Services India*. Available at: http://www.legalservicesindia.com/article/1103/Compliance-of-Trips-in-Indian-Patent-Law.html. Accessed 10. June 2021
Griffin, J (2001a)	The Presidential Address: Discrepancies between the Best Philosophical Account of HumanRights and the International Law of Human Rights.*Proceedings of the Aristotelian Society*, Vol. 101 (2001).
Griffin, J (2001b)	First Steps in an Account of Human Rights. *European Journal of Philosophy* 9:3
Griffin, J (2008)	*On Human Rights*. Oxford: Oxford University Press
Gurry, F (2011)	The Disclosure of Technology in the Patent System. Opening address to the Symposium on Access to Medicines, Patent Information and Freedom to Operate, held by WHO, WTO and WIPO. Geneva: February 18. Available on http://www.wipo.int/about-wipo/en/dgo/speeches/dg_who_wipo_wto_med_11.html. Accessed June 18, 2012.
Haag, T & Kilger, C (2013)	Myriad ruling vs. biotech patent eligibility in Europe. *Law360*, June 21. Available at: http://www.law360.com/articles/451636/myriad-ruling-vs-biotech-patent-eligibility-in-europe. Accessed October 16, 2014.
Habermas, J (1998)	Remarks on legitimation through human rights. *Philosophy & Social Criticism* vol. 24 no 2/3 pp. 157-171. Available at: https://journals.sagepub.com/doi/10.1177/019145379802400211. Accessed June 12tn 2020.
Hart, HLA (1958)	Positivism and the Separation of Law and Morals. *Harvard Law Review* vol. 71, Number 4
Haugen, HM (2007)	Patent Rights and Human Rights: Exploring their Relationships. *The Journal of World Intellectual Property* Vol. 10, no. 2, pp. 97–124.
Heins, V (2008)	Human Rights, Intellectual Property, and Struggles for Recognition. *Human Rights Revue* 9.
Helfer LR & Austin GW (2011)	*Human Rights and Intellectual Property: Mapping the Global Interface.* New York: Cambridge University Press
Hestermeyer, H (2007)	*Human Rights and the WTO: the Case of Patents and Access to Medicines*. Oxford: Oxford University Press
Hinsch, W & Stepanians, M (2006)	Human Rights as Moral Claim Rights. In Rex, M & David AR (eds.) (2006) Ch. 7.
Hobbes, T (1651)	*Leviathan.* Indianapolis: Hackett. 1994.

Hoekman, BM and Mavroidis, PC (2000)	WTO Dispute Settlement, Transparency and Surveillance. The World Economy. Volume 23. Issue 4, p. 527-542.
Hogerzeil, HV & Mirza, Z (2011)	*The World Medicines Situation 2011. 3rd Edition*. Geneva: WHO.
Hollis, A & Pogge, T (2008)	*The Health Impact Fund: Making New Medicines Accessible for All*. Incentives for Global Health.
Hume, D (1739-40)	*A Treatise of Human Nature*. Oxford: Oxford University Press 1978
Humphreys, M: Sachs, JD & Stigliz, JE eds. (2007)	*Escaping the Resource Curse*. New York: Columbia University Press
ICESCR (1966)	International Covenant on Economic, Social and Cultural Rights. New York: UN General Assembly. Available: http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx. Accessed September 12, 2014.
IFPMA (2011)	International Federation of Pharmaceutical Manufacturers and Associations. The Pharmaceutical Industry and Global Health: Facts and Figures. http://www.ifpma.org/fileadmin/content/Publication/2011/2011_The_Pharmaceutical_Industry_and_Global_Health_low_ver2.pdf. Accessed July 23, 2012.
IFPMA (2012)	International Federation of Pharmaceutical Manufacturers and Associations. Ending Neglected Tropical Diseases. http://www.ifpma.org/fileadmin/content/Publication/2012/IFPMA-NTD-NewLogoJUNE2.pdf. Accessed July 23, 2012.
IFPMA (2013)	International Federation of Pharmaceutical Manufacturers & Associations website: About IP Rights. Available at: http://www.ifpma.org/innovation/ip-rights/about-ip-rights.html. Accessed August 3, 2015.
IIPI (2000)	International Intellectual Property Institute. Patent protection and access to HIV/AIDS pharmaceuticals in Sub-Saharan Africa. http://www.wipo.int/about-ip/en/studies/pdf/iipi_hiv.pdf. Accessed February 27, 2013.
Institute for Healthcare Informatics, (2016)	Medicines Use and Spending in the U.S. Available at: https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf. Accessed June 24, 2021
Jaggar, AM (2010)	*Thomas Pogge and His Critics*. Cambridge: Polity Press.
Jamieson, D (1999)	*Singer and his critics*. Oxford: Blackwell. Reprinted 2000.
Kamm, FM (1999)	Faminine Ethics: the Problem of Distance in Morality and Singer's Ethical Theory, in Jamieson, D (1999).

