PHARMACEUTICAL PATENT POOLS: A SOLUTION TO INNOVATION AND CONSUMERS' ACCESS?

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ABSTRACT

The protection of intellectual property rights has been established to provide incentives that facilitate the disclosure of scientific knowledge. The pursuit of patenting may, however, encourage covertness, intensify rivalry and reduce cooperation among parties rather than the sharing of knowledge.

In recent years there are growing concerns that in the field of patent protection 'the pendulum has swung too far in favor of patent holders, resulting in an inefficient market for technology'.[1] The use of the current patent system seems to have created fragmented patents and patent thickets that, through increased transaction costs, lead to blockage throughout the system and 'there is a growing consensus that something needs to be done to minimize technology blocking'.[2] In response to the drawbacks resulting from the current system, an alternative institution has been sought for and a collecting rights management system such as 'patent pools' has been established as a mechanism to re-aggregate the fragmented rights and reduce transaction costs.[3]

In the field of biotechnology and pharmaceutical industries, the strengthening of patent protection has raised two major concerns. First, the growth of patent activities at the upstream level such as patents on gene sequence could block the whole line of R&D and downstream product improvements. Second, the introduction of pharmaceutical patents in developing countries can deprive people in these countries from the access to their life-saving drugs such as the anti-retroviral drugs for HIV/AIDS.

A collective rights management system like patent pools, which have been successfully used in telecommunications and electronics industries, have been advocated as a solution to the problem

[1] KENNETH CUKIER, *A survey of patents and technology: A market for ideas*, The Economist October 22nd 2005. at 8

[2] SHIRIN ELAHI, et al., Scenarios for the future: How might IP regimes evolve by 2025? What global legitimacy might such regimes have? (European Patent Office 2007). at 92

[3] Described by Dahlman as "search and information costs, bargaining and decision costs, policing and enforcement costs". Also explained by Coase in the following terms "In order to carry out a market transaction it is necessary to discover who it is that one wishes to deal with, to inform people that one wishes to deal and on what terms, to conduct negotiations leading up to a bargain, to draw up the contract, to undertake the inspections needed to make sure that the terms of the contract are being observed, and so on". See e.g. CARL J. DAHLMAN, *The Problem of Externality*, 22 Journal of Law and Economics 141, (1979).; RONALD H. COASE, *The Problem of Social Cost*, Journal of Law and Economics, (1960).

of blocking patents and patent thickets for pharmaceutical R&D and the problem of access to pharmaceutical products in developing countries. The objective of this paper is to assess the problem of blocking patents and patent thicket in biopharmaceutical industry and illustrates how a pharmaceutical patent pool can be used to address both the problem of patents on innovation and access.

PHARMACEUTICAL PATENT POOLS: A SOLUTION TO INNOVATION AND CONSUMERS' ACCESS?

CHONTICHA SAE-LIM*

I. INNOVATION TODAY

The essence of innovation is cumulative investigation combines with hypothesis testing.[4] Each invention is built on previous findings, companies draw upon their existing stock of knowledge while searching for ways to integrate and improve upon outside discoveries. This is especially true for the present time where the modern innovation process has changed from an individual approach to a collaborative approach. Companies are increasingly relying on the technologies developed by others and complex products are more likely to be the results of combined efforts from many parties rather than being 'stand-alone' products or produced by a vertically integrated organization.[5] In this complex and cumulative process the distinction between different types of technologies has gone blurred while interoperability of products especially standards have become an important element of the product. [6] The result is companies are forced to work together in new ways in order to protect and exchange their technologies. Thank to the patent system, industries are able to operate within a 'technology web'- a network where patent holders and companies are interconnected through their products, technologies and intellectual property[7] - and the degree of business specialization has been able to increase this, in turn; enhances economic efficiency.[8]

With regard to pharmaceutical products, the biotechnology industry has emerged as a main driver for the pharmaceutical industry R&D process.[9] The technological advances over the last few decades have allowed for the rapid sequencing of genetic information from a variety of

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[4] CARL SHAPIRO, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* Innovation Policy and the Economy, (Adam B. Jaffe, et al. eds., 2000).

[5] See ELAHI, et al. *supra* note 2 at 88

[6] Id

[7] Id

[8] Specialization is a result of 'division of labor' made possible by patents. With patents' transferability, companies that do the innovation process can be separated from companies that manufacture and commercialize the products, consequently companies have been able to concentrate on what they are good at and let other companies do the other parts. This, in turn, increases economic efficiency. See CUKIER. *supra* note 1 at 4

[9] COMMISSION ON INTELLECTUAL PROPERTY RIGHTS INNOVATION AND PUBLIC HEALTH, Public Health Innovation and Intellectual Property Right, Report of Commission on Intellectual Property Rights, Innovation and Public Health (World Health Organization 2006).

organism.[10] These, in turn, offer the prospect of comparable progress for new and effective intervention discoveries.[11] One of the most important consequences from such genomics advances is the opportunity to understand the causation of disease at the gene level and to determine more accurately the best medical intervention whether for diagnostic, prevention or treatment base on that understanding.[12] However, genetic information such as genetic sequences is only the first step in utilization of genetic information. To bring the information for use in, for example, the development of pharmaceutical products to treat the disease requires significant and intensive research efforts and there is no single company or organization that has the resources to develop any significant fraction of genetic information present in an organism.[13] Hence, cooperation and knowledge sharing are crucial for bringing in new discoveries to markets. Patents, licensing and contracts have been used as 'currency' of transactions in this collective network.[14]

II. THE CURRENT PATENT SYSTEM

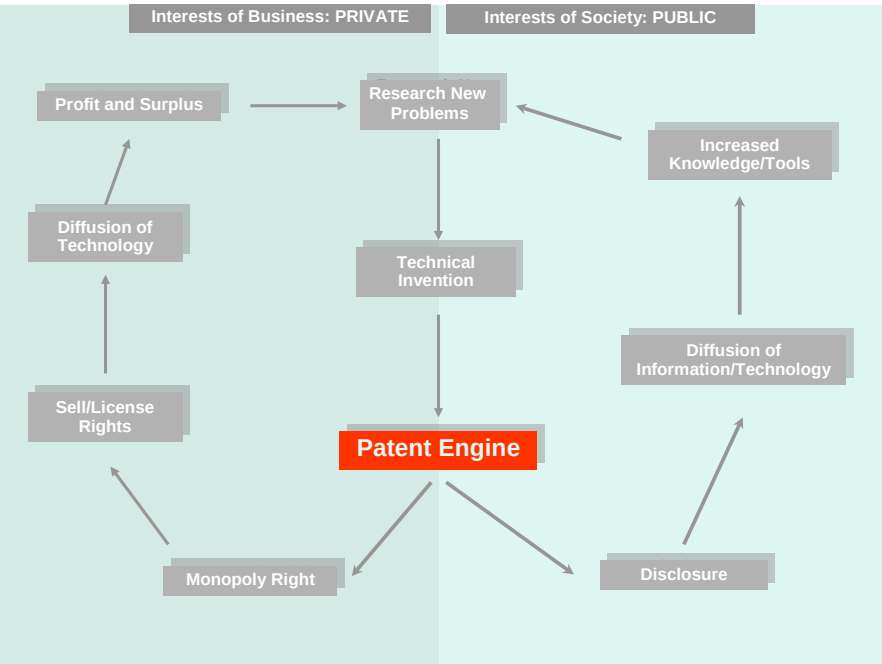
The last section has provided a brief overview on the important of knowledge for future innovation; this section will describe the working of the current patent system and how this system which intended to promote innovation has turned out to impede innovation especially in the pharmaceutical industry.

