



## Reflections on the International Networking Conference “Ethical and Social Aspects of Intellectual Property Rights – Agrifood and Health” Brussels, September 2011

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### *Abstract*

*Public goods, as well as commercial commodities, are affected by exclusive arrangements secured by intellectual property (IP) rights. These rights serve as an incentive to invest human and material capital in research and development. Particularly in the life sciences, IP rights regulate objects such as food and medicines that are key to securing human rights, especially the right to adequate food and the right to health. Consequently, IP serves private (economic) and public interests. Part of this charge claims that the current IP regime is privatizing the very building blocks of research and development – that used to be part of the commons. The public domain, in contrast to the private domain, may be the locus of much more diverse forms of creativity that at the same time ensures a wider plurality of productive traditions. An IP regime must support a sense of public morality because it is dependent upon civil support. This inevitably prompts questions of what are “good” exclusive rights and what are “bad” exclusive rights, and how shall such IP rights be developed. We argue that the democratization of the current IP regimes is an important first step to respond to these issues.*

*Keywords: intellectual property rights, global justice, open innovation, stakeholder conference*

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### **Introduction**

Public goods, as well as commercial commodities, are affected by exclusive rights secured by intellectual property (IP) rights. These rights serve as an incentive to invest human and material capital in research and development that is destined for a host of resources and goods. Particularly in the life sciences, IP rights regulate objects such as food and medicines that are key to securing human rights, such as access to adequate food and the right to health (1, 25.1). Consequently, IP serves private and public interests. Private interests consist of being able to enjoy the fruits of one’s labor, and public interests entail the provision of current and future public goods. Extensive research and development (R&D) enterprises are made rentable as

rights holders can market their products exclusively, securing the existence of new commodities and due to the temporal limits of IP, also the provision of future goods, as resources become part of the public domain.

As costs of developing a merchantable product in the life sciences have risen (for a recent study in the area of pharmaceutical see Munos, 2009 (1)), a more stringent market orientation has become more mandatory. Often, goods that were formerly free, must now be paid for by end-users due to high product-development expenses. With worldwide income inequalities it is becoming evident that if economically under – or undeveloped groups and nations are not allowed to make use of the technological innovations of developed countries, they may end up

even more impoverished and increasingly vulnerable both economically and geo-politically. Furthermore, objects predominantly needed in resource-scarce markets often are not developed, given that R&D expenses incurred (by either developed or underdeveloped nations) cannot be adequately recovered (this phenomenon is epitomized with the so-called “10/90 gap” (3,4)).

In order to discuss the implications of this status quo and the feasibility of alternatives, researchers and policymakers were convened at a conference in Brussels at the end of September, 2011.

### **The grounding idea of the conference**

How can appropriate IP regimes alleviate the huge welfare burden incurred by developing countries that engage progressive biotechnology? In other words, how can IP rights contribute to social justice? These questions prompted two Dutch research institutions – the Centre for Society and the Life Sciences and the Applied Philosophy Group (the position the group takes to this general problem is exemplified in Korthals, Belt and Korthals and Timmermann and van den Belt (5-7)) at Wageningen University – to engage philosophers, sociologists, experts in IP law, patent examiners, scholars and practitioners from biotechnology, alternative business modelling, development aid, innovation studies, political science, as well as state representatives and EU officials, to discuss the ethical and social issues generated by current IP protocols and paradigms.

### **Scope of the problem**

Research and development in the life sciences lead to huge business opportunities for knowledge economies, and also to possibilities for securing fundamental human rights, at national and international levels. The ever increasing globalization of trade, epitomized by the worldwide implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), negotiated 1994, has been important to such global biotechnology commerce and the balance of IP (8). Without doubt, scientific innovation has greatly improved the overall quality of life in the developed world, as well as a longer life expectancy, both due to a significant extent to achievements in biomedicine and in agrobiotechnology and nutrition. Indeed, science and technology could play a vital role in alleviating the predicament of developing and underdeveloped nations of the world, in particular by reducing the 18 million poverty related deaths. An extensive critique

on negative influence of trade regimes on world poverty is offered by Pogge (9). But, given that much of science and technology is provided as proprietary commercial enterprise – and its allocation and sharing regulated by IP governance – we must ask if and how such IP statutes could and/or should be construed so as to better meet the social obligations of science.

