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Intellectual Property Rights and Public Health

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FGS constitutes the German section of the **Pugwash Conferences on Science and World Affairs**, which were founded in 1957 and distinguished with the Nobel Peace Prize in 1995.

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A. Introduction

The recent paper is a first contribution of the Federation of German Scientists (Vereinigung deutscher Wissenschaftler, VDW) - the German section of the Pugwash Conferences on Science and World Affairs (www.vdw-ev.de) to the international debate on intellectual property rights (IPRs) in the field of public health.

As the work of the Economic Sciences Research Group of VDW addresses also other aspects of IPRs, future articles in 2008/2009 will cover two other knowledge-related areas, i.e. the interfaces between IPRs and biodiversity (comprising IPRs and the protection of seeds, genetic resources and traditional knowledge), as well as between IPRs and access to knowledge (regarding information and communication technologies (ICT) and the media).

It is of utmost importance to understand the economic impact of today's IPR regime on a globalized knowledge community. As we will partly illustrate in this and following papers, the current application in many countries of IPRs to the areas of pharmaceuticals, biodiversity and access to knowledge seems to suggest a one-sided focus on some private actors' interests, to the detriment of overall economic efficiency and the availability of public goods. This apparent trend justifies some deeper economic analysis of the current practice of IPRs, with a view to clarifying their actual benefits and limitations. The latter implies the need to reflect upon developing alternative sources of innovation where IPRs fail to provide sufficient incentives.

The present paper is structured as follows:

- A. Introduction
- B. Ethical aspects of IPRs
- C. Historical overview of the development of IPRs and the dissemination of knowledge
- D. The globalization of IPRs and its impact on public health
- E. New means of the global promotion of knowledge and innovation in the area of public health

Based on this paper (as extended to the areas of biodiversity and access to knowledge), VDW envisages a broader research project, which implies a qualitative survey in a number of African countries with respect to their domestic legislative frameworks on intellectual property (IP) as well as existing and potential scientific collaboration in the areas of IPRs, public health, biodiversity, and access to knowledge and their impact on the fight against poverty. The project will in particular focus on possible ways to improve collaboration between scientific bodies in the selected countries. An e-platform will be made available by the end of 2008 for further international discussions and as part of the preparatory process for an international conference in Berlin in late 2009.

B. Ethical foundations of IPRs

I. The notions of intellectual property and knowledge

IPRs are devices for the protection of immaterial goods, such as certain technological applications of knowledge in inventions, creative expressions in works of literature and art, as well as the creation and use of certain signs and symbols to identify products or services. IPRs provide enforceable rights to individuals or communities and enable the rights holders to exclude third parties, for a limited period of time, from a series of activities with respect to the protected goods or services.¹ Categories of IPRs are, *inter alia*, patents, copyright and related rights, design rights, trademarks, as well as geographical indications. Our paper is limited to those IPR categories that are pertinent to the creation and dissemination of knowledge, as opposed to art.

The notion of knowledge refers to the temporary understanding of certain findings as being true, taking account of the objective limitations of the human mind. In this context, it is important to recognize that the notion of knowledge should go beyond a strictly rational definition, in order to make any generation of knowledge subject to modern research, as long as such knowledge is commonly believed to be true in other cultural research contexts. The globalized knowledge community should not limit itself to findings based on positivism, but should be prepared to embrace non-rational sources, such as introspection, contemplation or meditation, provided these may be defended through logically structured reasoning.

II. Ethical foundations of IPRs

Exclusive rights as generated by IPRs have historically been justified in different ways.² The *rights-based approach* considers that the creator or inventor has a natural right to the results of his/her intellectual activity. Such approach could even lead to an understanding of IPRs as human rights.