At present both the access to knowledge and protection of companies' investments has done through the patent system which is based on a balance of private interests and public interests basis.[15] Information has the features of public good – its consumption is non-excludable and non-rivalry.[16] Hence in the absent of protection, inventors will not be able to recoup their investment. This, in turn undermines their incentive to undertake the necessary R&D investment. The patent system has been set up to incentivize inventors. The exclusive rights provided by patent will not

[10] JEANNE; CLARK, et al., *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?*, United States Patent and Trademark Office, (2000). at 2
[11] COMMISSION ON INTELLECTUAL PROPERTY RIGHTS INNOVATION AND PUBLIC HEALTH, Public Health Innovation and Intellectual Property Right, Report of Commission on Intellectual Property Rights, Innovation and Public Health (World Health Organization 2006). at 37
[12] See Id. at 35
[13] See CLARK, et al. *supra* note 10 at 3
[14] See Id. at 39
[15] See ELAHI, et al. *supra* note 2 at 17
[16] Non-excludable because the use by one person does not exclude other person from using the same good. Non-rivalry because the use by one person does not reduce the use of the same good by other person

only generate revenues that can be used to cover the initial investment and re-invest in future innovation but also diffuse the technology and knowledge embedded in the product to the public. While a patent examination process is used to ensure that only novel and innovative inventions worth the social protection are patented, the required disclosure is used to ensure that the patented technology and knowledge are publicly disseminated. This consequently reduces unnecessary duplication of knowledge production, increases the stock of public knowledge that could use as a basis for further R&D and more innovations in the future, resulting in a 'virtuous circle'[17] (see Figure 1).

Figure 1: The Patent System



Source: EPO Scenarios

In the field of pharmaceuticals, commercial therapeutic products can be derived only after a long and complex process with lots of uncertainties involved. Originating companies have to invest a lot of time and money in R&D before they could come up with one new drug.[18] The costs of imitation are, in contrast, relatively low. Giving their much lower costs, without patent protection

[17] See ELAHI, et al.17

[18] It was estimated that the average cost of each drug brought to the market (including the research projects that were initiated and abandoned) is US$ 402 millions with the clinical trial process necessary to obtain government approval accounted for about 70% of this cost. See e.g. HENRY G. GRABOWSKI, et al., *The Price of Innovation: New Estimates of Drug Development Costs*, , 22 Journal of Health Economics, (2003).

generic companies can undercut the originator's price and take away all the sales. Patents are, therefore, very important for originating pharmaceutical companies to maintain their viability.[19]

However, as the patent system evolves 'the assumption seems to be that to promote intellectual property is automatically to promote innovation and, in that process, the more rights the better'.[20] As a result, patent protection has been strengthened both substantively and geographically. Substantively, the duration has increased and the scope of protection has expanded to include many new areas that previously were not included such as business methods, software and gene sequence. Geographically, patent protection is now available in almost every country in the world as a result of international treaties especially the WTO's TRIPS Agreement. The consequences of such an increase in patent protection on the innovation process and the technology market will be discussed in the next section.

A. Patenting Activities, Patent Propensity and Patent Quality

On the patenting side, naturally a stronger protection encourages more patenting. Although it is not clear whether the inventions are new and innovative or not, both the numbers of patent applications and patent grants have proliferated dramatically.[21] The pharmaceutical industry contributes a significant part of patent activities. Pharmaceutical applications increase from

[19] The pharmaceutical industry is one of the industries that heavily relied on the patent system to protect its long and expensive inventions. A study of 48 product inventions done by Mansfield et al, for example, found that about 90% of the pharmaceutical inventions and 20% of the chemical, electronics and machinery inventions would not have been introduced without patents. The survey result on 1,478 R&D lab managers of manufacturing sectors in the U.S shows that patent protection is significantly more important as the central protection for pharmaceutical inventions than other inventions. The result of his study, however, also found that patents have been increasingly used as innovation and competition strategies to prevent copying, blocking or lawsuits. See e.g. EDWIN MANSFIELD, et al., *Imitation Costs and Patents: An Empirical Study*, 91 Economic Journal, (1981)., WESLEY M. COHEN, et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S.* Manufacturing *Firms Patent (or Not)*, National Bureau of Economic Research (NBER) Working Paper No.W7552, (2000).

[20] However, according to Prof. Boyle both assumptions are wrong. There are many areas where intellectual property rights are not the best way to promote innovation and in order to get the innovation that the society desire it is necessary to have the rules that set the correct *balance* between the private property and the public domain. See JAMES BOYLE, *A Manifesto on WIPO and the Future of Intellectual Property*, Duke Law & Technology Review No.9, (2004).

[21] Between 1997 and 2007, the number of applications filed with the European Patent Office rose from less than 73,000 applications in 1997 to more than 140,000 in 2007. The applications filed worldwide increased by 34% from approximately 1,380,000 in 2000 to more than 1,850,000 in 2007 while the number of patent granted over the same period increased by 46 % from almost 520,000 patents to more than 764,000 patents. See e.g. WIPO Statistics on Patents available at http://www.wipo.int/ipstats/en/statistics/patents/; The United States Patent and Trademark Office Patent Statistics Report available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/reports.htm

69,315 in 2001 to 83,521 in 2006.[22] More than 30,000 biomedical patents have been granted in the U.S during 1997 – 2003.[23] The pharmaceutical and the biotechnology industries were also the largest receivers of patents granted in 2006; together they received 7,863 patents out of the total 173,771 patents granted.[24] The industry has been one of the fastest growing fields in term of international patent applications that were published under the Patent Cooperation Treaty (See Table 1).

Regarding the patent activities in developing countries, 39% of the applications filed in India, the main generic drug producer, during 2005-2006 were for chemicals, drugs and biotechnology.[25] With the strengthening of patent protection together with the creation of new donor-funded markets for medicines in developing countries, it is anticipated that patenting in developing countries will be more extensive than in the past.[26]

It would be great news if these increases represent growth in innovation but the story is not so simple. A stronger protection affects not only companies' incentive to invest in R&D but also their incentives to patent and enforce their patents.

Table 1: PCT Applications Published by Field of Technology

	2000	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**% Change**
Instruments: Medical Technology	5,998	7,030	7,357	8,600	8,889	9,670	11,251	12,006	100%
Macromolecular	3,640	4,223	4,545	5,242	5,705	6,226	6,515	6,168	69%
Macromolecular chemistry, polymers	3,690	4,152	4,252	4,367	4,365	4,881	5,908	5,989	62%
Pharmaceuticals & Cosmetics	7,384	9,561	9,653	9,979	9,488	11,252	13,925	14,096	91%
Biotechnology	6,795	9,282	8,996	8,605	7,663	7,504	7,422	7,308	8%
Chemical Engineering	3,851	4,455	4,767	5,367	4,907	4,950	5,685	5,899	53%

Source: WIPO Statistics Database.

[22] WIPO Statistics on Patents at http://www.wipo.int/ipstats/en/statistics/patents/
[23] FRANK GRASSLER & MARY ANN CAPRIA, *Patent pooling: Uncorking a technology transfer bottleneck and creating value in the biomedical research field* 9Journal of Commercial Biotechnology, (2002).
[24] The United States Patent and Trademark Office, www.uspto.gov.
[25] PETER DRAHOS, *Regulating Patent Offices: Countering Pharmaceutical Hegemony*, 5 SCRIPTed 501, (2008). at 503
[26] UNITAID, *Cost Benefit Analysis for UNITAID Patent Pool*, (2008). at 15

Both the patent application and the granted patent growths accompany by an increase in the number of claims per patent have posed several challenges to the system. First, the high number of patent filed increases pendency at the patent offices this in turn increases pending time and uncertainty as regard to innovations' legal status.[27] Second, the effects on patent examination process and the quality of the granted patents. Facing with high pendency rate, patent examiners may be under pressure to work faster.[28] The result is inventions that do not meet the patentability criteria may be granted which in turn lowers the quality of the patents.[29,30]

Low quality patents not only do not contribute any additional knowledge to the society but also deplete the existing stock of knowledge from the public – with patent protection knowledge that once could be used freely can no longer be used without the consent from the patent holders.

