Assessing the Role of IPRs to foster R&D: The Case of Vaccines and Drugs for Neglected Diseases.

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Abstract

The role of Intellectual Property Rights (IPR)s as incentive for innovation in the pharmaceutical sector has been a considerable concern by different bodies at national and international level. This paper analyses the inadequacy of IPRs to foster Research and Development (R&D) for vaccines and drugs for neglected diseases, mainly in importance for developing countries. Based on this, the paper discusses in how far IPRs encourage innovation in different national and socio-economic contexts. Special emphasis is also given to the need to take the nature of different markets and the level of economic development into account in the making of global IPR frameworks. The paper makes a contribution to debates on the role of health care for development by discussing a range of mechanisms that may support health care R&D. Such framework can be used to address public health goals.

Introduction

The broader context for this study can be seen in the challenges that exist in the relationship between private and public interests regarding biotechnological innovations, and the role that Intellectual Property Rights (IPRs)[1] play in this relationship. The IPR system[2] was originally introduced to bridge the gap between public and private interests, by granting monopoly power over the invention to the

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investor, while at the same time requiring complete disclosure of the knowledge to society. However, this incentive to innovate does not always work sufficiently, and despite the incentive companies are not always encouraged to invest in Research and Development (R&D), as is the case for neglected diseases.

From the point of view of private companies, there is a need for rather strong patent protection in the industry due to the long, expensive and risky R&D processes in biotechnology (Mansfield, 1986, Levin et. al. 1987). While the industry requires strong Intellectual Property (IP) protection, in order to secure some returns for the expensive investment in R&D for new products, the protection that IP provides in this case still does not sufficiently fulfill its incentive role.

As a matter of fact, we have in recent years moved towards a regime of stronger IP protection. This trend became very apparent, for example, when the Agreement on Trade- Related Aspects of Intellectual Property Rights (TRIPs) has been put in place in 1994. But although stronger IP protection that is now provided through the implementation of TRIPs, this does not seem to have ameliorated the case discussed here.

The purpose of this paper is to contribute to the debate on difficulties concerning balances between public and private interests in relation to biotechnology innovations and argues that the patent system does not always fulfill its incentive role sufficiently. The paper concludes that we need a more holistic approach and recommends us to take more than one single policy instrument into account when trying to create a market for products for neglected diseases. It is therefore useful to apply a systemic perspective, rather than focusing only on

one component of a larger system, such as IPRs.

The main focus of this paper is to explore the inadequacy of IPRs to foster R&D for vaccines and drugs for neglected diseases[3] with main importance for developing countries. Theoretically, the paper discusses one particular aspect of innovation systems, and approaches the problem from an inter-disciplinary perspective. The paper therefore provides a presentation and discussion of legal and economic aspects of IP as they relate to R&D for drugs and vaccines for neglected diseases.

In this specific case, which is used to exemplify a more general theoretical problem, IPRs do not serve as an incentive to direct resources towards R&D for these diseases. This is despite the fact that there is a clear need for such investments. What we can observe in this case is an imbalance between private, commercial interests and public, societal needs. It appears, therefore, that the IPR system, is not fully capable of balancing different interests.

The paper is organized as follows. The first part deals with theoretical foundations, addressing the general institutional framework of IPRs, IP and its relation to innovation, the case of IP in biotechnology, as well as international standards of IP protection. The next part discusses the inadequacy of IPRs as policy instrument in the case of neglected diseases. The final part extends the discussion and draws some conclusions and policy implications.

The Role of Intellectual Property Rights

During the last decade, international interest in the protection of IPRs and their impact on competition, innovation and international technology transfer has grown. IPRs are today high priorities on the agenda of policy

makers, academics and business firms. As knowledge and immaterial products are increasingly important in the world economy, the role of IPRs is becoming more crucial. Their role has also been enhanced by globalization, where innovators, especially multinational companies, through the increasingly globalised production since "with the growth of globalised production, when innovators (in particular large transnational companies) gear R&D more and more to world than to national markets (Lall, 2003). The increasingly globalizing and knowledge- based economies in today's industrialized societies are characterized by rapid changes and we can observe how knowledge is rapidly diffused around the world and applied in products and processes at an advanced level. More then ever before policy debates on legal and managerial aspects of the creation, diffusion and appropriation of new knowledge, as in IPRs, are hot topics.[4]