This may be countered by referring to the temporary character of IPRs, and the fact that most IPRs, in order to be enforceable, have to be granted by a public authority. The *consequentialist or utilitarian approach* considers the results of any intellectual activity as generally falling into the public domain. This understanding is based on the fact that any intellectual activity builds upon freely available elements of knowledge. A creator can only be inventive or creative when applying the know-how acquired through a learning process that was made available by the state or by society in general (e.g. through educational institutions). Hence the creator's responsibility *vis-à-vis* society. Such responsibility exists in an even wider context, i.e. with respect to any being and the entire creation.

Against the background of this utilitarian approach, IPRs may be understood as *privileges* that are granted by society on a temporary basis. As a matter of fact, IPRs have historically been justified on this utilitarian basis. As will be shown below, IPRs have traditionally been used for the promotion of certain public policy goals, which reflected a country's particular economic situation and level of technological and cultural development.

¹ UNCTAD-ICTSD, *Intellectual Property Rights: Implications for Development*. Policy Discussion Paper, Geneva, 2003, p. 27 (hereinafter UNCTAD-ICTSD Policy Paper).

² UNCTAD-ICTSD Policy Paper, p. 31.

C. Historical overview of the development of IPRs and the dissemination of knowledge

I. From the promotion of innovation to the protection of investment

Throughout their history,³ IPRs have systematically been used as tools to promote the technological and cultural development of society. Depending on a given country's industrial, technological and cultural level of development, IPRs have been used to promote the immigration of foreign workers and the importation of foreign technologies; to reward the inventor with a view to promoting further inventive activity (including the means for industry to recoup its research and development (R&D) investments); as well as to promote the dissemination of knowledge.⁴

One of the key messages in this paper is to highlight that during the past 100, and especially 20 years, certain stakeholders have been promoting a significantly modified understanding of IPRs and of the rationale for their use: originally designed as instruments to promote the generation of new knowledge, IPRs are increasingly being used to protect existing knowledge (often in the hands of multinational companies) from access by competitors and to promote activities that require important financial effort rather than creativity and ingenuity.

Such understanding of the rationale for IP protection is by no means supported by the multilaterally binding rules of the World Trade Organization (WTO). The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) states in Article 7 that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

Thus, the TRIPS Agreement expressly confirms an agreement by WTO Members that the protection of IP should not constitute an end of its own, but that it should be a means to achieve certain public policy goals by balancing the interests of creators and users.

IPRs were extremely controversial in 19th century Europe, where many stakeholders (including industry associations) perceived them as undesired limitations to trade liberalization. Countries like Switzerland and the Netherlands prohibited patents throughout large parts of the 19th century,⁵ while in Germany and the UK, existing patent laws met with important resistance from the part of liberal policy influencers.⁶ Eventually, public opinion accepted the view that temporary exclusive rights constitute an appropriate means to promote people's motivation to invest time and money in R&D for new technologies or the creation of artistic works. This is particularly true for R&D-intensive manufacturing processes, where development expenses are high and the costs of quick copying by free riders are low.

³ The first patent laws go back to Renaissance Venice and England's Statute of Monopolies of 1624. For an historical overview, see UNCTAD-ICTSD Policy Paper, p. 33 et seq.

⁴ Ibid; toward the end of the 18. century, English case law introduced the concept of knowledge dissemination by means of disclosing the invention in the patent application. See R.P. Merges, *Patent Law and Policy: Cases and Materials* (second edition), Charlottesville, Michie Law Publishers, 1997, S. 657.

⁵ See E. Schiff, *Industrialization Without Patents: The Netherlands, 1869-1912, Switzerland, 1850-1907*, Princeton University Press, Princeton, 1971.

⁶ See F. Machlup and E. Penrose, *The Patent Controversy in the 19th Century*, in: *The Journal of Economic History*, vol. X, no. 1, May 1950, pp. 1-29 (24) (hereinafter Machlup/Penrose).