However, from a business point of view, a decrease in patent quality means the opportunity of getting patents is higher; this increases companies' incentive to patent. Consequently companies patent more and the number of patent applications and patent grants increase further. Moreover, a stronger protection also incentivizes patent owners to litigate more and the pharmaceutical companies are indeed engaging in many law suits to protect their patents.[31]

Worse is, rather than being a mean to promote innovation, patenting today to some extent has become an end in itself – some inventors patent just to preempt research efforts of others and to profit from such preemption with no intention to use the patented product or process.[32]

[27] Most investors are risk-averse and unwilling to invest if they are uncertain as who the patent owners are and whether they will be held liable for patent infringement.
[28] See e.g. COHEN, et al. *supra* note 19. The authors found that patent officers spend on average 8-25 hours on examination per application.
[29] Empirically COHEN, ET AL. found that poor quality patents increase as a result of a stronger patent protection and the one reason for such increase in poor quality patents is the lack of patent personnel. See e.g. COHEN, ET AL. *supra* note 19; MARCIA ANGELL, The Truth About the Drug Companies: How They Deceive Us and What To Do About it (Random House Publisher. 2004);JAMES BESSEN & MICHAEL MEURER, Patent Failure: How Judges, Bureaucrats, and Lawyers put Innovators at Risk (Princeton University Press. 2008).
[30] Another concern about the patent offices is their financial. Most patent offices are financed directly or indirectly by patent fees – both up front fees and renewal fees. These fees not only cover the administrative costs but also prevent low quality applications or renewal of low economic value patents. Renewal fees are, however, payable only on pending patents and granted patents. As a result patent offices have a potential bias toward granting.
[31] Pfizer, for example, stated in its 2006 business report that it will pursue an aggressive protection for its patents. See Pfizer Company Annual Report 2006.
[32] Also known as 'patent trolling'- these patent holders apply for patents in order to sell their patents to other people who want to produce the product or have unknowingly infringed the troll's patent. The patent trolls' ability to bring

B. Blocking Patents and Patent Thickets in the Pharmaceutical Industry

Proliferation of patenting activities and the associated lower quality patents have resulted in more fragmented patents and increases the number of patent per invention – the so called 'patent propensity'. These changes have led to 2 closely related problems – the 'blocking patents' and 'patent thickets' problem.

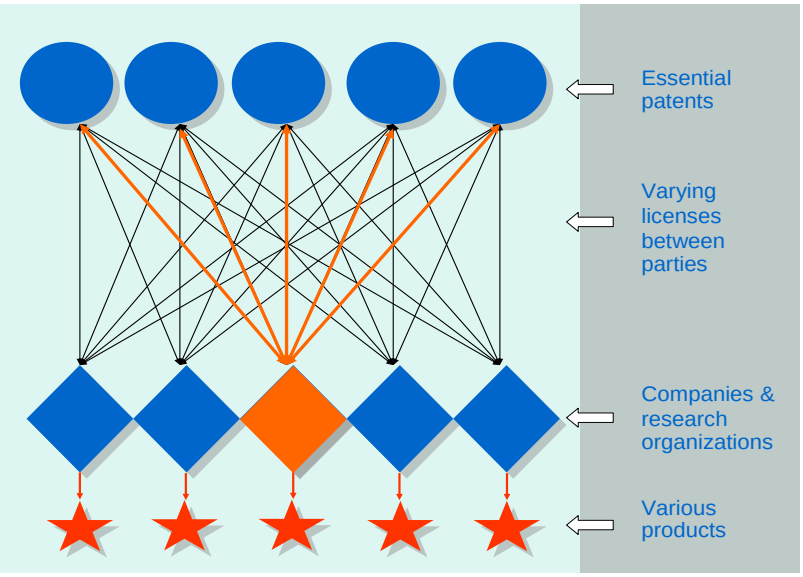
Patent rights are the right to 'exclude' in the sense that the patent holders can others from using the patented technology. Patents, however, do not always block the production of a product because other inventors can usually 'invent around' the technology contained in the patents. Nevertheless, there are some essential patents and a product cannot be made without using these patents. In such a case 'blocking patents' occur and other inventors who wish to use the patented technology have to obtain permission from the patent holders.

The increased patent propensity and patent fragmentation, however, make it more difficult for companies to invent around. This can lead to a 'patent thicket' which is a situation where a production of one product involves too many patents that are blocking one another and no single patent holder can produce the product without having obtained licenses from all other patent holders (Figure 2).[33] In such case potential producers/inventors have no choice but to license from the patent holders. However, with more patents to be identified and sought licenses for before innovation process can begin, the transaction costs increase. Moreover, in trying to get the patent licenses, these potential producers/ inventors are facing with the risk of being 'hold-up' by the patent holders and royalty stacking. Such increased uncertainty and transaction costs lessen both their expected profit and incentive to undertake the project.

down companies that actually produce and sell product have made them one of the toughest competitors in the market. Because patent trolls do not produce anything operating companies can not the counter-threat to negotiate with them. As a result operating companies have no choice but to comply with their request. See ELAHI, et al. *supra* note 2 at 92-93

[33] See Id.

Figure 2: Patent Thicket Problem



Source: Hartell (2007)

Thus, the patent exclusive rights that prevent other scientists to further their works can be harmful to the diffusion of knowledge and obstruct future research and install the whole cumulative process of scientific innovation. The consequences of blocking patents and patent thickets are delay in innovation process and decrease in social welfare - first because a delay in innovation process also means a delay of product availability in the market and; second because the higher license fees and other transaction costs are usually passed onto consumers in term of higher prices. The worst scenario is when the transaction costs involved is too prohibitive that companies decided to cease their innovation activity thereby obstructing the final development and manufacture of products.[34]. Hence, a strong patent protection has resulted in a 'tragedy of anti-commons' – a situation where many individual exclusionary rights have been given to dispersed right holders that prevent resources from being effective utilized with severe consequences on further innovation and the development and commercialization of a product or process.[35,36,37]

[34] ESTHER VAN ZIMMEREN, et al., *A Clearing House for Diagnostic Testing: the solution to ensure access to and use of patented generic inventions?*, 84 Bulletin of the World Health Organization, (2006). at 352

[35] Heller defined an anti-commons as a situation where 'multiple owners are each endowed with the right to exclude others from a scarce resource, and no one has an effective privilege of use' and 'the resource is prone to underuse'.

The potential impact of blocking patents and patent thickets on the biotechnology and the pharmaceutical industries are 2 folds. First, the impact on innovation and second the impact on access to pharmaceutical products.

1. Impact on innovation.

Impacts on innovation can be separated into impact on upstream R&D and impact on product improvement.

First, impact on the upstream R&D. The R&D process in the biotechnology industry is a cumulative process where knowledge such as genetic sequence information is essential research tools and platform technologies for future research and product development and there is the need for more research to develop more of these research tools in order to facilitate innovation.[38] The use of patent protection to protect investment in genome projects, however, can create a blocking patent that hampers other researchers' access to the information and materials crucial for future research.[39] It is possible for a patent on one isolated gene and all its fragments to block all generic testing for that particular disease.[40]

In his later work with Eisenberg, the anti-commons concept was applied to patent and the authors argued that the discovery and production of life-saving products may be delay as a result of granting too many patent rights in biomedical research. See MICHAEL A. HELLER, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 Davidson Institute Research Workshop on the Economics of Transition and Harvard Law Review, (1998)., MICHAEL A. HELLER AND REBECCA S. EISENBERG, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science, (1998).

[36] There are 2 types of externalities created by anti-commons. First, the static externalities – the fragmented rights are complementary to one another, the exercise of exclusion rights by one owner eliminates or reduces the value of similar rights held by others. Each patent holder, acting independently, does not take into account the effect of their decision on others and ask for a high license fee and, as a consequent, an inefficiently low number of licenses granted. This is under-use of resources and because productive resources under-used today may result in a lower number of products available in the future, this leads to the second externalities-the dynamic externalities. See e.g. FRANCESCO PARISI, et al., *Duality in Property: Commons and Anticommons*, 25 International Review of Law and Economics, (2005).