A primary rationale for IPRs has been that they are necessary for the provision of incentives to inventors in order for them to invent and disclose their ideas to society. When an invention is introduced to the market, it can in many cases be easily imitated[5]. Thus, in the absence of IP protection, inventors may find that others imitate their invention, and thereby the economic returns for those who originally had the idea are reduced. In this case, inventors would even face a disincentive, as they have invested resources for the invention, while others imitate it and without the initial costs may even achieve a superior economic position. Thus, what we find is a tension between the financial returns that are necessary in order to provide an incentive to invest in R&D and the rapid and widespread diffusion of new technology. Both these aspects are necessary for technology to contribute to economic growth and social welfare. Hence, a central issue is how we can achieve an appropriate balance between the incentive to

innovate and the diffusion of new technology. This is also a fundamental policy question at the international level (Wallerstein, B., Mogee, M.E. & Schoen, R., 1992: p.13).

Intellectual Property and its relation to innovation

Intellectual Property (IP) is one part of a company `s intellectual capital. IP assets are protected by systems of IPRs[6]. These are often seen as providing incentives for innovation, as they are considered as essential mechanisms for securing economic returns on certain kinds of innovation. Further, IPR systems can help innovators define, record, measure, value and manage knowledge assets for commercial purpose. The role of IPRs as incentive for innovation in the biopharmaceutical sector has been a matter of considerable concern for different bodies at the national and international levels[7]. There also continues to be concern and criticism of the extension of patent rights on pharmaceuticals in the developing world as required in the TRIPS agreement (Lanjouw, 2002).

Intellectual Property and its relation to innovation systems

Within the analytical framework provided by the concept of innovation systems (Lundvall, B.-Å. 1992; Nelson and Rosenberg, 1993), IPRs can be considered as forming part of the institutional framework of an innovation system. They can further be considered as being part of "the strategic options in the knowledge economy" (Ganguli, 2000: p. 167). Hence, the issue of "knowledge ownership" becomes important and relevant. It has been argued that the "success and survival of a `border-less knowledge world` is determined by appropriate frameworks which enable fair transaction of intellectual assets" (ibid). Moreover, "IPRs are not static legal structures but have to undergo directed metamorphosis to fine tune with the

changing national and global socio-economic, technological, trading and political developments" (ibid, 2000: p.172). Due to advances in science and technology, it is constantly necessary to review the legal structures on a local as well as global scale, so as to ensure relevant and appropriate IP laws.

The IPR system can, furthermore be regarded as "an institution that tried to solve the problem of market failure by providing private producers with incentives to supply public goods" (Verspagen, 1999a: p. 5). Thus, the IPR system represents one possible way to solve the problem of market failures. However, as we have seen, there are cases where the system does not reach this goal. Moreover, IPRs are an important aspect of issues concerning the role of institutions in technology transfer. They are "the part of legal institutions that connects most closely to the process of technology itself" (Verspagen, 1999b: p.16).

Intellectual Property and Biotechnology

Biotechnology[8] is widely recognized as being one of the most promising frontier technologies in the contemporary knowledge-based economies (EC, 2002).[9] An important part of the European Commissions policy formulations for a coherent strategy for biotechnology are the regulatory principles, such as those set down in IPRs. The field of biotechnology shows "an impressive array of inventions which involve the manipulation and use of genes and genetic elements, and there has been a surge in patenting in this area in recent years" (OECD, 2004). The protection of IP is at the core of the business for firms and is of great importance in relation to the use of new knowledge in productive activity. In general, patents, licensing, and plant breeders rights are common forms of IPRs in the field of biotechnology. In the biopharmaceutical

sector, we can observe that despite strong patent protection the IPR system is in the case of neglected diseases a "necessary but insufficient incentive to encourage companies in the developed or the developing world to commit R&D resources towards neglected diseased" (Kettler & Collins, 2002: p.10). They have further argued that the protection and the marked that is secured for the innovator is insufficient for such investment.