The development of IPRs throughout the 20th and the early years of the 21st century has been characterized by a gradual expansion of exclusive rights and a corresponding shrinking of the public domain (i.e. the information and knowledge that is not or no longer protected through exclusive rights). A number of developments have raised concerns among stakeholders about IPRs becoming a potential obstacle to innovation and creativity, rather than an incentive.⁷ Some of these concerns relate to the following issues:

- Increased patenting of trivial inventions, for instance in the pharmaceutical sector, as favored by a rather lax application of patentability requirements by a number of patent offices, has contributed to IPRs being increasingly used for strategic purposes, such as preventing competition and chilling competitors' R&D efforts for fear of lengthy and expensive patent infringement litigation.⁸
- Even where a pharmaceutical patent is not granted, the underlying substance may become subject to a new category of exclusive rights, i.e. rights conferred for the protection of clinical pharmaceutical test data. As opposed to the classical subject of IP protection, the creation of a test data file requires neither creativity nor ingenuity, but is the result of repetitive, time consuming and costly clinical trials required for the granting of marketing approval of a new medicine. Data exclusivity rights will prevent the quick market entry by generic competitors (see below). To what extent the commercial benefits are actually reinvested in pharmaceutical R&D or are instead used to cover marketing expenses for existing products, is a very controversial issue.⁹
- The protection in some WTO Members of information-relevant data contained in databases through exclusive rights is not based on any alleged intellectual effort for the generation of such data, but on the considerable investment that may be required in this respect.¹⁰ Concerns have been raised about the privatization of data as the "building blocks of knowledge and learning".¹¹ Again, IPRs risk being used in a way contrary to their agreed purpose in the TRIPS Agreement, i.e. for the promotion of innovation, in a manner conducive to social and economic welfare.

⁷ See, for example, the US-based *Coalition of Patent Fairness* (i.e. a group of mostly information technology -oriented companies) in their statements on the US patent reform, quoted in H. Disney/M. P. Pugatch, "Commentary - The Patent Reform Act - Divided We Are, United We Stand", in *Know IP - The Stockholm Network's Monthly IPR Journal*. Volume 3: Issue 6. August 2007, pp. 1-4.

⁸ The arms race. Companies are preparing for the intellectual property battle, in: *The Economist*, 22 October 2005, special edition "A market for ideas. A survey of patents and technology", pp. 8/9.

⁹ See for example International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), "Data Exclusivity: Encouraging the Development of New Medicines", July 2007; for the opposite view see M. Angell, "The Truth About the Drug Companies: How They Deceive Us and What to Do About It", Random House, New York, 2004; summary available at <http://www.nybooks.com/articles/17244>.

¹⁰ See for example Article 7.1 of the EC Database Directive (Directive 96/9/EC of the European Parliament and of the Council of March 11, 1996, on the Legal Protection of Databases, Official Journal of the European Union 1996, L 77, 20).

¹¹ Statement by Professor Ruth L. Okediji, William L. Prosser Professor of Law, University of Minnesota Law School, on 15 May 2007 at the ACP Secretariat in Brussels at a workshops on "Intellectual Property and Economic Partnership Agreements: Negotiating Options and Prospects for Development in ACP Regions". The EC Database Directive, for instance, does contain exceptions for the non-commercial use of data. However, concerns persist regarding the effect of exclusive data rights on access to knowledge and have resulted in a rejection of comparable legislation in the United States.

II. The emergence of a globalized knowledge-based society

In the globalized economy, knowledge is the key determining factor of economic success. In order to draw the benefits from globalization, national economies are increasingly dependent on their capacity to quickly translate their expertise into innovation and technological change and from there to marketable products. According to endogenous growth theories, national economies only keep their dynamism to the extent that they are capable of absorbing new knowledge and thereby generating expertise among their inhabitants. Considering the multitude of challenges faced by the global society, even industrialized countries and their highly developed research communities may benefit from a growing number of researchers and institutions worldwide to tackle urgent global issues, such as the availability of global public goods like health, knowledge and biodiversity.