Kant, I (1796)	*Toward Perpetual Peace and Other Wrirings on Politics, Peace , and History*. Kleingeld, Pauline ed. New Haven: Yale University Press.
Kant, I (1797)	*The Metaphysics of Morals*. New York: Cambridge University Press 1996.
Keohane, RO (2011)	Global governance and legitimacy. *Review of International Political Economy.* 18:1. Available at: https://doi.org/10.1080/09692290.2011.545222. Accessed July 10, 2021
Kilger, C; Feldges, J & Jaenichen, HR (2005)	The Erosion of Compound Protection in Germany: Implementation of the EU Directive on the Legal Protection of Biotechnological Inventions - the German Way. Journal of the Patent & Trademark Office Society July 2005. Available at: http://www.fh-k.com/wp-content/uploads/2014/09/20.pdf. Accessed October 16, 2014.
Klitzike, RA (1959)	Historical Background of the English Patent Law. *Journal of the Patent Office* 41(9), 615-650. Available at: http://www.compilerpress.ca/Library/Klitzike%20Historical%20Background%20English%20Patent%20Law%20JPO%201959.htm. Last accessed June 26, 2018
Kohler, Lexchim, Kuek & Orbinski (2010)	Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort? *Healthcare Policy* Vol.5 No.3.
Krishna, RJ & Whalen, J (2013)	Novartis Looses Glivec Patent Battle in India. The Wall Street Journal. Available at: http://online.wsj.com/article/SB10001424127887323296504578395672582230106.html. Accessed April 5, 2013.
Kuper, A (2002)	More Than Charity: Cosmopolitan Alternatives to the "Singer Solution". *Ethics & International Affairs* 16, no. 2.
Lanjouw, JO and Jack, W (2004)	Trading Up: How Much Should Poor Countries Pay to Support Pharmaceutical Innovation? *Center for Global Development November*, Volume 4, Issue 3. http://www.cgdev.org/publication/trading-how-much-should-poor-countries-pay-support-pharmaceutical-innovation. Accessed April 14, 2013.
Liddell, K (2010)	The Health Impact Fund: a critique. In Pogge, T; Rimmer, M & Rubenstein, K eds.: *Incentives for Global Public Health*. Cambridge: Cambridge University Press.
Locke, J (1690)	*Second Treatise of Government*. Indianapolis: Hackett 1980.
Loff, B (2003)	Debate that "This house believes the essential drug concept hinders the effective deployment of drugs in developing countries." *Transactions of the Royal Society of Tropical Midicine and Hygiene* 97, 6-9
Loff, B and Heywood, M (2002)	Patents of Drugs: Manufacturing Scarsity or Advancing Health? *Journal of Law, Medicine & Ethics*, 30: 621-631
Lumina, C (2008)	Free trade or just trade? The World Trade Organisation, human rights and development (Part 1). *Law, Democracy & Development*. Volume 12 (2).
Lumina, C (2010)	Free trade or just trade? The World Trade Organisation, human rights and development (Part 2). *Law, Democracy & Development*. Volume 14.

Macer, DRJ (2002) *The Pharmacogenomics Journal* (2002) 2, 361–366. Available at: http://www.nature.com/tpj/journal/v2/n6/full/6500140a.html. Accessed October 13, 2014.

Magnus, D.; Caplan, A.; and McGee, G. eds. 2002 *Who Owns Life?* Amherst: Prometheus Books.

Mansfield, E (1986) Patents and Innovation: An Empirical Study. *Management Science*, Vol. 32, No. 2. Available at: https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.558.5482&rep=rep1&type=pdf. Accessed Mars 11, 2021.

Marshall, TH (1950) *Citizenship and Social Class*. In TH Marshall & Tom Bottomore: Citizenship and Social Class. Chicago: Pluto Press 1992. Reprinted 1996.