The patent system

Early IP notions developed in connection with the development of trade and technology in the Middle Ages, showing the long history of the IPR system[10]. IPRs have thus had a longstanding and close relation to the development of capitalism, and many difficulties in the IPR system - such as those considered in this paper - seem to be due to the nature of capitalist economies where markets and demands[11] are needed in order to invest in R&D.

Currently the patent protection in the EU is ensured by two systems, the European Patent System and the national patent systems (EC, 2002). The current patent systems consist of "a complex structure of national laws and customs, international private agreements and practices, and international conventions and arrangements" and can be considered as constituting "a key institution of the Knowledge Economy" (Sideri & Giannotti, 2003: p.13). In order to understand the role of patents for innovation, it is important to know what purposes a patent serves, as well as the general criteria necessary for patentability.

A patent is "a right granted by the government to inventors to exclude others from imitating, manufacturing, using or selling a product or process for commercial use during a certain period (usually 17-20 years)" (Harison,

2004: p.4). Thus, a patent awards a private right in return for public disclosure of an invention. This is the essence of the patent law: it provides society with additional technical knowledge and at the same time gives an incentive to the investor by providing patent protection for inventions. A patent has to meet three requirements of patentability, which are novelty, utility and non-obviousness. Novelty refers to the subject matter, which must be new and include a certain level of "originality over the existing body of technological knowledge in the particular field" (ibid). It must further be industrially applicable and useful, which is the utility requirement. The non-obviousness criterion refers to "a non-trivial inventive step which is approved by a `person skilled in the art` (official examiner who has the necessary knowledge)" (ibid). Once the patent is granted there needs to be *complete disclosure* of the invention to the public. Thus, the system reflects the competing interests that are involved in the protection of intellectual property. "On the one hand, inventors are vested with a "right" to their creations. On the other, the federal government secures this right to promote invention for the benefit of the public" (Ackiron, 1991: p. 148).

It has been implicit in the discussion of this paper so far that we can find two different interest models with regard to the patent system. One is the public model, and one the economic. There is generally an agreement that the patent system was primarily created in order to serve public interest, through the disclosure of the discoveries. In this model, the benefit for the public is viewed as the main goal of a patent system. We can also find an economic model, regarding the incentives of the inventor to expend resources on innovative activities. Regarding the high costs in a high-tech industry such as biotechnology, this model evaluates whether the investment "will be made only with the expectation of receiving patents" Therefore, awarding a

monopoly to a successful inventor is economically justified when monopoly output restrictions are outweighed by the fact that, without the promise of such protection, there would not have been an invention" (Ackiron, 1991: p. 149).

The economic rationale or model of a patent system is based on the problem of appropriability (Arrow, 1962, Nelson, 1959). This refers to the fact that in order to have an incentive to undertake R&D a firm must be able to appropriate returns sufficient in order to make the investment worthwhile. However, as in our case, patents do not work in practice as in theory. Thus, the appropriability is not optimal. If intellectual capital is not protected it can rather easily be stolen, copied and sold elsewhere without authorization. In the biopharmaceutical industry this can occur when drugs are imitated and sold for lower prices (OECD, 1999). Patent propensity changes in different sectors and is of special importance in the biotech and pharmaceutical industry (Mansfield, 1986; Levin et.al. 1987) where patents protect both the products and the idea behind, thus serving as an incentive for further investment in R&D. The following sections provide more concrete examples of how IP protection relating to new technologies is dealt with at the international level.

International standards of IP protection

Patentability requirements have been negotiated on an international level during the Uruguay Round in 1993 which resulted in the TRIPS Agreement. After the signing of this agreement in 1994, all member countries of the WTO are required to implement minimum standards of protection for patents, trademarks, copyrights and other IPRs. Thus, a common standard for all countries was established through the agreement, without taking socioeconomic and technological differences into account,

i.e. the same standard of protection is applied in developing as well as industrialized nations. However, a transition period was given to developing countries for an extended period of time to implement the new standards.

What are the implications of the TRIPs agreement for the biopharmaceutical sector? With the TRIPs agreement all WTO member countries are obliged to grant patents for pharmaceutical products. Under previous international treaties, this obligation did not exist. Surveys of multinational companies commissioned by the World Bank show that patent policies are now ranked high by pharmaceutical companies in their decision criteria for foreign direct investment.