### **Opportunities and reforms**

No single solution will address the justice issues raised by the existence of intellectual property regimes – this was recognized and widely appreciated by the participants of the conference. A more scrutinous view of current IP schemes led to posing of three alternatives to existing IP regimes; these are 1) “open innovation”, 2) the “access to knowledge movement” and 3) the concept of a “health impact fund”. The subjects were discussed in keynote lectures and dedicated workshops, and of particular note was an approach proposed for Brazil, a new emerging economy.

#### *The current IPR regime*

Nikolaus Thumm, Chief Economist of the European Patent Office, provided an overview of the justification of current IP regimes: The function of a patent is to address a particular market failure. Research and development costs, especially in biotechnology, are extremely high yet it is relatively affordable to reproduce a product once it has been developed. This reflects a lack of incentive to invest in research and development if/when there is little possibility to recoup the expenses involved. This is where the patents come into play. An inventor has, under a given set of constraints, the option to apply for temporary exclusive rights if he is willing to disclose relevant information to assemble the object of innovation. In this way, civil society limits what is presently in the public domain in order to secure the potential existence of future public goods. The nature of a patent is therefore instrumental: it is a tool to ensure that innovators who produce objects with reasonable research and development costs, and that find a sufficient market, will recover expenses and gain sufficient resources to render such investment worthwhile and thereby continue to make those goods. However, there are limits to which inventions can qualify for exclusive rights. New market opportunities, or the enlargement of the knowledge pool, are not goals to be pursued at all costs; the perception that a patent might conflict the *ordre public* has roots anchored in patent law. (An early exposition of Thumm’s early perspective on the ethical implications of patenting is offered in Ibarreta and Thumm, 2002 (10)).

The notion that patenting is good, more patenting is even better lacks empirical evidence. As too little protection of new inventions can limit the future existence of some goods, too much protection can also deter some innovators from developing products in adjacent areas.

As well, patent offices offer civil society the possibility to file for appeals. This is an opportunity to instil checks and balances to confront possible negative effects upon public welfare that were not evident at the time of patent issue. The quality of patents in this sense therefore depends on the active engagement of civil society.

### *Open innovation*

Richard Jefferson, Executive Director of Cambia, an autonomous not-for-profit organisation connected with Queensland University of Technology, Brisbane Australia, provided an overview of his efforts in making biotechnology research and development more accessible. Concepts such as “open access”, “open source” and “open innovation” address not only different levels of accessibility, but represent a sense of attitude and commitment to the public (11). “Open innovation” does not mean free-of-cost, but free in the sense of being transparent and unrestricted. The complexity of IP regimes often poses a threat to the openness of science by adding uncertainty, and increasing risks of wrong or frankly socially disruptive investments. Jefferson’s soon to be released “The Lens”, is a public search tool that takes into account patent literature as well as incorporates more public databases and open access journal articles to both inform how R&D are done, who is doing R&D, and where R&D are being done (12). The question of whether openness leads to fairer distribution is something that remains unresolved until further research.

The workgroup discussions started with a short critical statement by Pieter Lemmens emphasising the role of commons for the future production of knowledge and their potential to rebalance uneven power relations. (P. Lemmens offers a wider introduction to his viewpoint (13)).

### *Access to knowledge*

According to Carlos M. Correa of the University of Buenos Aires, there are two streams of the “access to knowledge” movement, one that aims to build an information society where knowledge is openly available without restriction, and a second that seeks a general expansion of the public domain. Correa posed the question of if and how can these

ideas could be reconciled with initiatives for protecting traditional knowledge through exclusive rights? Many points of his talk can be found in Correa, 2010 (14). It became clear that an attempt to protect traditional knowledge by exclusive rights was at odds with those philosophical approaches that are based on sharing, rather appropriating, knowledge. Still, a consistent issue in whether those conventions are of actual interest to the individual indigenous communities, particularly the predominance of Western conceptions of intangible property with customary laws, and the extent to which various international statutes might consider the nature of traditional knowledge. (This distinction is exemplified in Robinson, 2008 (15)).

Henk van den Belt re-introduced the topic in the especially assigned workshop with a short statement that started with an historical overview of the movement and ended emphasising the dual role of “access”: consumption and participation.

### *The idea of an impact fund*

Linking profits to exerting positive impact on urgent problems is of particular interest for the development of targeted products not covered sufficiently by market incentives (such as medicines for neglected diseases or improvements in agrosociences especially targeted for the needs of the poor). An elaborate proposal for this is the Health Impact Fund (16). Doris Schroeder, of the University of Central Lancashire (UK) and University of Melbourne (Australia), noted that the idea behind the fund is to offer a reward to companies that aim at maximizing quality-adjusted life years (QALY) of people suffering a particular disease or disorder. While keeping IP rights, the company must be committed to sell medicines at cost-price in order to be rewarded financially proportional to the product impact in increasing QALY.

