Life Sciences, Intellectual Property Regimes and Global Justice

(excerpt)

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Life Sciences, Intellectual Property Regimes and Global Justice

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1.

General Introduction

Science has brought both great benefits and numerous hazards to humankind. It affects our social relations, comprising those nearby and the many we never get to see. Now, more than ever before, technology is influencing the way we live our daily lives. The shape and direction taken by science and the technologies developed in its wake are however something we can to a great extent control or at least attempt to steer with more or less success. A variety of incentives can align scientific progress with pre-established targets. Yet, increasingly scientific agendas are being shaped by market incentives. In order to make scientific research lucrative intellectual property rights are granted to those who meet certain criteria that are defined by law. Exclusive rights have aroused fierce controversies for innovation in such vital areas as the life sciences. In a world of extreme inequalities this way of "incentivizing" innovation is bound to clash with deeply rooted notions of justice.

Realizing that the direction science takes is something we can steer, creates a moral obligation to align the course of science more closely with the benefit of the larger global population. This demand however already reveals a normative position and as such, maintenance, deviation or intensification thereof becomes something that has to be justified. The liberties of some will clash with the rights of others.

Background of the research project

Whilst states leaders from all around the world gathered in 1994 to sign the Trade-related Aspects of Intellectual Property Rights Agreement, few realized the enormous consequences this will have on everyday life. The binding agreement made minimum intellectual property standards mandatory for all World Trade Organization member states. The agreement has strong power, as it is backed with an arbitration system to penalize non-compliers with trade sanctions. The fact that the protection of intellectual property rights is now effectively a worldwide system calls traditional justifications of intellectual property protection into question and raises new ethical issues, especially with regard to global justice. Another prominent trend in recent decades has been the progressive enlargement of the subject matter that can be brought under intellectual property protection. The domain of patentable subject matter, for example, has been extended to include gene sequences, cultured cell lines and tissues, live organisms, computer programs and also (in the United States at least) new business methods. As intellectual property rights increasingly cover the strategic information-intensive assets of the new knowledge-based bioeconomy (like seeds, food, medicines and diagnostic tools), they become deeply implicated in the essential requirements for the sustenance and flourishing of human life.

The discussion on intellectual property in the life sciences and global justice has primarily concentrated on two issues: accessibility and availability of the resulting objects of innovative efforts.[1] Accessibility means in this context that innovations should be accessible to those who urgently need them. Availability is a term used to discuss the problem of a highly skewed allocation of research efforts, as exemplified in the well-known "10-90 gap" in pharmaceutical research, where no more than 10 per cent of the entire research effort is reportedly devoted to finding cures for diseases that afflict 90 per cent of the world's population. Similar gaps exist in other fields of research.

While it is acknowledged that innovators should be fairly remunerated, allowing access to only those who pay the established prices is controversial for such objects as vital medicines. After the successful eradication of such dreadful diseases as smallpox the scientific community finds itself under huge pressure to repeat earlier achievements by making medicines available for other diseases as well. The suffering of millions of people is not perceived anymore as an inevitable burden on daily life that we are not capable to curb. Similarly technological solutions are sought for countless other social problems, be it food security, pollution control or climate change mitigation and adaptation.[2]

Although those first two allocation problems – accessibility and availability – are far from solved, two further issues that are somewhat neglected in the discussion also deserve attention: the highly unequal distribution of intellectual property rights themselves and the manner those exclusive rights affect the practice of science.

The highly unequal distribution of intellectual property rights between the Global North and the Global South can be identified as the third distributive justice problem raised by intellectual property regimes.[3] Such extreme inequalities have a negative effect on multiple dimensions. First, the divide between technology receivers and technology producers widens, thus creating a situation where financial flows occur mostly one way: from the Global South to the Global North.[4] Second, people who regularly use the system are placed in a position of advantage due to their greater legal expertise on what is patentable and what is not. A number of institutions have used their legal expertise to

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[1] cf. Pogge (2005)
[2] cf. Acharya et al. (2004)
[3] cf. DeCamp (2007)
[4] cf. De Schutter (2011)

acquire patents on foreign inventions that were not or insufficiently protected. This is a phenomenon that in the life sciences is widely known as biopiracy. Especially indigenous innovators are vulnerable to such abusive practices and thereby lose an opportunity to be recognized and rewarded for their creativity. Third, managing a vast patent portfolio gives companies some control over follow-up innovations. Newcomers are often in a position of disadvantage, as they may have to spend considerable funds in acquiring licenses. This is generally a problem for companies and research institutions with smaller budgets.[5] Patents may even discourage or stifle follow-on innovation, contrary to their official rationale.