Technological change and growing connectivity of information providers have an important impact on R&D activities, which are increasingly subject to worldwide competition, but also benefit from the quick availability of enormous quantities of information. This constantly increases the importance of public R&D activities, international R&D networks and alternative incentives for innovative free and open source models.

D. The impact of globalized IPRs on public health

The worldwide expansion of the scope of exclusive rights, the creation of new IPR categories, and the introduction of binding minimum standards of IP protection may have an important bearing on the policy space of WTO Members to effectively pursue certain public policy goals, especially to ensure a sufficient allocation of public goods such as public health. The TRIPS minimum standards on patents generally prevent governments from promoting the low-cost production of many pharmaceutical substances by generic manufacturers. Depending on a given country's level of development and industrial structure, exclusive rights in certain areas of technology may be considered either as a driver of development or as an obstacle.¹²

This being said, even in more advanced economies, increased levels of IP protection do not necessarily yield more innovation or improve access to medicines.¹³ Governments therefore need to strike a balance between the exclusive rights of inventors on the one hand and the public domain for researchers and freedom for competitors on the other hand. The TRIPS Agreement provides governments with a range of tools ("flexibilities") to strike such a balance. These will be briefly discussed under the next section.

Policy makers' awareness and use of the full range of these flexibilities is essential in the context of sustainable public health policies, as IPRs may otherwise prevent the development and production

¹² UNCTAD-ICTSD Policy Paper; UNCTAD-ICTSD, "Technology Transfer and Intellectual Property Rights: Lessons from Korea's Experience", Issue paper No.2, by Linsu Kim, Geneva, 2003. An interesting example in this respect is the Indian pharmaceutical industry, which between 1970 and 2005 developed considerable domestic manufacturing capacity thanks to the possibility to reverse engineer foreign drugs. This was authorized under the domestic patent law, which did not make available patent protection for pharmaceutical products. See UNCTAD-ICTSD Regional Research Agenda, "Post-2005 TRIPS Scenario in Patent Protection in the Pharmaceutical Sector: The Case of the Generic Pharmaceutical Industry in India", by Biswajit Dhar, 2006 (http://www.iprsonline.org/unctadictsd/regional_research.htm).

¹³ See Swiss Federal Institute of Intellectual Property, "Reasonable patent protection with a statutory research exemption", by Nikolaus Thumm; IPR Helpdesk Bulletin no. 29, September/October 2006 (<http://www.ipr-helpdesk.org/newsletter/29/html/EN/IPRTDarticleN11320.html>), discussing the link between technological innovation and the level of IP protection.

of affordable generic medicines and thus complicate access to medicines not only in developing countries. Expansive IPRs may block the use of substances needed for R&D in follow-on innovation, thereby preventing competition, not only in the pharmaceutical sector.¹⁴

This does not mean that the concept of IPRs has failed in general. In order for IPRs to unfold their beneficial effects, it is important to tailor domestic IP laws to the particular needs prevailing in a given country. Even such tailoring will not suffice, however, where the incentives generated by exclusive rights are useless, because of lacking market demand. This is particularly the case of diseases disproportionately affecting developing countries, such as the so-called type II and type III diseases (e.g. malaria, tuberculosis, river blindness, etc.). In these cases, it is necessary to come up with alternative incentives for the development and production of essential drugs of high quality, needed quantity and at affordable prices

The final section of this paper will briefly review the existing tools to promote innovation in the pharmaceutical sector and access to medicines, as available under the TRIPS Agreement. It will then turn to alternative means for the promotion of pharmaceutical innovation, taking account of the market failures that the IP system cannot address.