Cristian Timmermann raised the problems involved in any proposal that leaves the current global distribution of IP rights intact. (A revised version of his statement can be found in Timmermann (in press) (17)).

Of noted interest was how far the impact fund construct might be implemented in other areas, such as agriculture and climate change mitigation and adaptation. The main criticisms of the impact fund idea question the prerequisite of patents for fund rewards and the maintenance of current power relations. (Meanwhile Thomas Pogge has informed us that the revised version of the Health Impact Fund proposal has loosened up this criterion (16)).

Emerging countries: Brazil as a case study. A delegate of the Brazilian Mission to the European Union, Eduardo Ferreira provided a detailed overview on the country's new law on the protection of cultivars. Although the law was introduced in order to "1) facilitate the exchange of genetic material and the genetic enrichment of Brazilian agriculture 2) allow imports of commercial seeds and 3) assure that Brazil can export this kind of material", it became evident that the country was also aiming at a stronger enforcement of exclusive rights granted to domestic and foreign seed producers and providing a safe harbour for foreign investment while improving the grounds for future scientific collaboration (18).

### **Problems**

Different approaches underline the difficulties of generating revised or new IP regimes that more saliently reduce extreme poverty, powerlessness and vulnerability of individuals, communities and nations.

#### *Human rights and IP rights*

The right to adequate food and the right to health as per the Universal Declaration of Human Rights (1, 25.1) are not the only two rights that are potentially negatively affected by liberties granted by the use of exclusive rights secured by IP regimes (1, 25.1). There is a strong plea for a democratization of science, a demand for openness and inclusion, both in active participation and decision-making, that in the human rights discourse are encompassed in the right to share in the advancement of science (1, 27.1). There is a widespread indignation about the ways IP rights restrict freedom to operate, and constrict high-level science to be a luxury reserved for developed nations.

IP regimes could play a much more favorable role in improving global human welfare and in securing human rights (TRIPS, art. 6). At present, there is insufficient incentive to both provide innovations that would alleviate problems that predominantly affect the poor, and to make those innovations widely accessible.

European states have a long-standing tradition in securing their citizens the minimum requirements for adequate living standards. The successful eradication of extreme poverty in Western Europe has led to viewing poverty as a definitive harm to human welfare that is unacceptable, and also preventable.

#### *Human rights commitments*

Antony Taubman, Director of the Intellectual Property Division, World Trade Organization (WTO), addressed the role of exclusive rights when acknowledging intellectual property, namely that society grants a temporary exclusive right for bringing into existence a future public good. Taubman noted that by revising theory and international conventions there is no human right to intellectual property, rather only the right to benefit from the material interests of scientific production (1).

Some essential liberties are also affected by current IP regimes. We must ask ourselves if and to what level "individualist atomistic innovation" will be favored at the cost of "cumulative, collective innovation of indigenous communities"? Might this constitute a violation of rights, and if so, to which rights? Or, does this simply amount to a lamentable loss of diversity in scientific practices that could be deemed acceptable on utilitarian terms? This inevitably prompts the question of what human goods may be sacrificed for efficiency in technological advancement?

#### *IP rights and the needs of small and medium enterprises and industry*

The current IP system has unintended consequences that render increasingly larger-scale players domination in the markets. This has a foreseeable adverse effect on the rate and quality of inventions, and the survival of small and medium size enterprises. In particular, newcomers from the developing world face numerous difficulties.

The Paris convention of 1883 largely set the "rules of the game" for patenting. The late 19th century was an era where differences between bigger and smaller companies were less pronounced, and the implications of biotechnology were yet unforeseeable. We must ask how those rules might be out-dated, and what negative costs for public welfare and business opportunities are bound to such anachronistic legislation. We may also question if something similar accounts for Union internationale pour la Protection des Obtentions Végétales (UPOV, the first international agreement on plant variety protection, 1961), given that differences in the membership of more and less developed countries are today more varied than in the year that treaty was drafted. This is the conclusion of Orlando de Ponti, former President of the International Seed Federation. The industrial sector has the capacity to provide much of the innovation needed to provide suf-

efficient food for a growing world population, but to do so it needs better access to a broad variety of biotechnology. Specific exemptions in patent laws must be clearly defined in order to not jeopardize future inventions. This clarity could also equalize the highly uneven competition between bigger and smaller companies, and result in enhanced innovative collaboration and cooperation.