Maskus, KE (2000) *Intellectual Property Rights in the Global Economy*. Washington DC: Institute for International Economics

Matthews, D (2002) *Globalising Intellectual Property Rights*. Abingdon: Routledge.

Matthews, D (2004) WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: a Solution To the Access To Essential Medicines Problem? *Journal of International Economic Law* 7 (1), 73-107.

Maxmen, A (2012) The great gene-patent debate. Nature News. Nature Publishing Group. Jul. 20. Available at: http://www.nature.com/news/the-great-gene-patent-debate-1.11044. Accessed January 21, 2015.

May, C & Sell, SK (2006) *Intellectual Propery Rights. A Critical History*. Boulder: Lynne Rienner Publishers

May, C (2002) The Venetian Moment: New Technologies, Legal Innovation and the Institutional Origins of Intellectual Property. Prometheus, 20:2, 159-179. Available online at: https://doi.org/10.1080/08109020210138979

Mazzoleni, R and Nelson, RR (1998) The benefits and costs of strong patent protection: a contribution to the current debate. *Research Policy* 27. Elsevier Science B.V.. Available at: https://www.sciencedirect.com/science/article/abs/pii/S0048733398000481. Accsessed June 10, 2021

Melgård, M (2011) Business bedre enn bistand. Dagbladet November 29. Available at: http://www.dagbladet.no/2011/11/29/nyheter/angola/erik_solheim/trond_giske_and_haakon/bistand/19189536/. Accessed September 29, 2014.

Milanovic, B (2011) *The Haves and the Have-Nots*. New York, NY: Basic Books.

Miller, D (2006) Collective Responsibility and International Inequality in The Law of Peoples. In Rex, M & David AR (eds.) (2006)

Miller, D (2007) *National Responsibility and Global Justice*. New York: Oxford University Press.

Milstien, J & Kaddar, M (2006)	Managing the effect of TRIPS on availability of priority vaccines. *Bulletin of the World Health Organization* May; 84 (5): 360-365.
Monsanto Co. V. Rohm and Haas Co. 1970	312 F.Supp. 778 (1970). United States District Court, E. D. Pennsylvania.
Mossoff, A (2001)	Rethinking the Development of Patents: An Intellectual History, 1550-1800. *Hastings Law Journal*. Volume 52, Issue 6. Available at: https://repository.uchastings.edu/hastings_law_journal/vol52/iss6/2/. Last accessed June 21, 2018
Nagel, T (1986)	*The View from Nowhere*. New York: Oxford University Press.
Nagel, T (2005)	The Problem of Global Justice. *Philosophy & Public Affairs* 33, no. 2.
Novak, K (2003)	The WTO's balancing act. *The Journal of Clinical Investigation*. November, volume 112, number 9.
Novartis website	Patents and Medical Progress. Novartis undated website available at: https://www.novartis.com/news/statements/patents-and-medical-progress#ui-id-1=4. Accessed August 3, 2015.
Nozick, R (1974)	*Anarchy, State and Utopia*, New York: Basic Books.
Nuffield Council on Bioethics (2002)	The ethics of patenting DNA. A discussion paper. London: Nuffield Council of Bioethics.
Nunn, AS; Fonseca, EM; Bastos, FI; and Gruskin, S (2009)	AIDS Treatment in Brazil: Impacts and Challenges. *Health Affairs* July/August vol. 28 no. 4 1103-1113. Available at: http://content.healthaffairs.org/content/28/4/1103.full#sec-13. Accessed January 12, 2015.
Oddi, AS (1987)	The International Paten System and Third World Development: Reality or Myth. *Duke Law Journal*, Nov., Vol. 1987, No. 5. Available at: https://www.jstor.org/stable/1372691?seq=1. Accsessed June 10, 2021.
Oh, C (2000)	Patents versus Affordable Medicines at Geneva 2000. Third World Network. Available at: http://www.iatp.org/documents/patents-versus-affordable-medicines-at-geneva-2000. Accessed August 3, 2015.
O'Neill, O (1993)	Duties and Virtues. London: Royal Institute of Philosophy Supplement; Vol. 35, (September): 107-120.
O'Neill, O (2001)	Agents of Justice. *Metaphilosophy* vol. 32, nos. 1/2, January 2001
O'Neill, O (2004)	Global Justice: Whose Obligations? In Chatterjee (2004).
O'Neill, O (2005)	The dark side of human rights. *International Affairs* 81, 2.