It has been argued that "it is still too early to judge the impact on developing countries` infant pharmaceutical industries of introducing IPR laws that comply with TRIPS of the World Trade Organisation" (Kettler & Collins, 2002: p.11). It has been predicted, though, that, for instance, the introduction of product patent protection in India will put "hundreds of small local generic companies out of business". On the other hand, it will provide opportunities for companies that are able to invest in necessary R&D, as well as for larger companies that are in a position to enter and compete for contracts in global markets (ibid). A number of challenges are associated with the TRIPS agreement, and concern has been raised from a public health perspective. In summary, the main issues are:

1) The patent holder can exclude direct competition, and charge higher prices for patented medicines than would have prevailed in a competitive market. Life-saving drugs can thus be made unaffordable.

2) Most developing countries are excluded from the benefits of protection for inventions as they lack the scientific infrastructure and the capital needed for R&D. Moreover, high costs for the development of patentable pharmaceuticals put this beyond reach for most of them.

3) Most of the pharmaceutical companies that invest in R&D focus mainly on diseases that are likely to yield high return for their shareholders. Diseases of the poor, such as malaria or tuberculosis, are thus neglected.

4) Despite expectations, the TRIPS agreement has so far not contributed to an increase in FDI or technology transfer in pharmaceutical production in developing countries.

5) A significant part of industry `s R&D expenditure is allocated not to developing new drugs but to expanding the coverage and lifetime of patent protection for existing ones, which is done by patenting minor improvements or modifications such as new crystalline forms, combinations and formulations (Correa, 2001: p.381).

The above stated considerations do not imply that patents cannot work as stimulation for R&D in new drugs. However, they do suggest that strengthened IPRs affect developing countries differently than technologically advanced countries.

Against this background, it is relevant to analyze the implications of the extended protection on innovative activities. Patents grant a monopoly right to their holder in order to sell or apply an invention (this can be a product or a process) for a limited period of time. While there are positive impacts of such monopoly (as for instance the

incentive for innovation) there also exist negative impacts. These are mainly related to high prices for the products. Key determinants of the optimal extent of protection reside in the extent to which the prospect of greater profits actually leads firms to increase investment in R&D, as well as the degree to which this further investment is leading to innovations that address societal needs.

These considerations lead directly to the central issues in this study. The study `s purpose, as noted previously, is to investigate whether increased IP protection is potentially leading to an increase of R&D activities in certain biopharmaceutical products.

It has been argued that an optimal patent system will still need to vary and take into account differences according to countries (the level of economic development of a country), industry and type of knowledge. This means that "the optimal patent system will not be the same for all industries, all types of knowledge, or all types of inventors" (Thurow, 1997: p.11). In other words, we cannot implement a `one –size – fits all` type of policy or system. A problematic aspect of international standards on IP, though, is that the nature of different markets and the level of economic development does not seem to be taken into account.

This problem becomes obvious when it is taken into account that the industrialized countries have by definition reached a more advanced stage of economic development compared to the level of economic development of developing countries. Thus, by "harmonizing" IP standards and striving from the `optimal` global patent system, we expect LDCs to behave in a similar way as industrialized countries. This amounts to forcing them to adjust their specific regulations according to the level of economic

development of developed nations.

That the introduction of TRIPS will encourage companies in developing countries to invest in treatments for neglected diseases is less evident. Only slight developments in malaria patent and investment behavior were reported in a global study on tropical diseases post – 1980, and despite many new entrants to the R&D pharmaceutical industry all others were stagnant (Cockburn & Lanjouw, 2000).

It has been argued that explicit policies and initiatives above and beyond IPRs are needed in order to direct some of the resources and capabilities that are available in the pharmaceutical industry towards neglected diseases. Among some of the suggested policy options are ways to set up public- private partnerships to address the R&D gap for vaccines for specific diseases and incentives to invest in neglected diseases. A "pull" proposal is, for instance, "to offer companies a patent extension on a product of their choice in exchange for their successfully developing and marketing, at affordable prices, a product for a neglected disease" (Kettler & Collins, 2002: p.13). This is in line with the rather clear position of research based pharmaceutical and biotechnology companies, who will not engage in R&D work without patent protection.