[37] The problems of anti-common are likely to persistent in the production of products that require highly complementary inputs supplied by independent parties. See e.g. ROSEMARIE H. ZIEDONIS, *Don't Fence Me In: Fragmented Markets for Technology and the Patent Acquisition Strategies of Firms*, 50 Management Science, (2004).; KNOWLEDGE ECOLOGY INTERNATIONAL, *IGWG Submission on Collective Management of Intellectual Property - The Use of Patent Pools to Expand Access to Needed Medical Technologies*, (2007).

[38] HEALTH. *supra* note 9 at 48

[39] CLARK, et al. *supra* note 10 at 2-3

[40] TED J. EBERSOLE, et al., *Patent Pools as a Solution to the Licensing. Problems of Diagnostic Genetics*, 17 Intellectual Property & Technology Law Journal, (2005).

The case of diagnostic genetic tests used to identify specific mutations in an attempt to assess the risk of a particular disease is one example of how patent protection can reduce rather than encourage innovation. Genetic tests can be used either as a final product or as a research tool for further research. Before performing any genetic testing it is necessary to determine mutations that are significant for identifying the carrier or for diagnosing the disease.[41] The patent thickets and anti-commons problems arise if the chosen mutations and mutational diagnostic tests are patented by different parties.[42] Any clinician who is interested in using the test to aid their patients will have to obtain a license from the patent owner. Thus, access to the product is limited and drug devilment at the downstream level is impeded because other researchers are blocked or delayed from identifying a new mutation for the disease.

In practice, there are cases on genetic patenting which reveal that the potential and threat of patents blocking innovation are real. A survey result of over 100 American laboratories, for example, revealed that patenting and licensing practices in this field had had a negative impact on both the clinical use and the development of further research[43]. A survey of 103 Indian pharmaceutical companies conducted for the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)[44] also shows that limited access to patented upstream technologies as a result of contractual difficulties was likely to have the strongest impact among variables that could determine their decision to abandon R&D projects.[45] Some laboratories have ceased to perform tests and/or refrained from test development as a result of patent enforcement policies.[46] For example, it has been reported that 30 % of US laboratories stopped developing or offering the test on after the patents were granted for the hereditary hemochromatosis genetic testing.[47] As the technology matures, the problem of patent thicket and anti-commons will become worse.

[41] See Id.
[42] See Id. at 6
[43] HEALTH. *supra* note 9 at 49
[44] The CIPIH has been set up by the WHO with the main mandate to "produce an analysis of intellectual property rights, innovation and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries. Its report was published in 2006.
[45] HEALTH. *supra* note 9 at 50
[46] ZIMMEREN, et al. *supra* note 34 at 353
[47] EBERSOLE, et al *supra* note 41 at 7

These evidences are obstacles on mainstream research of potential commercial value caused by patent thickets. Although there is little evidence about the impact of patent thickets and blocking patents in developing countries, it is expected that transaction costs on those working with limited resources on projects on diseases particularly affecting developing countries will weigh more heavily.[48,49]

Second, the impact on product improvement. Most products, including pharmaceutical products, can be improved to lower the production costs and/or increase the qualities but patent protection can put a stop to such product improvement process.

The impact of patent protection on product improvement is particularly relevant to developing countries because most modern drugs were developed to meet the developed countries markets. The developing countries' conditions are, however, very much different from the developed countries. As a result, drugs for developed countries can be further refined to better meet the developing countries specific conditions. The production of local specific drugs is in fact one of the claimed benefits the proponent for a stronger patent protection in developing countries often put forward. On the one hand empirical evidences has shown that given the small markets in developing countries, the patent incentive alone is not enough to induce such necessary adaptation from the originating companies.[50] Imposition of patent protection in developing countries, on the other hand, prevents local companies or other generic producers from using the patented knowledge to develop new diagnostics, new doses, new combinations or new drugs that better suit with their local conditions. Global welfare can increase if local companies in developing countries are able to make local adaptation which the originating companies have no

[48] HEALTH. *supra* note 9 at 50

[49] The Malaria Vaccine Initiative that seeks to develop a vaccine for malaria, for example, has spent time and considerable money to confront with more than 20 partially overlapping patents related to the antigen MSP-1. According to a representative of the Initiative developers would have to obtain licenses from at least eight organizations in order to assure of the rights to use MSP-1. Although it is possible, this type of licensing takes years, requires significant time and costs. From a business perspective, such efforts may not worthwhile for products with little commercial values such as vaccines or drugs for diseases that affect mainly developing countries. As a result, potential developers are more reluctant to invest in such cumbersome technology acquisition process. See Id.

[50] The Treatment Timebomb. pt. (2009). at 64

interested in doing.[51] Hence, the availability of patent protection in developing countries has prevented them from having more effective and efficient products.

The case of HIV/AIDS fixed dose combinations used in most developing countries is an example of how patents impede further development. Compare to taking several pills of different quantities and at different times of the day, a single tablet of fixed dose combinations is easier to take which, in turn, improve adherence which is the most important factor for an effective treatment. The fixed dose combinations are also cheaper and easier to ship and store.

In the past these fixed dose combinations were developed as a response to market demand rather than patent incentives. The development was possible due to the absence of pharmaceutical patent in most developing countries especially India where most major generic producers are. These fixed dose combinations have not been patented this, in turn, shows that R&D can be viable and profitable even without patent protection. However, pharmaceutical product patents are now available in India. As a consequent any company wishing to develop a new fixed dose combination or co-package therapy will have to acquire all necessary patents before any development process could begin.

2. **Impact on access**.

The exploding costs of drugs are one major factor contributing to the growing skepticism on the patent system as a mechanism to support pharmaceutical research. The patent monopoly rights have been claimed as the main cause of high drug prices that deprived many people from their essential life-saving drugs especially the poor in developing countries. The problem of pharmaceutical patent protection is it creates a big gap between the prices and the production costs which not only makes drugs unaffordable in many cases but also leads to a huge amount of economic inefficiency.[52] Compare to other trade barriers which raise products prices by 10-20%, on average patents on drugs raise the prices by more than 300 – 400 % above the competitive

[51] For welfare effect of pharmaceutical patents in developing countries see e.g. KEVIN OUTTERSON, *Fair Followers: Expanding Access to Generic Pharmaceuticals for Low- and Middle-Income Populations, in* THE POWER OF PILLS, (Jillian Clare Cohen, et al. eds., 2005).
[52] DEAN BAKER, Financing Drug Research: What are the Issues? (2008).

market price and have estimated to have caused inefficient 'deadweight loss'[53] of approximately $25 billion in 2004 – the amount that is roughly comparable to the amount of research currently supported by the patent system.[54] It is projected that patent supported drugs will lead to higher distortion in future; therefore, it is necessary to look for a strategy that would deal with the problem of access to pharmaceutical products.[55] The problem of access to HIV/AIDS drugs to the poor has 'alerted much of the world to the darker side of intellectual property protection'.[56]

The high transactions costs resulting from patent thickets and blocking patents intensify the access problem by discourage generic drug companies from entering into the market. The competition in the market will reduce and the consequences of this are not only prices will remain high but the variety of products available will also lower too. The reason for this is companies in a monopolistic market are less innovative than companies in a competitive market. As a result there will be no or less drugs specific to developing countries' conditions.