Outterson, K (2006)	Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries. *American Journal of Law & Medicine*, 32: 159-173.
Palmer, TG (1990)	Are Patents and Copyrights Morally Justified? The Philosophy of Property Rights and Ideal Objects. *Harvard Journal of Law & Public Policy*, Volume 13, Number 3 Summer 1990.
Parry, B (2005)	From the Corporeal to the Informational: Exploring the Scope of Benefit Sharing Agreements and their Applicability to Sequence Databases. In Thiele, F and Ashcroft, RE (2005).
Peterson, M; Hollis, A & Pogge, T (2009)	A Critique in Need of Critique. *Public Health Ethics*, 2009, 1-8.
Pettit, P (2017)	Political realism meets civic republicanism. *Critical Review of International Social and Politica Philosophy* 20:3, 331-347. Available at: https://doi.org/10.1080/13698230.2017.1293912. Accessed November 23, 2019
Pogge, T & Moellendorf, D (2008)	*Global Justice. Seminal Essays*. St. Paul, MN: Paragon House.
Pogge, TW (1989)	*Realizing Rawls*. Ithaca: Cornell University Press
Pogge, TW (2002)	*World Poverty and Human Rights*. Cambridge: Polity Press. 2008 Edition.
Pogge, TW (2005)	Severe Poverty as a Violation of Negative Duties. *Ethics & International Affairs*, Volume 19.1 Spring.
Pogge, TW (2010a)	Responses to the Critics. In Jaggar (2010).
Pogge, TW (2010b)	*Politics as Usual*. Cambridge: Polity Press.
Popper, KR (1957)	*The Poverty of History*. London: Routledge & Kegan Paul. Second edition 1960, reprinted 1976
Puymbroeck, RV Van (2010)	Basic Survival Needs and Access to Medicines – Coming to Grips with TRIPS: Conversion + Calculation. *The Journal of Law, medicine & Ethics 2010*, volume 38: 3.
Rae, F (2010)	Intellectual Property Rights versus the Right to Access Essential Medicines. HAI Essay Competition. http://haieurope.org/wp-content/uploads/2011/02/Winner-2010-HAI-Europe-Essay-Competition.pdf. Accessed August 2, 2012.
Rajagopal, D (2012)	Novartis India keeps fingers crossed as SC hears Glivec patent case. March 5. The Economic Times, March 5. Available at: http://articles.economictimes.indiatimes.com/2012-03-05/news/31124126_1_glivec-imatinib-anti-cancer-drug. Accessed August 3, 2015.
Rawls, J (1993)	*Political Liberalism*. New York: Columbia University Press. Expanded edition 2005.
Rawls, J (1999)	*The Law of Peoples*. Cambridge: Harvard University Press.

Raz, J (2007)	Human Rights Without Foundations. *University of Oxford Faculty of Law Legal Studies Research Paper Series*. Working Paper No 14/2007. Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=999874. Last accessed November 9. 2018
Raz, J (2009)	Human Rights in the Emerging World Order. *Transnational Legal Theory* Volume 1, 2010 - Issue 1. Available at https://www.tandfonline.com/doi/abs/10.1080/20414005.2010.11424500. Last accessed June 28. 2021
Resnik, DB (2001)	DNA Patents and Scientific Discovery and Innovation: Assessing Benefits and Risks. *Science and Engineering Ethics* 7, 29-62
Resnik, DB (2002)	The Commercialization of Human Stem Cells: Ethical and Policy Issues. *Health Care Analysis* 10.
Resnik, DB (2004)	*Owning the Genome*. A Moral Analysis of DNA Patenting. Albany: State University of New York Press.
Rex, M & David AR (eds.) (2006)	*Rawls's Law of Peoples. A realistic utopia?* Malden: Blackwell Publishing
Risse, M (2012a)	*On Global Justice*. Princeton: Princeton University Press
Risse, M (2012b)	*Global Political Philosophy*. London: Palgrave Macmillan
Ropp, A & Taubman, T (2006)	Bioethics and Patent Law: The Case of Myriad. WIPO Magazine, Issue 4, August. Available at: http://www.wipo.int/wipo_magazine/en/2006/04/article_0003.html. Accessed October 15, 2014.
Rosenberg, A (2004)	On the Priority of Intellectual Property Rights, Especially in Biotechnology. *Politics Philosophy Economics* 3:77.
Rozek, RP (2000)	The Effects of Compulsory Licensing on Innovation and Access to Health Care. *The Journal of World Intellectual Property*, 3: 889–917.
Sagoff, M (2002)	Are Genes Inventions? An Ethical Analysis of Gene Patents. In Burley, J and Harris, J (2002).
Satz, D (2005)	What Do We Owe the Global Poor? *Ethics & International Affairs* Vol. 19, Issue 1, March.
Scheffler, S (2001)	*Boundaries and Allegiances*. Oxford: Oxford University Press.
Schüklenk, U & Aschcroft, RE (2002)	Affordable Access to Essential Medication in Developing Countries: Coflicts Between Ethical and Economic Imperatives. *Journal of Medicine and Philosophy* Vol. 27, No. 2, pp. 179-195.
Sherkow, J (2013)	A closer look at Supreme Court's decision on gene patenting. *Scope*. http://scopeblog.stanford.edu/author/jsherkow/. Accessed March 27. 2014.
Shiel, WC Jr. (undated)	Definition of Generic drug. *MedicineNet*. Available at: https://www.medicinenet.com/script/main/art.asp?articlekey=33073. Accessed June 11, 2021