Intellectual property has had also a strong effect on the practice of science. First, it has profoundly strengthened the belief that science can and should be self-financeable. This has a negative effect on all types of scientific work that cannot be protected by intellectual property, most prominently: rediscovery, much of indigenous innovation, fundamental research and incremental innovation. Second, favouring one type of scientific work over other forms implies that one has a greater societal value than the other. In many cases this has nothing to do with social utility – many individuals and communities who provide vital services to society are widely misrecognized for their work. Additionally, one has to keep in mind that most people do not have the resources to apply for intellectual property protection. Third, intellectual property demands that innovation offers products that are homogeneous, something that disfavours indigenous innovation and is a disincentive for the maintenance of agrobiodiversity.[6] Innovators who primarily produce a heterogeneous output are less attractive research partners to collaborate with.

Research questions

The vast problems and opportunities raised by the intellectual property regimes in the life sciences give rise to a number of questions. However, a major issue that is inadequately addressed in the discussion is the necessity to make research and technology development a more inclusive endeavour. Since this matter is worthy of more scholarly attention I have decided to make it central by building the following six main research questions around this topic. First, I deemed it necessary to offer a brief exposition of the main ethical arguments that justify access to innovation and demand that technological solutions that address the problems of the poor become available. An over-emphasis on access and availability made me however ponder a world where scientific participation possibilities are deliberatively left aside. This led to the formulation of the

[5] cf. Eppinger and Vladova (2013)

[6] On the problem of industrial agricultural innovation and genetic erosion, see De Schutter (2011)

second question. In the third question I articulate the main problems brought up by highly unequal formal research capacities distributions between the Global North and the Global South with a corresponding pattern in the allocation of intellectual property rights. To counter arguments coming from neoliberal quarters I found it necessary to criticize conventional methods to judge the quality and quantity of research outputs. Hence the fourth question. The fifth point I want to bring into discussion is a specific problem raised by the way intellectual property affects scientific practice: the fate of traditional knowledge. Much of traditional knowledge becomes lost by the lack of incentives to continue its development. The last question raised wraps up the thesis by evaluating amendment proposals.
Verbatim, the guiding research questions are:

1. *What are the main ethical theories that justify fairer access to innovation?* This question addresses the different theories used to justify access and availability of innovations for those in need.
2. *Should one consider scientific participation possibilities as a luxury to be left aside until subsistence rights for the great majority of people are secured?* Access to innovation and sufficient research attention (availability of solutions) can be justified under subsistence rights. Efforts to make science more inclusive are often left aside with the argument that subsistence rights take precedence.
3. *Should extreme inequalities in research capacities between the Global South and the Global North be fought even when the objects of innovation are made accessible worldwide?* Since inequalities in research capacities will unavoidably affect the allocation of exclusive rights, this question addresses the third distributive justice problem: the negative impact of highly unequal distribution of intellectual property rights.
4. *What are the benefits to be expected from research and innovation and how do we judge that the international system of science and technology is working properly?* Is the number of patents an appropriate metric for measuring innovative output? Different inventions that have the same function often vary strongly in terms of positive and negative side effects. How do we make sure that innovations with the most valuable externalities are made available to the poor?
5. *How can we secure the moral and material interests of indigenous innovators using the current intellectual property regimes?* Much of indigenous creative efforts are not patentable. Incentivizing indigenous innovation as a parallel system of innovation would make the current science and innovation practice (the earlier mentioned fourth issue) much more inclusive by facilitating the participation of those who currently are underrepresented.

6. *Is there, among the various proposals that have been brought forward to enhance the global justice of the international intellectual property and research system, any amendment proposal that should be clearly favoured?* An evaluation is needed to identify which amendment proposal best addresses the issues of access to and availability of objects of innovation, reduces the negative effects of highly unequal distribution of intellectual property rights and is conducive to good science and innovation practices.

Having introduced the questions, I will move on by explaining the research methodology used in this thesis.