E. New means of the global promotion of knowledge and innovation in the area of public health

I. Promoting pharmaceutical innovation through appropriate IP rules

The TRIPS Agreement not only introduced certain minimum standards of IP protection; it also provides an array of tools ("flexibilities") to strike a balance between the interests of owners and users of intellectual property. In a nutshell, the mainly relevant flexibilities in the public health context are the following:

- LDC transition periods

WTO Members agreed to exempt least-developed countries (LDCs) until 2016 from the obligation to implement the TRIPS standards on patent law and the protection of undisclosed information with respect to pharmaceutical products. Accordingly, generic producers in LDCs may reproduce pharmaceutical products patented in other countries, which used to be the practice in India until 2005 and in many OECD countries until the 1970s. The German Government in collaboration with the United Nations Conference on Trade and Development (UNCTAD) and the United Nations Industrial Development Organization (UNIDO) are currently taking advantage of the 2016 window of opportunity to promote the production of innovative pharmaceutical products in selected LDCs. In order for an LDC to benefit from the 2016 transition period, it needs to implement the waiver in its domestic law.

¹⁴ See "The Proper Balance of Competition and Patent Law and Policy". A Report by the Federal Trade Commission, Oktober 2003 (<http://www.sensortime.com/ftc_rpt.htm>9).

- The patentability criteria

The restrictive application of the patentability criteria (novelty, inventive step, industrial applicability) constitutes an important tool for a WTO Member to prevent the granting of exclusive rights on trivial inventions. The new Indian patent law follows such approach, requiring for the patentability of new forms of known pharmaceutical substances a significant increase in efficacy.¹⁵ In the United States, the Supreme Court in 2007 in landmark judgment decided that the lax application of the non-obviousness (i.e. inventive step) requirement under US patent practice is incompatible with US patent law.¹⁶

In developing countries, many inventors may not have the capacity to meet stricter patentability requirements. However, rather than accommodating patent law to their limited capacities and thus sacrificing important parts of the public domain, policy makers should be aware of alternative incentive structures specifically tailored to the needs and capacities of small-scale inventors, such as utility models (providing shorter periods of exclusivity than a patent) or compensatory liability regimes (applying a "use-and-pay" approach, thus denying any exclusive rights to the inventor, but instead granting a right to remuneration).¹⁷

- Exceptions to granted patent rights

In the public health context, two kinds of patent exception take center stage: the experimental use exception and the regulatory review exception. Switzerland is in the phase of implementing an interesting example of the experimental use exception: in order to promote the generation of new knowledge and innovative products, the Swiss draft patent law provides the possibility for experimental use of a patented substances without the authorization of the patentee, even for commercial purposes, provided such use reveals new knowledge about the patented substance. Such new knowledge may then be used to produce competing products that are not covered by the patent claims on the original invention.

According to a WTO panel, regulatory review exceptions may authorize the use of a patented substance, without the consent of the patent holder, in the context of approval procedures for the marketing of generic medicines.¹⁸ Many WTO Members have implemented this exception in their domestic laws to facilitate the early entry into the market by generic competitors.

- Parallel imports

Under the TRIPS Agreement, Members are free to authorize or to exclude parallel imports of IPR-protected goods. Parallel importers take advantage of the price difference between countries, purchasing the product in a low-price country and reselling it in a high-price market, undercutting the prices offered by the IPR holder. It is important to emphasize that parallel imports are no counterfeit goods but the original products manufactured by the IP/patent holder and sold in a foreign territory. Parallel imports may in principle constitute an important means for poor countries

¹⁵ See Section 3(d) of the Indian Patents Act. An Indian court in August 2007 rejected claims by Novartis alleging the inconsistency of Section 3(d) with the TRIPS Agreement. However, the court did not decide on the merits, but considered the issue as not falling under its jurisdiction. See Reuters: "Chennai court rejects Novartis patent challenge", in IP Health Bulletin of 6 August 2007.

¹⁶ Supreme Court of the United States, *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. ____ (2007).

¹⁷ On the latter, see Professor J.H. Reichman, "Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation", *Vanderbilt Law Review* 53:1743-1798 (2000).