Shklar, J (1989)	Shklar, Judith N. 1989. The Liberalism of Fear. In Liberalism and the Moral Life, ed. Nancy L. Rosenblum, 21–38. Cambridge, MA: Harvard University Press. Available at https://tuxdoc.com/download/judith-shklarthe-liberalism-of-fear_pdf. Acessed February 4, 2021
Simmons, AJ (1999)	Justification and Legitimacy. *Ethics*, Vol. 109, No. 4 (July)
Singer, P (1972)	Famine, Affluence, and Morality. *Philosophy and Public Affairs*, Vol. 1, No. 3.
Singer, P (1981)	*The Expanding Circle*. New York: Farrar, Straus & Giroux, 2011.
Singer, P (2002)	*One World*. The Ethics of Globalization. New Haven: Yale university Press. 2004 edition.
Singer/Kuper debate (2002)	Peter Singer and Andrew Kuper in a debate over global poverty relief. *Ethics & International Affairs*16, No.1
Slotboom, MM (2003)	The Exhaustion of Intellectual Property Rights, different Approaches in EC and WTO Law. *The Journal of World Intellectual Property*, 6: 421-440.
Smart, JJC & Williams, B (1973)	*Utilitarianism, For and Against*. Cambridge: Cambridge University Press
Sonderholm, J (2010)	Intellectual Property Rights and the TRIPS Agreement. The World Bank Development Research Group: Policy Research Working Paper 5228.
Steinberg, RH (2002)	In the Shadow of Law or Power? Consensus-Based Bargaining and Oputcomes in the GATT/WTO. *International Organization* 56, 2. Available at https://www.cambridge.org/core/journals/international-organization/article/abs/in-the-shadow-of-law-or-power-consensusbased-bargaining-and-outcomes-in-the-gattwto/495056DB0D41A7F53D07CAE4CDE182F7. Accessed June 20, 2021.
Stenvik, A (2006)	*Patentrett.* Oslo: Cappelen Akademisk forlag
Sterckx, S (2005)	Can drug patents be morally justified? *Science and Engineering Ethics* 11, 81-92.
Sterckx, S (2006)	The Moral Justifiability of Patents. *Journal of the European Ethics Network* 13, No. 2. Available at: http://www.ethical-perspectives.be/viewpic.php?LAN=E&TABLE=EP&ID=973. Last acessed October 9, 2019.
Stiglitz, JE (2006)	Scrooge and intellectual property rights. *BMJ* Saturday 23-30 December.
Tasioulas, J (2002)	Internatiional Law and the Limits of Fairness. *European Journal of International Law* Vol. 13 (2002) No. 4. Available at: http://www.ejil.org/archive.php?issue=32. Accessed June 9, 2020.
Tasioulas, J (2007)	The Moral Reality of Human Rights. In Pogge, T (2007)
Tasioulas, J (2010)	*The Legitimacy of International Law*. In Besson, S & Tasioulas, J eds. (2010)