Research methodology

Insights to answer the research questions were gained by an extensive study of literature. In the selection of material I made sure that works from all relevant disciplines were included. Most of the analysed literature comes from philosophy, political science, law, economics and anthropology. To a lesser extent literature from disciplines such as life sciences, development studies, business and innovation management, history of science and technology, public health and engineering was also examined.

While this is a philosophical thesis, I also used methods that are not commonly employed in the discipline. The thesis gained in strength by including the methods of empirical philosophy, a practice that has become fairly widespread in the Netherlands: conversations with stakeholders and critical analysis of empirical data. One of the highlights here was the organization of a networking conference in Brussels September 2011.[7] Michiel Korthals and I organized the conference with substantial support from the Centre for Society and the Life Sciences. We brought together specialists from a diverse range of disciplines working in academia, public sector, industry and NGOs. This exceptional environment fostered a high level of discussions dealing with global justice concerns raised by the intellectual property regimes in the life sciences. There was ample room to debate ideas and concerns and this opportunity was well used. I gained immensely from discussions with the participants, some of which commented on later developed papers. Thomas Pogge's work also was exemplary in showing how to harness a critical analysis of empirical data for the purpose of ethical assessment.

My involvement in several research environments gave substantial material input to the subject of investigation. Based at Wageningen University, I

[7] Korthals and Timmermann (2012) [here reproduced as Chapter 4]

participated in the interdisciplinary "Commons Seminar" and in a series of guest lectures, meetings and seminars. The university's focus on agriculture and international development gave me countless opportunities to gain new insights and rectify false assumptions. Being also a member of interuniversity research group, the Centre for Society and the Life Sciences allowed me to discuss topics with people working primarily on health-related issues. A two-month research stay at the Brocher Foundation gave me the opportunity to strengthen the knowledge gained through extensive interdisciplinary discussions with researchers from different parts of the world.

Overview of the thesis

After this general introduction, the *second chapter* commences by setting out the major arguments for making objects of innovation accessible and directing research attention to make technological solutions for the global poor available. The research question here answered is: *What are the main ethical theories that justify fairer access to innovation?* After that I state what makes life sciences different to other fields of knowledge.

The *third chapter* is the main theoretical chapter. A philosophical interpretation of a segment of article 27 of the Universal Declaration of Human Rights serves as the centrepiece of this chapter that introduces the concept of global justice used throughout the thesis. The aim of this interpretative analysis is to give an extensive answer to the second research question: *Should one consider scientific participation possibilities as a luxury to be left aside until subsistence rights for the great majority of people are secured?* Here the consequences of prioritizing any of the two elements of this article, i.e. the possibility to share in scientific advancement or to benefit from access to and availability of objects of innovation, are analysed in regard to global justice. This chapter also addresses partly the third research question: *Should extreme inequalities in research capacities between the Global South and the Global North be fought even when the objects of innovation are made accessible worldwide?* Huge inequalities in research capacities are condemned with the introduction of the concept of dependency: the situation where one party is always the one "saving" the other through technological aid.

In the *fourth chapter* we move from discussing the theoretical framework to offering a report representing the current state of the debate. This chapter reports the outcomes of the "Network Conference on Ethical and Social Aspects of Intellectual Property Rights – Agrifood and Health" held in Brussels, September 2011 and concludes by offering a philosophical reflection on the debate. This chapter turns around two questions: what are the main problems of the current intellectual property regimes? And, what can society do to mend them? It also provides some accounts on the negative effects raised by the high concentration of intellectual property rights among a few major multinational companies.

After the theoretical framework and the current state of the debate have been presented, we continue with the analysis of three proposals that seek to alleviate the negative effects of current intellectual property regimes. Those proposals are the Access to Knowledge movement, the Health Impact Fund and open innovation models. In order to offer a critical perspective, each proposal is discussed in relation to a specific problem field: access to medicines, the promotion of climate-friendly technologies and the issue of traditional knowledge.

Chapter 5. The access to knowledge movement is discussed by using the most prominent conflicting issue with the patent system: the need to make medicines accessible for the poor and stimulate research on neglected diseases. The chapter offers a historical overview of the debate since the early 1980s. The landmarks of the debate are narrated by addressing the question: What initiatives have been taken in making medicines available and accessible during the last thirty years? The chapter also evaluates the strengths and weaknesses of these various initiatives.