I will now introduce the case of neglected diseases, and based on that discuss in how far / why we find an insufficient policy instrument in the patent system with respect to the case.

The case of neglected diseases

The category of "neglected diseases" is given low priority by both private and public investors in

pharmaceutical R&D (Lanjouw and Cockburn, 2001; Global Forum for Health Research, 2000).

For at least 12 such diseases, 99 to 100 % of all cases globally are located in developing countries. The 100% category includes: malaria with over 24 million sufferers (1996), chagas disease, dengue, encephalitis, lymphatic filariasis, schistosomiasis, tetanus, trachoma. In the 99 + % category we find leishmaniasis, measles, polio, syphilis, diphtheria. The figures for tuberculosis and HIV are 91 and 65 %, respectively (Lanjouw & Cockburn, 2001).

The actual demand for R&D related to these diseases is small, despite a large number of patients and need for new medicinal products. One reason for this is the targeted populations inability to pay for the new medicines. Therefore, companies find small markets and expect only low returns from the sales. As mentioned above, the R&D process is long, risky and expensive, regardless of the disease. However, once a new product is tested, the marginal cost of producing pharmaceuticals, is low. This permits generics firms "to manufacture and sell products at prices a fraction of that offered by the innovator. Patent protection for the innovation, therefore, is considered an essential mechanism for securing economic returns on the innovation" (Kettler & Collins, 2002: p.11). In the case of neglected diseases, however, the protection and the marked that is secured for the innovator is insufficient to invest in R&D (ibid).

It has been argued that "the major objectives of innovation policy are economic growth and international competitiveness" (Lundvall & Borras, 2003: p.18). It is acknowledged that innovation might also be seen as solving problems related to "pollution, energy, urbanism and

poverty", but the main focus remains "the creation of economic wealth (ibid). One of the instruments that can be used to achieve this goal is the regulation of IPRs (ibid).

The phenomenon we can observe here can be viewed from different angles and seems to be a complex problem. On the one hand, it can be seen as non attractive to invest in this type of R&D, which is partly due to the existing, insufficient incentive system. On the other hand, there is a clear demand, a societal need for that type of investment leading to innovation. The case can also be viewed as an innovation opportunity that is not taken.

Recall that IPRs can be considered as part of the institutional framework of an innovation system, as helping to define the `rules of the game`. As institutions, they constitute constraints and/or incentives for innovation (North, 1990 in Edquist, 2001: p.228). Certain institutions, such as for instance the patent law, which is created by public agencies and these institutions may serve as important innovation policy instrument (ibid).

In the case of lack of sufficient R&D for neglected diseases we have clearly identified a `problem`, which is a "necessary condition for pursuing an innovation policy" (Edquist, 2001: p.234), i.e. it is a first step. Obviously, in this case the policy instrument is not achieving its goal, so what aspects need to be changed in the present system? Are the incentives for innovation in this field inappropriate? How can they be changed? Can innovation policy manage to link different interests, or on the part of the private sector even "create" interest?

Discussion

In the case discussed here we can observe a tension between public and private interests and a gap between the expected financial returns and those that are necessary in order to provide an adequate incentive to invest in R&D and promote the rapid and widespread diffusion of new technology. Both these aspects are necessary for technology to contribute to economic growth and social welfare. Hence, a central issue is how we can achieve an appropriate balance between the incentive to innovate and the diffusion of new technology. This is also a fundamental policy question at the international level (Wallerstein, B., Mogee, M.E. & Schoen, R. (1992: p.13).

What we find in this case is an inadequacy of IPRs to foster R&D for vaccines and drugs for neglected diseases. This occurs despite the strong patent protection that we find in the industry. In this particular case, therefore, we find that the innovative possibilities are not exploited. In these cases where innovation does occur, strong patent protection hinders developing countries` ease of access to the knowledge that would enable them to produce similar drugs and vaccines. The interplay between scientific, legal and economic aspects makes the case such a complex and rather difficult issue.