Tasioulas, J (2013)	Human Rights, Legitimacy, and International Law. *The American Journal of Jurisprudence*, Vol. 58, No. 1. Available at https://academic.oup.com/ajj/article/58/1/1/152203?searchresult=1. Last accessed 28. August 2019.
The European Patent Convention Part II, Art. 52 (1)	available here: http://documents.epo.org/projects/babylon/eponet.nsf/0/00E0CD7FD461C0D5C1257C060050C376/$File/EPC_15th_edition_2013.pdf. Accessed January 6, 2014.
The National Archives (UK), online	Statute of Monopolies. Available at: http://www.legislation.gov.uk/aep/Ja1/21/3/contents. Last accessed 12. June 2018.
The United Nations (1948)	The Universal Declaration of Human Rights: http://www.un.org/en/documents/udhr/. Last visited June 20, 2012.
Thiele, F and Ashcroft, RE eds. 2005	*Bioethics in a Small World*. Heidelberg: Springer.
Timmermans, K and Hutadjulu, T (2000), (eds.)	*The TRIPS Agreement and Pharmaceuticals.* ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals. Jakarta, 2-4 May 2000.
Tvedt, MW (2010)	*Norsk genressursrett*. Oslo: Cappelen akademisk forlag.
UN (2000)	E/C.12/2000/4 The right to the highest attainable standard of health. United Natons. Economic and Social Council.
UN (2006a)	A/61/338 The right of everyone to the enjoyment of the highest attainable standard of physical and mental health. United Nations.
UN (2006b)	E/C.12/GC/17 General Comment No. 17 (2005). United Nations. Economic and Social Council.
UNHCHR (2001)	The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights. UN Commission on Human Rights. E/CN.4/Sub.2/2001/13.
UN-OHRLLS (2021)	Profiles of LDCs. Webside of the UN Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Develoing States. Available at: https://www.un.org/ohrlls/content/profiles-ldcs. Accessed May 30, 2021.
US Supreme Court No. 12–398	Association for Molecular Pathology et al. Petitioners v. Myriad Genetics. Inc., et al. June 13, 2013.
USPTO (2013)	Types of Patents. Alexandria, VA: US Patent and Trademark Office.
Velásquez, G & Boulet, P (1997)	Globalization and access to drugs. Geneva: WHO 1999 ed. Available at: http://apps.who.int/medicinedocs/en/d/Jwhozip35e/. Accessed January 15, 2016.
Westerlund, L (2002)	*Biotech Patents. Equivalence and Exclusions under European and U.S. Patent Law*. New York: Kluwer Law International.

WHO (2006)	Public Health. Innovation and Intellectual Property Rights. Report of the commission on intellectual property rights, innovation and public health. World Health Organization
WHO (2013)	Essential medicines and health products. WHO website. Available at: http://www.who.int/medicines/services/essmedicines_def/en/. Accessed August 3, 2015.
WHO on the Doha declaration	The Doha Declaration on the TRIPS Agreement and Public Health. http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html. Accessed September 19, 2014.
Williams, B (1981)	*Moral Luck.* Cambridge: Cambridge University Press, 1993.
Williams, B (1985)	*Ethics and the Limits of Philosophy*. London: Fontant Press. The 1993 impression.
Williams, B (2005)	*In The Beginning Was the Deed*. Princeton: Princeton University Press
Wilson, J (2002)	Patenting Organisms. In Magnus, D; Caplan, A; and McGee, G, eds. (2002).
WTO	Responding to least developed countries' special needs in intellectual property. Date unknown. Available at https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm. Accessed June 6, 2021.
WTO (2003)	Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health. General Council. WT/L/540 and Corr.1. 1 September.
WTO (2006a)	Obligations and exceptions. Fact sheet. Available at: http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm. Last accessed September 27, 2014
WTO (2006b)	Developing countries' transition periods. Available at: https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm. Accessed August 3, 2015.
WTO Doha Declaration (2001)	Declaration on the TRIPS Agreement And Public Health. Available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf. Accessed June 18, 2012.
WTO TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights. Available at: http://www.wto.org/english/docs_e/legal_e/27-trips.pdf. Accessed October 9, 2014.
Young, IM (2006)	Responsibility and Global Justice: a Social Connection Model. *Social Philosophy & Policy* vol. 23, Issue 1, January.
Øfsti, A (2002)	Solidarity, Egoism and Universalism. In Burckhart und Gronke (2002), pp. 272-294.

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