Chapter 6. Focussing on the latest version of the Health Impact Fund proposal, we criticise the hard prioritarian position defended by Thomas Pogge and see it as a major hurdle for ensuring scientific participation possibilities for the global poor. As climate-friendly technologies do not necessarily have to be rooted in industrial innovation to meet their target, excluding the stimulation of grassroots innovation becomes even harder to justify. Grassroots innovators are developing many methods that can be useful to reduce the carbon footprint in agriculture – stimulating them would not only do good to the planet but also support a more inclusive innovation system. This chapter responds to the third and fourth research question: *Should extreme inequalities in research capacities between the Global South and the Global North be fought even when the objects of innovation are made accessible worldwide?* And: *What are the benefits to be expected from research and innovation and how do we judge that the international system of science and technology is working properly?* A special emphasis on the latter question is given by criticizing the use of a unique metric (quality-adjusted life years) to measure the positive impact of a whole group of innovations. Widening the circle of innovators is suggested as a strategy to make sure that inventions are brought up who have valuable externalities. I also critically discuss the widely used metric of the number of patents as a purportedly reliable measure of innovative output.

Chapter 7. Open innovation is not the ideal solution to secure the material interests of traditional knowledge holders. Using a dynamic concept of traditional knowledge, that encompasses all the innovation done by small-scale farmers and indigenous communities, I argue that worse than seeing one's profits opportunities forgo is to see one's innovative efforts go to waste. Open innovation models allow users to secure their moral interests as recognized by law, i.e. the right to attribution of authorship and the possibility of having control over the integrity of one's work. In addition to that, I argue that another fundamental moral interest that is not protected by law can be secured with the use of open innovation models: that one's invention is fairly evaluated in terms of its capacity to promote societal welfare. Those are the central arguments that provide an answer to the fifth research question: *How can we secure the moral and material interests of indigenous innovators using the current intellectual property regimes?*

The final part of the thesis re-examines the insights gained earlier and tries to see how far apart they are from positions defended by groups involved in the intellectual property and global justice advocacy.

The aim of the *eighth chapter* is to wrap up the thesis by analysing the question *Is there, among the various proposals that have been brought forward to enhance the global justice of the international intellectual property and research system, any amendment proposal that should be clearly favoured?* Here an assessment of six major proposals to alleviate the negative effects of the current intellectual property regimes is made. Those include the three analysed proposals: the Health Impact Fund, the Access to Knowledge movement and open innovation models. Three additional proposals were added to make this study more extensive: prize systems (including advanced market commitments), South-South partnerships and compulsory licenses.

Finally, *Chapter 9* will offer some concluding remarks. Here I will briefly discuss the answers to the research questions stated at the beginning of the thesis.

Appendix.

Summary

The human right to participate in the advancement of science is frequently overlooked in the intellectual property and global justice discourse. This thesis is a contribution to efforts that aim at filling this gap in the overall discussion on proper incentives for the life sciences.

Three distributive justice problems are raised by our intellectual property regimes (cf. DeCamp 2007). First, high prices make objects of innovation inaccessible, even in those cases where the object is urgently needed (i.e. the accessibility problem). Second, research efforts concentrate primarily in fulfilling the wishes of richer customers. This has lead to the 10/90 gap in pharmaceutical research, the situation where 90% of the resources are destined to solve the problems and desires of 10% of the world population. The consequence thereof is that research and development addressed to make available solutions for the needy is insufficient (i.e. the availability problem). Third, the distribution of intellectual property rights themselves is highly imbalanced between the Global South and the Global North. This brings with itself a huge transfer of resources from the developing to the developed world and it gives intellectual property owners a considerable amount of control over follow-up innovation. The first two problems have attracted a considerable amount of scholarly work and policy studies. Therefore I have concentrated my attention to the third problem and identified a fourth issue that is in need of more careful analysis: the influence intellectual property has on scientific conduct and scientific participation possibilities.

The thesis starts with two introductory chapters, the second briefly exposes the different arguments that justify pro-poor innovation: utilitarianism, compensatory duties, the basic rights doctrine, the human rights and capabilities discourse, recognition theories, cooperative justice arguments, the need to (re)claim the commons and uphold shared scientific values. In the same manner arguments for restricting access are discussed before listing some of the issues that make life sciences special in relation to intellectual property.