¹⁸ *Canada - Patent Protection of Pharmaceutical Products*, WT/DS114/R of 17 March 2000.

to import medicines at lower prices than would have normally been offered by the patent holder. Originator companies make the bulk of their benefits in OECD markets. In order to preserve these benefits, OECD countries may (and have actually done so) prevent parallel imports from developing countries. Thus, originator companies may apply differential pricing strategies without having to fear the loss of their major markets. Should a patent holder charge uniform prices among different developing countries, despite different levels of income in these countries, and should this practice result in the medicines becoming unaffordable in particular countries, such practice could possibly be considered as abusive and be sanctioned under domestic patent or competition laws.

- Compulsory licenses

The TRIPS Agreement authorizes the granting of compulsory licenses without limiting the substantive grounds for such grant. In 2003, WTO Members agreed on facilitated procedures for the exportation of pharmaceutical products manufactured under compulsory license to countries in need of medicines, but lacking the capacities to produce them domestically. While in theory, compulsory licenses may be beneficial, such effect presupposes a number of economic, legal and political conditions that are not present in all developing countries. It is particularly the new procedures for exportation of pharmaceutical products to countries without manufacturing capacities that have been criticized as imposing burdensome and lengthy requirements on both the exporter and the importing country. Therefore, compulsory licenses should be complemented by other measures, including the use of pooled procurement strategies to attract foreign investors.¹⁹

- Competition law & policy

By effectively controlling abuses of dominant positions, such as the unjustified refusal by the patent holder to license an invention for the purpose of extending monopoly power to a secondary market not covered by the IP right, competition law and policy may make important contributions to the design of an IP system that appropriately balances incentives for originators and the promotion of follow-on innovation. Developing countries may find some important guidance in the jurisprudence of the European Court of Justice and its "essential facilities" doctrine.

II. Promoting pharmaceutical innovation through alternative means

The basic concept of IPRs, i.e. to provide crucial incentives for innovation, works only in situations where inventors may reasonably expect adequate returns on investment, which implies a sufficient demand for products created on the basis of their invention. Demand is defined as "need" plus the necessary resources to cover this need. In cases of lack of the needed resources, market failures are the logical and *de facto* consequence, as profit-oriented entities will not be prepared to invest in research and development activities under such circumstances.

It is more than obvious that essential medicines to fight poverty-related, tropical or neglected diseases affecting primarily developing countries (so called type II and III diseases) constitute a typical case of such a market failure. As the problem cannot be resolved by private charity or other voluntary contributions due to its magnitude and the need for a sustainable solution, strong public

¹⁹ For details, see J.H. Reichman, "Procuring Essential Medicines Under the Amended TRIPS Provisions: The Prospects for Regional Pharmaceutical Supply Centers", paper submitted for the UNCTAD Seminar on "Intellectual Property Arrangements: Implications for Developing Country Productive Capabilities in the Supply of Essential Medicines" of 20 October 2006.

intervention is needed to enable alternative solutions. The most widely discussed alternatives at this stage are:

1. Multilateral public health research and prize funds

Individual states cannot realistically be entrusted with the task of funding a global public good such as the worldwide availability of medicines. What is needed is a multilateral agreement obligating countries to collaborate in respect of basic R&D in the area of neglected diseases. It has been proposed that participating governments contribute to a fund, which will then be used to reward those inventions that have a positive effect on neglected disease research.²⁰

2. Patent pools and patent buy-outs

Prize funds could be combined with patent pools, where patent holders make available to the other pool members their respective patents free of charge. For instance, rewards from the prize fund could be limited to inventions that have voluntarily been ceded to patent pools.²¹ A particular form of the prize fund idea is the recently proposed suggestion of "patent buy-outs". According to this approach, states or intergovernmental organizations would buy patents from their holders in countries where, due to a lack of purchasing power, the patentee would not be able to market the protected pharmaceutical product.²²

3. Public-private product development partnerships (PPDPs)

In general, there are two types of PPDPs: those with equal participation by public and private sector partners, and those dominated by public sector players, with contractually agreed private sector contributions. The efficiency of PPDPs in the development of cures against neglected diseases may be illustrated by the Drugs for Neglected Diseases Initiative (DNDi), a spin-off of Doctors Without Borders (MSF), which in collaboration with Sanofi-Aventis has developed an off-patent anti-malarial to be produced in Morocco.