From the above theoretical discussions it is obvious that from an economic point of view one might tend to argue that IPRs can contribute to overcome the problem of market failure and create a market. The international standards on IP protection were supposed to be one important step in this direction as they should serve as incentive for R&D. Indeed, from an innovation system perspective we would surely not expect one policy instrument, as the IPR system, as being enough, since the issue is much more complex. Due to its systemic understanding the innovation system approach clearly

offers important and useful insights when dealing with such problems. As shown in this paper, IPRs alone are not sufficient as a means of market creation. Instead, we need to think in a more comprehensive way to understand the various aspects that are included when creating a market. Therefore, we should not only focus on IPRs, but also on other policy instruments as well as other factors that play a role for the creation of a new market. This underlines the importance of considering an innovation system as a whole, and not only parts of it.

For instance, when dealing with developing countries it is also important to be aware of that the innovations systems are often still at a more fragmented stage and less integrated than in developed countries. In addition, the development of innovation systems in an underdeveloped context is often characterized by a number of constraints that those countries are facing (e.g. Szogs, 2004**,** Muchie, M.; Gammeltoft, P.; Lundvall, B.-Å. 2003). While these countries are still on a different stage of socio-economic development in trying to overcome the market problem, we still tend to focus solely on one aspect of the very complex issue of how IPRs can constitute an incentive to encourage R&D investment which may result in new products and thereby a market creation. The point made is that we also need to consider the specific nature of these countries' systems of innovation in the discussion about IPRs as an incentive. Therefore, the conclusion is that it is of major importance for policy-makers to consider more than one single policy instrument as well as carefully examine the nature of the socio-economic infrastructure and the stage of development in developing countries, when designing policies to overcome problems such as the one discussed here.

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Notes

[1] IPRs protect the Intellectual Property of firms and universities. This protection varies between countries and is regulated by IPRs, which include different types such as patents, copyrights, trademarks, trade secrets and industrial design. IPRs can serve as incentive for innovation, but they can also exclude others from commercially using and selling the claimed invention.

[2] I refer here to an IPR system as forming part of the regulatory framework of an innovation system; they are therefore an important component of all innovation systems. IP regulations affect the creation and protection of innovation. An IPR system defines the set of `rules` of how and to which extent IP is protected in a country, thus they regulate the protection of IP.

[3] For at least 12 diseases, 99 to 100 % of all cases globally are located in developing countries. The 100% category includes: malaria with over 24 millions sufferers (1996), chagas disease, dengue, encephalitis, lymphatic filariasis, schistosomiasis, tetanus, trachoma. In the 99 + % category we find leishmaniasis, measles, polio, syphilis, diphtheria. The figures for tuberculosis and HIV are 91 and 65 %, respectively (Lanjouw & Cockburn, 2001).

[4] For developed countries this means, for instance, debates about what it should be allowable to patent – e.g. access to genetic resources. For developing countries it typically means discussions about the trade-related aspects of intellectual property (TRIPs Agreement).

[5] In the case investigated here, imitation of drugs may occur in

developing countries, where standards of IP protection are not yet implemented as required by TRIPs. However, another disincentive in this case is the lack of a market from the point of view of the companies.

[6] When talking about systems of IPRs it is referred to IPRs as forming part of the regulatory framework of an innovation system, they are therefore an important component of all innovation systems. IP regulations affect the creation and protection of innovation. The IPR systems define the set of `rules`of how and to which extent IP is protected in a country, thus they regulate the protection of IP. These systems differ between countries.

[7] See for example: National Institute for Health Care Management. Prescription drugs and intellectual property protection: finding the right balance between access and innovation. Washington, DC, 2000.

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[8] The Biodiversity Convention defines “biotechnology” in a very broad way, covering “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use” (Article 2). In this proposal the term is used to refer to advanced biotechnologies and in particular to the use of recombinant DNA technologies for the production of organisms, micro organisms, cells and cell lines, substances and compositions.

[9] “On average, companies plough some 45 % of their annual income into R&D”, which means “nearly half of the value of the industry is embedded in its intellectual capital.” (OECD, 1999).

[10] For an overview and introduction on the history of the IPR system see for instance, Granstad (2003).

[11] In the case of R&D for neglected diseases we have a demand, however from a public/ societal point of view which does not seem to match with the private view of demand, where it is seen in economic term. From the point of view of the companies there exists no market for drugs and vaccines for neglected diseases.

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