#### *Biodiversity and traditional knowledge*

Yet unresolved are issues such as how should indigenous knowledge be treated, in what way should biodiversity be maintained, and how should biosafety dossiers be regulated? It is important to assess to what extent those issues should be addressed by IP regimes, or to what extent IP regimes have created situations that evoke those issues.

Biodiversity is often seen as something vital, but there are insufficient empirical studies to provide clear evidence in support of such a stance. Success of promoting the conservation (or even enhancement) of biodiversity depends upon the outcomes of such studies. Similarly, claims of the importance of traditional knowledge as a cultural heritage of mankind might not be enough. Rather, what is required is a demonstration of those ways that indigenous scientific practices and knowledge have been or real and meaningful value and innovation. But, can such indigenous practices simply be up-taken into a global R&D effort? It will be evermore crucial to work on gaining indigenous communities as partners for long-term cooperation and not merely as entities to exploit or develop long term dependencies after one-time transactions. Current practices do little to address past errors and to actively gain those communities as cooperation partners – a point well-noted by Bram De Jonge. (For his position on Benefit-Sharing see De Jonge, 2011 (19)).

#### *Governance*

Evidence is urgently needed to define whether current IP systems are efficient, promote innovation and do not unnecessarily limit access or set unacceptable constraints for fostering innovations destined for poorer markets. Ingrid Schneider (20) has focused on the need for evidence on the possible negative effects of current IP regimes, such as the extreme expense in its demand of researchers' time and resources, and the wide contingent of IP experts that must be financed by reallocating funds originally destined for research, development, and product application. Also, the "one-size-fits-all" approach propagated with

the TRIPS agreement, is less suitable for innovations in the life sciences than for research and development in the electronic, chemical or mechanical industry. (Although those areas are also not immune to criticism, see Bessen and Meurer, 2008, Chap. 3 (21)). We cannot just balance business opportunities lost in one area in favor of another; to be sure, a detailed assessment of the unused potential to secure human rights is required. Anything that counts as a setback from the realization of human rights must be approved by those who are subjects of those rights, i.e., the human beings involved as shareholders in such decisions about and applications of science and technology research and development (22).

Worries about the actual negative impact of data exclusivity in biosafety dossiers are also a factor in the discussion. Here not only issues like ever-greening of exclusive rights come in, but also the repetition of clinical trials using human subjects in which medicines are tested, not to show their safety, as has been already done, but to have additional data that are not protected in order to secure sales permissions as a generic manufacturer, and repetition of tests using animal subjects which are becoming harder to justify.

A clearer division of labor and confinement of tasks between the different stakeholders is necessary. Competition law, careful examination of patents, filing appeals to seemingly unjust patents, making use of 'flexibilities' as formulated in the TRIPS agreement, are all tools to counteract the negative effects of IP regimes, which must be used by governmental and civil society experts to counteract the misuse of power relations and balances. For example, in the European Union (EU), a better cooperation between EU and the European Patent Organisation (EPOrg) is desirable to compensate for fragmentation due to national patent offices, and can be achieved by a relatively high degree of harmonization by patent granting via EPOrg.

#### *Participation: Top-down vs. horizontal*

Many important stakeholders feel that their interests and voice are not taken into sufficient consideration in the negotiation and drafting of IP laws. Justice demands a fairer distribution of objects of innovation, and an availability of biotechnological solutions for the problems that impact the poorest people of the world's countries. Obviously, however, being able to participate at all levels of the innovation process, and having a say in research agendas

remains something completely out of reach for most of the world's population.

Various civil society efforts have been made to foster a wider participation in innovation efforts. As G. Pakki Reddy, Executive Director Agri Biotech Foundation, Hyderabad (India), has noted, a solid example is the Indian Honey Bee Network and its collaborating institutions. Those networks afford a more just distribution of resources, and also stimulate innovation through recognition of the work of small-scale innovators, granting them an opportunity to have wider publicity of their inventions. However, it remains to be seen how far the Indian example of innovation and networking know-how can be transferred to other nations and societies.

### **Future policy items**

It has become clear that patents exert broader effect, beyond simply the producers of patented technologies and the buyers of end-products. The existence of an object that is made artificially scarce by exclusive rights, which at the same time could alleviate problems of human welfare, is controversial. Similarly, having scientific infrastructure in place to provide technical solutions to many of the problems that afflict developing and underdeveloped nations, while not making full use of it speaks strongly to the need for a wider and more inclusive discourse to address the problems instantiated by current IP regimes.