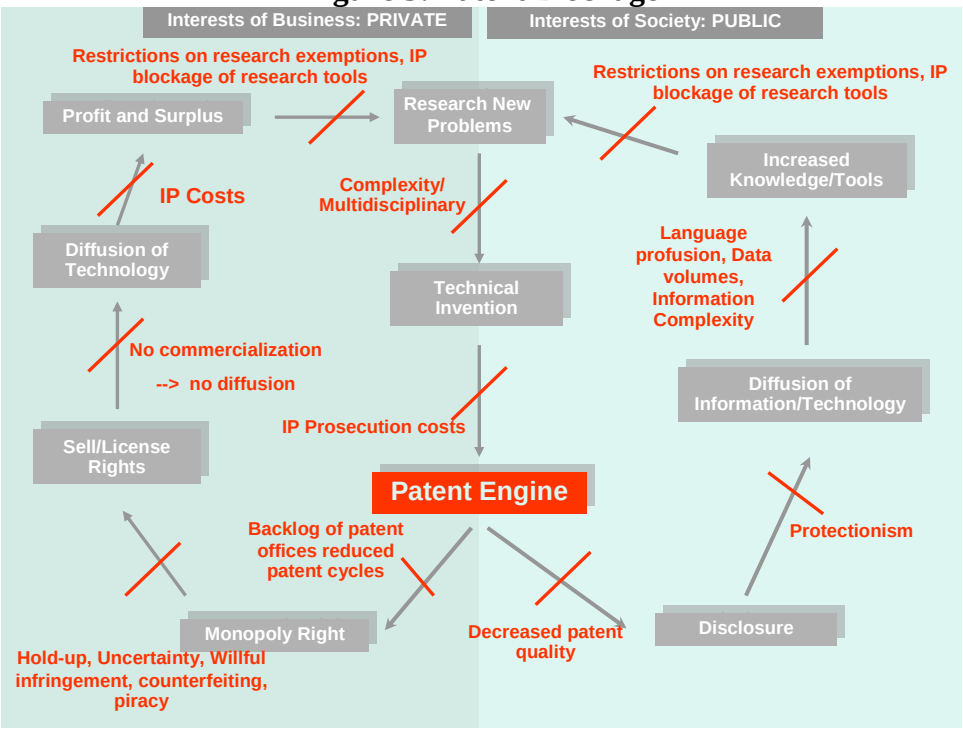
In sum, the empirical results seem to suggest that the problem of blocking patents and patent thickets exist in biotechnology and pharmaceutical industries. The escalating number of overlapping and fragmented patents and the associated transaction costs can lower industry's return on investment to the point that innovative investments are actually less than they would be without patents.[57] Hence, rather than being an incentive for companies to invest in innovative activities and a society's knowledge diffused tool as it was intended, the current patent system seems to have led to a 'blockage' throughout the system (Figure 3).[58] This has led to a

[53] A loss of economic efficiency resulting from a decrease in beneficial transaction caused by from monopoly pricing - with a higher monopoly price, consumers who are willing to pay more than the production costs but less than the monopoly price charged will not buy the product.
[54] See BAKER. *supra* note at 2
[55] See Id.
[56] ROCHELLE C. DREYFUSS, *Introduction: Designing Intellectual Property Institutions for the Twenty-First Century*, 12 The Journal of World Intellectual Property, (2009).
[57] RONALD J. MANN, *The Myth of the Software Patent Thicket.* , bepress Legal Series. Working Paper 183, (March 11, 2004). at 58
[58] A report prepared for the European Commission argued that as a result of the technology market failure to deal with the problem of assembling necessary intellectual property rights, at some point the fragmentation of intellectual property rights among agents starts to impede progress while an OECD report on the business sector's innovation estimates a stronger intellectual property protection to have a significant positive impact on patenting but may have negative impacts on the diffusion of technologies. According to the EPO Scenarios for Future, the "disadvantage of rigid patent protection is that it may slow the process of innovation, by preventing competing companies from building on each other's progress". This fact has been recognized by business executive as well. Bruce Sewell, general counsel of Intel, for example mentions that "the patent system, if not reformed, will…begin to impede American competitiveness around the world". See H CAMERON, Strategic Dimensions of Intellectual Property

fundamental question of whether patents promote innovation at all[59] and 'there is a growing consensus that something needs to be done to minimize technology blocking'.[60]

The next part will illustrate how a collective rights management system like patent pools can be used as one possible mechanism to solve both the problem of R&D and access caused by patent thickets and blocking patents.

Figure 3: Patent Blockage



Source: EPO Scenarios

III. PATENT POOLS

Blocking patents and patent thickets are resulted from too many fragmented exclusive rights over one invention have been granted. The best solution is therefore to not granting such patents; nonetheless, this solution may not be possible under the current system of most nations and

Rights in the context of Science and Technology Policy (European Commission Publication. 1999).; Patents and Innovation: Trends and Policy Challenges. pt. (2004)., ELAHI, et al. *supra* note 2 and CUKIER. *supra* note 1

[59] Observers have begun to wonder whether exclusive rights are needed at all. Scholars have argued that by reducing to cost of creating and distributing innovative materials, new technologies render exclusivity unnecessary and make intellectual property protection unhelpful. See e.g. ELAHI, et al. *supra* note 2; DREYFUSS. *supra* note 56

[60] ELAHI, et al. *supra* note 2 at 92

cannot be used to solve the problem of already granted patents. Moreover, the problem got noticed only as a result of such grants.[61]

The other solution is to reduce transaction costs by re-aggregating the fragmented rights back into an efficient bundle. However, each patents owner - in their attempt to re-aggregate the fragmented rights - is faced with the transaction costs and strategic costs. When there are many patents involves the tasks can be complicate and the costs associated can be higher than the benefits for any individual company. The result is similar to any other market failure cases - when the private costs outweigh the private benefits the product is either not produced or under-supplied despite the fact that the benefits to the society are higher than the costs. (The reason why companies do so will be illustrated using game theory in the later section of this part). In response to this market failure, institutions that 'bundle' the fragmented rights together in a useable and accessible unit, "moving from too many owners, each exercising a right of exclusion, to a sole decision maker, controlling a bundle of rights" are needed to simplify and reduce the transaction costs associated with patent licensing.[62] In practice this kind of collective right management institutions has been taken place, with the impetus not from lawyers or policy makers but the business sectors themselves.[63] This part will analyze the possible use of a 'patent pool' which is one of such mechanisms in the pharmaceutical industry.

A. Definition & Concept

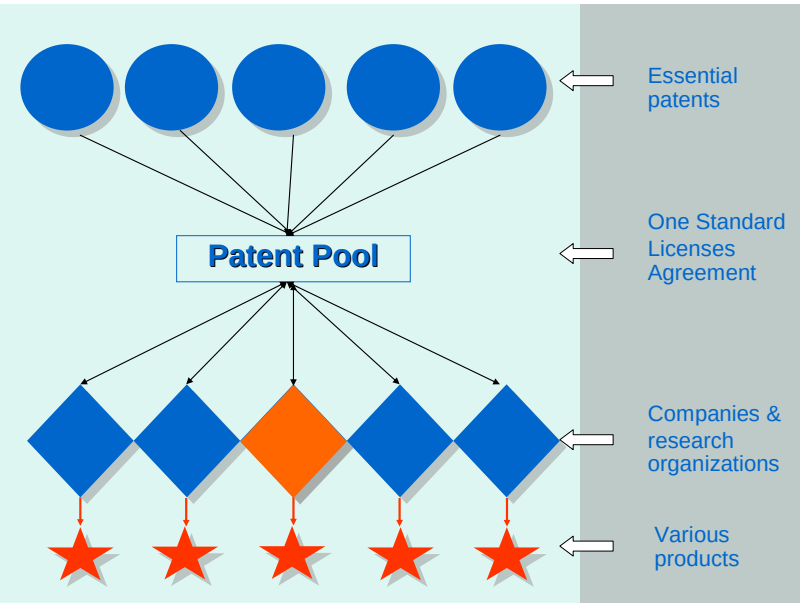
There is no precise definition for a patent pool but in general a patent pool can be defined as an agreement between two or more patent owners to aggregate their patents and to license them to one another and/or to third parties, whether directly by patentee to licensee or through an entity set up specifically to administer the pool.[64] Standard licensing terms are usually offered and a

[61] See HELLER. *supra* note 35
[62] See Id. at 670
[63] See CUKIER. *supra* note 1 at 8
[64] ROBERT P. MERGES, Institutions for Intellectual Property Transactions: The Case of Patent Pools (University of California at Berkeley (Boalt Hall) School of Law 1999).

portion of the licensing fees is allocated to patent owners according to the pre-determined formula or procedure.[65]