4. Public purchase commitments

This proposal seeks to develop R&D incentives for neglected diseases through the establishment of public purchase guarantees. As this proposal focuses primarily on multinational pharmaceutical companies based in OECD countries, it has met with competition-related and other concerns and has lost support among certain OECD governments.

²⁰ Such "Prize fund" has been proposed by Knowledge Ecology International and CPTech, see, e.g., CPTech's proposal to the WHO Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property (http://www.who.int/phi/public_hearings/first/15Nov06JamesLoveCPTech.pdf) [hereinafter CPTech]. See also James Love and Tim Hubbard, [The Big Idea: Prizes to Stimulate R&D for New Medicines](#), KEI Research Paper 2007:1, March 2007; Benjamin Krohmal, [Prominent Innovation Prizes and Reward Programs](#), KEI Research Note 2007:1; James Love, Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R&D. UC Davis Law Review. 40(3):679-715.

²¹ Carl Shapiro, "Navigating the Patent Thicket: Cross-Licenses, Patent Pools, and Standard-Setting", University of California/Berkeley, March 2001 (<http://faculty.haas.berkeley.edu/shapiro/thicket.pdf>). Nobel laureate Joseph Stiglitz has suggested the use of patent pools in the context of pharmaceutical research. See J. Stiglitz, Patents, Profits, and People; in: Making Globalization Work. New York: W.W. Norton & Company. 103-132.

²² For details, see K. Outterson, "Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries". American Journal of Law and Medicine, Band 32, 2006 (http://papers.ssrn.com/sol3/papers.cfm?abstract_id=873402).

III. Conclusion and Consequences

This paper seeks to illustrate how the protection of IPRs, which according to its ethical foundations, its historical development and the TRIPS Agreement should serve the promotion of public interests, has increasingly been used to promote the economic interests of particular stakeholders.

Expansive exclusive rights may result in monopolies that threaten innovation by preventing product improvement and competition. Multilateral IP rules have partly contributed to this development. At the same time, however, the TRIPS Agreement provides a number of tools which, where applied in harmony with a country's economic level of development, may help avoid such problems. However, in the area of poverty-related, tropical or neglected diseases, the protection of IPRs has failed to develop innovative solutions and must therefore be complemented by alternative means to promote pharmaceutical innovation, some of which we briefly presented in this paper.

Germany's Governmental Programme on Intellectual Property and Pharmaceutical Production has been created as contribution to foster alternative mechanisms for the development and production of essential medicines to fight poverty-related, tropical and neglected diseases by making full use of existing TRIPS flexibilities to enhance local research and production activities in developing countries. This programme, which was initiated in 2005 by the German Federal Ministry for Economic Cooperation and Development (BMZ) is executed by the German development cooperation agencies (e.g. GTZ, InWEnt, KfW/DEG) as well as in cooperation with UNCTAD and UNIDO and in agreement with WHO. Activities to fight HIV/AIDS, malaria and tuberculosis have been implemented until now in 17 African and Asian countries, with a total amount of more than 15 Mio. Euros.

The WHO Global Strategy on Public Health, Innovation and Intellectual Property, which was agreed at the World Health Assembly in May 2008, is a crucial step forward in this regard. It foresees various activities to implement alternative means to foster research and development for neglected diseases and gives WHO an important role in helping development countries to make full use of existing TRIPS flexibilities. A Global Plan of Action will be elaborated in the course of this year and a task force within WHO will immediately start its work to seek possibilities for substantial additional funding.

As stated before, this paper is not meant to be exhaustive or conclusive, but a first element of further discussion.

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