In the main, we hold that the main questions for this discussion are:

- a. What could be a socially desirable balance between the types of IP exclusivities innovative enterprises require, and the inclusive public goods protection such innovations are said to serve? How is this proper balance to be achieved?
- b. What old and new ideas (such as Open Innovation and the Access to Knowledge movement) about exclusivities and their optimal integration with the public good and fair invention are interesting and worthwhile for debate, experimentation, and ultimate development and use? What studies should be pursued?
- c. In what way(s) can a property rights system become inclusive, not only attending to patent holders, but

also to those stakeholders that are affected by the patent system?

- d. How can inventions be stimulated that are specifically designed to alleviate urgent problems and to reach global targets, such as the millennium development goals and caps in gas emissions that affect climate change?
- e. Why are some flexibilities of the TRIPS agreement regarding human welfare (8, a6) not used in national IP regimes, and why does the full potential of TRIPS seem to be underused? What steps can be taken to ensure better use of those flexibilities?
- f. How can ethical principles and values of a nation or a group of nations be protected and what does this mean with respect to a broad interpretation of the ordre public and public policy exemptions to patentability (8, a27.2 and a27.3)?

This discourse should be inclusive: involving all parties, not only patent holders, industrial countries and their governmental officials. Moreover, it is important to focus on general challenges, such as the place of IP rights in a pluralist world, rather than on specific situations and environments. We should analyse the greater picture and make an overall judgement.

### **Future research issues**

Five major research issues can make the recommended public discourse and ultimately science and technology IP rights more relevant to current and future conditions in a global economy:

First, taking into account the lack of transparency, and to make the patent system more accessible to non-patent holders, mechanisms should be developed to make public, comprehensible and not misleading all information about patent files. This information should be made publicly available without restricted access.

Second, research is necessary to answer the question how, given the democratization of information, the current IP system can be made more democratic, (e.g., by including the voices of non-patent holders).

Third, research is required into alternatives, complements and other, new ideas to achieve a balanced relation between exclusive entitlements and inclusive ends-in-view that comprise public goods (such as open innovation, Access to Knowledge (A2K), common pools, alternatives and complements to the current IP regimes). Equity and inclusivity should be leading principles, both in intention and outcome (impact).

Fourth, further inquiry is required to examine other, freedom restricting regulations or practices, such as steward regulations concerning biosafety dossiers of patented inventions, which allow owners to keep those dossiers restricted from public access without time limits.

Fifth, research is needed to assess the social and technological impacts of current IP systems and of alternatives, taking into account inter alia questions of stakeholder involvement and how it might prevent power relationships determine unfair use of property systems.

### **Concluding ethical reflection**

Intellectual property rights are a means to an end – and the current regime is only one of many conceivable systems of incentives. The current regime can be praised for bringing out many inventions that have benefited a wide public, but the IP system also faces a serious charge of sustaining a specific culture of developing products and doing scientific work that may be directly at odds with the needs and vulnerabilities of a significant number of people. If this charge is indeed related to the current IP regime, we have to ask ourselves what responsibilities and duties arise to mitigate and remedy this effect. Part of this charge claims that the current IP regime is privatizing the very building blocks of further research and development – components that were once part of the commons. The public domain, in contrast to the private domain, may in fact be a locus of much more diverse forms of creativity that also ensure a plurality of ideas, traditions, and translations.

Antony Taubman stated during the conference that “IP law or treaty may be greater than the sum of its parts”. We can see this in *ordre public* clauses in patent law that are conceptualized to avoid the creation of incentives that create objects that are socially undesirable, and/or are perceived to be offensive by the general public. During this last decade, the world is coping with disastrous effects of financial hubris on public welfare, and economic

rationality is evermore widely seen as secondary to social and political welfare. Moreover, the old concept of *ordre public* may need to be revised and expanded, parallel to the way public morality has expanded from a set of values and duties that only were valid for a smaller community, to the now more predominant cosmopolitan sense of justice. The IP regime must do justice to this sense of public morality because is dependent upon civil support. Here we inevitably confront the question of who shall be the moral gatekeeper in deciding what are “good” exclusive rights and what are “bad” exclusive rights. It may be that the democratization of the current IP regimes is a first step to respond to this problem.

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