In the absent of a patent pool, licensees will have to engage in a negotiate process with all patent holders. When there are many patents involve such negotiation process can be difficult and expensive to the point of practical impossibility. A patent pool replaces the system of an individual bargain for each transaction with a 'one stop shop' where licensees can acquire all necessary licenses without having to seek license from each individual patent holder. By bundling all necessary rights together in the most efficient unit (Figure 4), patent pools have been able to simplify the negotiation process and reduce companies' transaction costs and enforcement costs significantly. [66]

Figure 4: Patent Pool



Source: Hartell (2007)

[65] Collective Management of Intellectual Property - The use of Patent Pools to expand access to essential medical technologies. pt. (2007).; DAVID SERAFINO, *Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures*, KEI Research Note 2007:6, (2007).; MERGES. *supra* note 64

[66] See e.g. CLARK *supra* note 10, CLARK, et al;MERGES. *supra* note 64

Patent pools are not new. The system has been used to solve both upstream R&D and downstream access problems. One prominent example of the early patent pools is the Manufacturers Aircraft Association (MAA), the government intervention aircraft pool created in 1917 among almost all U.S aircraft manufacturers in order to overcome patent barriers for scaling up aircraft manufacturing which was very crucial as the U.S was preparing to enter World War I.[67,68]

In recent years patent pools are frequently used to solve the problem of blocking patents in technologies fields that require interoperability standards such as the MPEG_2 compression technology[69], the DVD-ROM and the DVD-video.[70,71] The main driving force for these pools' establishment is the common standards. In industries with standards, access to the standard's essential patents is very important as non-conformance would result in the product that cannot be operated with other systems and will not be produced. However, standards often associated with patents hold by several different companies.[72] As a result, companies have to cross-license in order to be able to produce and commercialize their products. In order to reduce the time and

[67] INTERNATIONAL. *supra* note 35

[68] The MAA was a response to the U.S government policy. Prior to the pool formation, most of the essential patents on airplane manufacturing components were held by the Wright brothers and Glenn Curtiss. The royalties charged were high, the time and costs involved in litigation made the industry production nearly come to a halt at the time when the U.S needed to purchase more airplanes for use in World War I. Formation of a patent pool was recommended, backed by the Naval Appropriations Act of the fiscal year 1918 which allocated $1 million 'for the purchase or condemnation of basic aeronautic patents'. The pool started with eleven aircraft manufacturers and would expand to include all important manufacturers of aircraft the federal government purchased. After formation of the pool, the royalty charged fell from $1,000 per patent per plane to a package of $ 200 for all patents; the rate charged was reduced to $100 in the following year. As a result of the pool, the costs of airplane declined, supply increased and innovation skyrocketed. See SERAFINO.

[69] MPEG-2 is a video compression technology that reduces the number of bits in a file which, in turn, makes video available over a lower bandwidth carrier and easier and faster to transmit. MPEG-2 patent pool, created in 1997 by Columbia University, Fujitsu, General Instrument, Lucent Technologies, Matsushita, Mitsubishi, Philips, Scientific-Atlanta and Sony; offers non-discriminatory access to patents 'essential' to the 'MPEG-2 Video and Systems coding standards used in set-top boxes, DVD players and recorders, TVs, personal computers, game machines, cameras, DVD Video Discs and other products' against 'fair, reasonable and non-discriminatory' royalties. The royalties collected are shared among the pool's participants. According to MPEG LA, the independent agency that administrates the pool; 'Wide acceptance of the MPEG-2 Patent Portfolio License has helped produce the most widely employed standard in consumer electronics history'. http://www.mpegla.com/main/programs/M2/Pages/Intro.aspx

[70] The first patent pool for DVD is DVD3C formed in 1998 by Sony and Phillips who also acts as the pool licensor. Pioneer and LG agreed to join later. The objective of the pool is to provide a 'one stop shopping' of all essential licenses for the manufacturing of DVD products. The second pool the DVD6C was created in 1999.

[71] INTERNATIONAL. *supra* note 35, SERAFINO. *supra* note 63

[72] The implementation of MPEG-2 standard, for example requires more than 895 essential patents hold by almost 30 different entities worldwide. For more information on MPEG-2 standard see e.g. http://www.mpegla.com/main/programs/M2/Pages/Agreement.aspx

transaction costs involved, patent pools have been set up to simplify and regularize these transactions.

Contrary to the way they organized, patent pools are a technology transfer system that can be pro-competitive.[73] Past patent pools have shown to increase competition both at the upstream R&D level and downstream production levels and proved to be very useful and essential for the utilization of and promoting investment in new innovations.[74] According to the U.S Department of Justice and Federal Trade Commission, 'intellectual property licensing allows companies to combine complementary factors of production and is generally pro-competitive'.[75] There are at least 4 favorable outcomes that can be achieved via patent pools. First, it reduces licensing transaction costs. Second, it removes blocking patents, reduces or eliminates litigation risk. Third, it permits and encourages wider use and adoption of the pooled technology which increase the rate of return on R&D. Forth; it spreads risks and benefits of technology implementation among players in the field.[76]

B. Pharmaceutical Patent Pools

The problem of blocking patents and patent thickets in biotechnology and its potential adverse affect on global health have been recognized by various stakeholders including government agencies of the U.S that are in favor of a strong patent protection and the pharmaceutical industry itself.[77] Patent pools have been recommended as a mechanism to deal with both the problem of blocking patents in biotechnology industry and access to pharmaceutical products. A study by the U.S. Patent and Trademark Office on patent pools and biotechnology patents, for example, states that "The use of patent pools in the biotechnology field could serve the interests of both the public and the private industry, a win–win situation".[78] The CIPIH recognizes that patent pools of upstream technologies may be useful to promote innovation and recommends the WHO and WIPO to play a bigger role in promoting the creation of patent pools where it would

[73] See GRASSLER & CAPRIA. *supra* note 21
[74] See INTERNATIONAL. *supra* note 35 at 2
[75] U.S. DEPARTMENT OF JUSTICE AND THE FEDERAL TRADE COMMISSION, Antitrust Guidelines for the Licensing of Intellectual Property (U.S. Department of Justice and the Federal Trade Commission ed., 1995). at 2
[76] See GRASSLER & CAPRIA. *supra* note 23
[77] See EISENBERG. *supra* note 35 , CLARK, et al. *supra* note 10
[78] See CLARK, et al. *supra* note 10

facilitate product development.[79] The OECD considers the patent pools for biotechnology to be interesting but calls for further study as to whether the amenability to pools of the technologies and markets for generic inventions.[80] At the production level, patent pools have been proposed as a mechanism to mitigate the problem of access to drugs in developing countries.[81] This section will show how patent pools can be used not only to solve the problems of innovation and access caused by the increased transaction costs resulting from patent thickets but also the problem of low quality patents which is the origin of the patent thicket problem.

1. Pharmaceutical innovation

As already seen from the previous section - access to knowledge is important for modern innovation process and more patenting activities increases companies' transaction costs and discourages R&D investment in the biotechnology and pharmaceutical industries. Nevertheless, patent pools which have been used to solve the problem of high transaction costs in the electronics and telecommunication industries can be used in biopharmaceutical industries as well.

Most existing drugs can be improved further but the current environment of the pharmaceutical industry does not stimulate such improvement. The reason is the current pharmaceutical industry is relatively concentrated with most of the products in the market supplied by a handful of multinational companies. Facing with a low level of competition in the market, naturally pharmaceutical companies have less incentive to invest in R&D for new product and/or product improvement than companies in more competitive markets.

The pharmaceutical industry has been able to maintain its rather monopolistic market partly because of the existence of patent protection which acts as an entry barrier for potential companies. Potential companies may see the business opportunities but refrain from entering into the market because the difficulties in getting all the necessary knowledge. Since companies will enter into the market only after they have developed their expertise, the absent of universal access to new drugs' manufacturing process knowledge is one reason that attributes to a fewer

[79] HEALTH. *supra* note 9 at 52
[80] ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, *Genetic Inventions, Intellectual Property Rights and Licensing Practices-Evidence and policies*, (2002).
[81] See UNITAID, *The Medicines Patent Pool initiative*. (2009), at http://www.unitaid.eu/images/projects/PATENT_POOL_ENGLISH_15_may_REVISED.pdf., HEALTH. *supra* note 9

competitors in these markets.[82]The increased transaction costs as a result of a stronger patent protection intensify the problem.