The third chapter defends the ethical standpoint sustained throughout the thesis. Using the capabilities approach it is argued that being able to actively care for others should not only apply to efforts made through physical work, but also that one should be in a position to help others by using one's intellectual capacities. With the help of recognition theories the relation of technological dependency between the Global South and the Global North is criticized. People should be able to mutually influence each other and be able to assist one another. Those two main ideas are used to justify a right to partake in the advancement of science as a peer.

After having set out the moral framework used in the thesis, the state of the debate is presented through a report on a stakeholder conference held in Brussels in September 2011 on the ethical and social aspects of intellectual property in the life sciences. This report constitutes the fourth chapter.

A series of proposals and alternatives have been put forward to alleviate the negative effects of intellectual property regimes. In this thesis three of these are analysed in terms of their strengths and weaknesses: the Access to Knowledge movement, the Health Impact Fund and open innovation models. In order to gain a clearer insight, these alternatives are evaluated by contrasting them to a particular problem. First, the Access to Knowledge movement is analysed in terms of its capacity to improve global health. Then, it is examined how the idea behind the Health Impact Fund could be used to promote the development of climate-friendly technologies. Lastly, open innovation models are tested in regard to their potential to conserve and incentivize innovation in indigenous communities.

Chapter five analyses the access to medicines movement during the last twenty years, describing how the movement changed from being one about corporate social responsibility towards being a matter of justice. The situation where the Global North is developing nearly all the essential pharmaceuticals has some drawbacks for the poor. Medicines are mainly developed to be effective against pathogens prevalent in the Global North and little attention is paid that medicines are still effective in resource poor settings. In addition, market incentives make the development of “me-too drugs” lucrative and generally encourage researchers to enclose their work which often leads to unnecessary repetition of research efforts. The chapter ends with a spark of optimism by presenting some new initiatives that work with “open laboratories”, thus making science a more inclusive endeavour.

Chapter six critically examines the potentials and shortfalls of the Health Impact Fund. The criticism concentrates around the failure to tackle the strong research divide between the Global North and the Global South. The chapter is sceptical about the opportunities to overcome this divide even after considering modifications to the original proposal. The application of a modified version of the Health Impact Fund for propagating climate-friendly technologies is even more problematic than its original use in the context of medicines. Technologies that help mitigate climate change may have considerable positive side-effects for its users. Incentivizing the fuel efficiency for luxury boats or the improvement of stoves that also reduce the exposure to fumes in crowded households are very different things – having chosen one strategy instead of the other is something that one has to be able to morally defend. The example of biochar is discussed in the chapter. In order to be politically feasible, the drafters of the Health Impact Fund make too broad concessions to major players of the political arena.

The next chapter discusses the third movement. Open innovation models may not be the best alternative to secure the material needs of indigenous innovators. However, they have great potential in protecting the moral interests of these creative minds. Here the idea of moral interest is understood in a broader sense than the one specified by law. Not only do innovators have an interest in attribution of authorship and retaining a control of the integrity of their work, but also in a fair evaluation of their invention. Being unjustly forgotten contradicts this interest. Platforms that make indigenous innovation visible – especially among people living in similar conditions in other parts of the world – have a great potential in addressing this latter interest.

Chapter eight offers a critical assessment of how six prominent proposals relate to the International Bill of Rights. After providing an extensive analysis of how intellectual property affects rights and freedoms protected by human rights law, the three above mentioned alternatives are examined in addition to the wide use of compulsory licences, prize funds and promoting South-South collaborations. During this assessment human rights are not understood in the purely juridical sense, a lay assessment is offered instead. The purpose being that with such type of understanding the origin of much confusion can be understood. The result of this assessment is that the heterogeneity and diversity of needs we find in the world requires a much more complex solution. Some affected parties will often interpret concessions catalogued as minor by one section of the world as being major. A single major amendment will be far from solving this complex problem in its totality.

Throughout the thesis I have been keen to state the need of making science and technology development a more inclusive endeavour. Here I share the same spirit with many other political philosophers in persistently claiming that participation is crucial for a well-functioning society. In the realm of science and technology development participation can only be meaningful if systematic discrimination is absent and sufficient possibilities to learn the needed skills are present.

10.

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