As a result a pharmaceutical patent pool that reduces the transaction costs for obtaining the patented knowledge can encourage more entries from generic companies. The competition bought forward by these new companies will, in turn, increases innovation in the market.

A pharmaceutical patent pool can be an important tool for local R&D investments in developing countries that usually do not have the infrastructure and capacity necessary for break-through inventions. The local companies are, nonetheless, capable of doing minor improvement and able to increase drug efficacy by modifying the existing drugs to meet their specific conditions.

The problem is patents of most modern drugs are held by multinational companies. As a consequent, any local company wishing to adapt these drugs to the meet the local conditions will have to incur high transaction costs in trying to obtain all necessary patents. The recent strengthening of pharmaceutical patent protection has further increased patenting activities and transaction costs of companies in developing countries. This, in turn, lessens local companies' incentive to invest in drug improvements. Transaction costs matter more for local companies in developing countries than for multinational companies. The reason is developing countries' markets are rather small and the purchasing powers are low. As a result local companies neither can sell a large quantity of product at a low price nor sell at a high price for a small quantity of product to recoup their necessary investments including the patents licensing related transaction costs. For this reason, any increase in their costs will have major impact on their incentive to invest in R&D.

A patent pool that pools all essential patents together can lower transaction costs of all potential manufacturers and inventors. This, in turn, increases companies' expected profits and incentive to investment in R&D or product development. A patent pool also increases certainty with regard to the patents' status. With the presence of a pool of all essential patents, companies can invest in their R&D project without having to fear that they might be hold up by a holder of an essential

[82] See UNITAID. *supra* note 26 at 12

patent or face with royal stacking. Patent pools can, therefore, increase innovating activities that would lead to more new drugs and drug improvements in developing countries.

2. Access to drugs

Although there are many explanations for the problem of access to drugs, the first-order explanations lays in the current structure of the intellectual property regime that delays the sale of generic drugs and keeps drug prices high.[83] This is especially true for developing countries where the incomes are low and the local production does not exist. Multinational companies, on the one hand, have no incentive to lower the prices in developing countries in the absence of local competition[84]. Strengthening of patent protection, on the other hand, lessens local companies' incentive to produce by reducing their expected profits. Market competition, as a result, declines further. A patent pool that lower transaction costs can increase local production and increase competition which drives prices down and boosts quantities supplied.

In addition to the problem of transaction costs associated with patents, patent pools can be used to address other intellectual property issues relating to access to affordable drugs such as the use of clinical trial data for drug registration. Pharmaceutical industry has long claimed that a strong patent protection is necessary for the industry to recoup its high investments. Study, however, shows that about 70% of these expensive investments are spent on the clinical trials which is the least innovative process but necessary to prove that the drug is reasonably safe and effective. The results from these clinical trials results are protected as undisclosed information under the current intellectual property system but they too can be shared and used by other companies. The originating companies will receive royalty that covers the costs of conducting the trials while the licensees can save both time and money from having to conduct similar trials. Pooling of such information will reduce redundant investments significantly. The resources saved can be use for other projects. The overall investment costs per drug to the society will be lower. Moreover, as the number of people using the product increase because of the reduction in price, companies would be able to expand their production and enjoy the economies of scale and; in some case,

[83] Processes and Issues for Improving Access to Medicines: Willingness and Ability to Utilize TRIPS Flexibilities in Non-Producing Countries. pt. (2004).

[84] In addition to the lack of local competition, multination companies are charging high prices in developing countries partly to circumvent parallel imports which will reduce profits in other high-profits markets such as those in developed countries.

economies of scope and the drugs can be produced at greatly reduced costs. Such reduction in costs will be returned to the society in term of lower drug prices which in turn increases overall access.

As production costs decreases, the need for a strong protection as well as the negative effects of a stronger protection will reduce as well. Rather than concentrating on the strategy of selling a small number of units at high prices, pharmaceutical patent pools use the alternative strategy that is selling a larger quantity at a lower margin. The industry can maintain its profit at the same level by using either strategy. The benefits to the society is, however, much higher with the later strategy.

A pharmaceutical patent pool can influence competition and prices even when the patent owners are not parties to the pool. This is because the existence of the pool enhances global norm for open competition which in turn raise expectations for a product price to be closer to its manufacturing costs.[85] In case of AIDS drugs, it has been estimated that open licensing of via a patent pool could reduce the prices of second line treatments by 50% below originator prices in low-income countries and by 70% in middle income countries.[86]

Hence, a pharmaceutical patent pool can mitigate both the problem of innovation and access to drugs at the same time.

3. Patent quality

Both the industries and the academic studies seem to focus their attentions on the role of patent pools in promoting innovation and increasing access to drugs. But patent pools can improve patent quality and mitigate the patent thicket problem at its cause as well. As already seen from the beginning of the paper that a patent thicket is caused by the increasing number of patents especially the low quality patents, patent pools can solve the problem of low quality patents through the income incentives they create.

Only essential patents will be included in and receive loyalties from the pool to recover their R&D investments. Patent pools as a consequent changes patent holders' return on investments

[85] See UNITAID. *supra* note 26 at 16
[86] See Id. at 17

from monopoly prices to license fees. Unimportant patents, including all low quality patents, will not be included in the pool and the licensing of these patents has to rely on an individual transaction basis. There are 2 ways patent holders can earn revenues – license fees and (high) product prices. However, the chance for these unimportant patents to get licensed or licensed with a high royalty is lower when there is a patent pool with a collection of all essential patents. The unimportant patents will not be able to recoup their investment from the traditional method of charging high product price too because their products will have to compete with the products produced by the holder of essential patent and/or patent pool's licensees.

Therefore the best solution for the patent owners is to invent in something that is truly innovative and essential for their patents to be included in the pool. As companies compete, race to the top in innovation process will occur and the society is better off by the competition which has been bought about by patent pools. The pools will act as an additional gatekeeper against bad patents and the social disaster resulting from granting a low quality patent will not be as severe as it might have been.

C. Patent Pools and Competition Laws

Patent pools 'bundle' rights together, thereby, subject to competition laws. Recognizing the increasingly important of patent pools to the scientific progress and social welfare, competition authorities of the world's three major economies have laid down principles for the establishment and administration of patent pool. These guidelines include the 'Antitrust Guidelines for the Licensing of Intellectual Property' (U.S Guidelines) issued in 1995 and the 'Antitrust Enforcement Intellectual Property Rights: Promoting Innovation and Competition' (the IP Report) issued in 2007 by the U.S Department of Justice and the Federal Trade Commission, the 'Commission Regulation (EC) No. 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements' (EC Regulation) issued by the European Commission and, the 'Guidelines on Standardization and Patent Pool Arrangements' (Japan Guidelines) issued by the Japan Fair Trade Commission. These documents identify major factors on which the responsible authority is likely to base its judgment of competitiveness

Though these guidelines and report do not create any law or regulation that is legally binding on a pool formation, they reflect the view of the authorities responsible for anti-competition issue

assessment and can be treated as definitive. The position expressed in these documents is that on balance a patent pool must be pro-competitive rather than anti-competitive. However, it is recognized that patent pools that integrate complementary technologies are on balance pro-competitive. The U.S Guideline, for example, states that 'by promoting the dissemination of technology, cross-licensing and pooling arrangements are often pro-competitive'.[87] According to the Guidelines, the pro-competitive effects of a patent pool include 1) integrating complementary patents, 2) reduce licensing transaction costs, 3) clear blocking patents, 4) reduce infringement litigation costs.[88]

Nonetheless, this does not mean that the use of patent pools is without any problem. Pooling of patents can have anti-competitive effects in some circumstances. Many patent pools of the 19th century were in fact used to create cartel and fix prices.[89] To avoid the anti-competitive effects which the pool intends to promote as well as running afoul of competition law, the license terms and conditions will have to be carefully crafted. In order to promote innovation and avoid anti-competitive effects, the following are some of the major elements that need to be considered cautiously:

1. Patents

Theoretically patent pools that combine valid 'complementary patents'[90] are pro-competitive if their licensing terms do not restrict downstream production.[91] This means the pool shall include only patents that are essential to the technology under consideration. Whether a patent pool contains only essential or not is indeed one of the main factor the DOJ and FTC used to determine the pool's compliance with their enforcement principles.[92, 93] Determination of essentiality is rather straightforward for technology with standards. A patent is deemed essential

[87] COMMISSION. *supra* note 75 at 28
[88] For a survey of changes in the U.S. antitrust policy toward patent pools see RICHARD J. GILBERT, *Antitrust for Patent Pools: A Century of Policy Evolution*, Stanford Technology Law Review (2004).
[89] For a survey of previous pools and their objectives see SERAFINO. *supra* note 65
[90] Patents are complementary when their claims cover the same areas, and utilizing the technologies of one patent cannot be done without utilizing the technologies of the other.
[91] U.S. DEPARTMENT OF JUSTICE & FEDERAL TRADE COMMISSION, Antirust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition (2007).
[92] RICHARD GILBERT, *The Essentiality Test for Patent Pools* UC Berkeley: Competition Policy Center. *at* http://escholarship.org/uc/item/1wf59608. at 2
[93] In the DVC3C patent pool case, the DOJ has included patents that compliance with the standard are inevitably infringing it and patents that economically unfeasible as essential patents.

if it cannot be substituted by other technology inside or outside the pool and it constitutes a necessary part of the package of technologies for the purpose of producing the products or carrying out the process to which the pool relates.[94] When essential patents are complements to the standard' s implementation, licensing by an entity that pools all complement patents together like a patent pool is relatively more pro-competitive than individual licensing.[95] The reason is with individual licensing; each patent holder will not take into account the effect of the royalty he charged on the demand for other patents necessary to implement the standard (the externalities) and charges high royalty. Because licensees are faced with 'double-monopolization', their demand for patents necessary to implement the technology reduces. These externalities will be internalized in the patent pool and the royalty the pool charges will be lower than the total of royalties charged by individual patent holder.[96]

A patent pool that includes substitute patents[97] can eliminate competition between patent holders that lead to higher product prices.[98] In addition the exchange of competitively sensitive information such as pricing, marketing or R&D information via the pool can facilitate collusion which also leads to higher prices.[99]

2. License terms

The effects of a patent pool on market competition which in turn affect innovation in the industry and access to the products depend very much on the terms and conditions of the pool's license agreement. Some important license terms include the following:

a. **In-license (license to the pool):** for a product to be produce at a lower cost over time, both the pool's licensors and licensees need to be able to combine technology either to compete or improve the pool technology. The in-license should be non-exclusive where the licensor retains the right to use the licensed technology and associated patents include licensing to other parties outside the pool. Non-exclusive licenses enable inventors to invent around the pools' patents to compete with the pool which promotes

[94] See Gilbert *supra* note 93 at 11
[95] See Id.
[96] See e.g. SHAPIRO *supra* note 4
[97] Patents are substitute when either patent can be used to produce the product.
[98] For example of a patent pool see the case of Summit-VISX alternative surgical procedures.
[99] See COMMISSION *supra* note 91 at 67

innovation. Exclusive license, however, can be pro-competitive and desirable if it provides the licensee the incentive to invest in complementary assets.[100] This, in turn, has to be determined taking into account the specific facts of the pools.

b. **Out-license (license from the pool):** according to the U.S Guideline patent pool does not need to open to all who would like to join. However, it also recognizes that under some circumstance exclusion among parties that collectively possess market power may harm competition and subject to the Agencies' evaluation as to whether such exclusion is reasonably related to 'the efficient development and exploitation of the pooled technologies'. Anti-competitive effects are likely to result from vertical restrictions or other restrictions that affect competition related to the patented products or processes.[101] Hence, a patent pool is unlikely to inflict anti-competition concerns if licensees are not prevented from developing alternative technologies.[102]

c. **Grant-back provision:** a grant-back is 'an arrangement under which a licensee agrees to extend to the licensor of intellectual property the right to use the licensee's improvements to the licensed technology'.[103] A grant-back can have anti-competitive effects if it lowers rivalry in innovation markets by significantly reduces the licensee's incentives to invest in R&D. However, a grant-back can be pro-competitive as it allows licensor and licensee to share risks and allow the licensor to use the information of the licensee for the licensor's future innovation. As a result, the incentive for both the initial innovation and the subsequent licensing of the innovation's results are strengthened. This is especially true for a non-exclusive grant-back which allows the licensee to license his/her technology to other parties outside the pool. According to the U.S DOJ and FTC such a non-exclusive grant-back may be crucial to ensure that the licensor can effectively competing by having access to the improvements developed from his/her technology. Under the U.S. laws, grant-back provisions will be evaluated under the rule of reason. The subsequent innovations, however, should be license back to the pool and the licensee should receive royalties from his/her innovations. Nonetheless, only essential subsequent innovation should be included in the pool.

[100] See Id. at 79
[101] See GILBERT *supra* note 92 at 10
[102] See COMMISSION. *supra* note 91
[103] See Id. at 80

d. Royalty: royalties charged should be fair, reasonable and non – discrimination or the so-called 'FRAND' term. At present there are several formulas available. Nevertheless, the chosen formula should tie to the amount of drug sales to incentivize voluntary participation from the patent holders' side. As new patents are added the royalties distributed to the patent holders will have to be redistributed. The antitrust authority, in general, does not assess the reasonableness of the pool's royalty.[104] The U.S DOJ has noted in the MPEG-2 and DVD pools Business Review Letters that royalties are unlikely to be use to coordinate downstream prices when they are only a small part of the downstream prices. However, this does not necessary mean that royalties which are a large part of the downstream prices would raise concerns and other indications of price coordination are needed for the Agencies to begin their investigation. Moreover while investigating alleged price coordination, the Agencies may investigate the structure and amount of royalties each licensee pays. However, different royalties faced by different licensees by themselves are not presumed to be anti –competitive.[105]

e. Other intellectual assets: beside patents, there are other intellectual assets associated with an invention. For example, the technology know-how and, more importantly for the pharmaceutical industry is the undisclosed information related to clinical trial data mentioned earlier. To make the most of the resources already invested in developing a drug and lower the drug development cost, thereby reducing drug prices as much as possible; the pool management should consider the inclusion of clinical data in its license. With access to clinical data, out-licensees will be able to focus on other aspects of the test rather than repeating the test previously done by the patent holder. The development and production costs of the licensees (generic producers) will be lower than it without such data license this, in turn, enable them to afford a higher license fees. Patent holders, on the other hand, knowing that they can recoup the costs of their clinical trial through by license the result of their clinical trial, will have more incentive to conduct clinical trial. Other intellectual property beside patents can be licensed together with the essential patents in a single package or can be offered as an optional separate package in addition to the essential patent license.

[104] See Id. at 82
[105] See Id. at 83

f. Access to Information: From the social point of view, care has to be given to competitively sensitive information of the licensors and licensees which the pool administrative agency has access to while administering the pool. The licensors and licensees may compete against one another at the downstream product development level and patent pools can be used a mechanism that promote price coordination which reduces competition in the market

3. Patent Pool Management

The objective of the pool is to provide reasonable access to licensees and reasonable return to patent holders. As a result an impartial and independent administrator that is neither a licensor nor a licensee is needed to assure impartial administration of the pool. The administration of the pool should include an independent expert that identifies and evaluates essential patents relate to the R&D and product development of a particular disease. It may be desirable that the pools have an independent and neutral dispute resolution mechanism.

D. Pharmaceutical Industry Incentives for Participating in Patent pools

In principle patent pools can be used to solve the problem of access to both the knowledge necessary for further innovation and the products in pharmaceutical industry in a similar way as in the electronics and telecommunication industries.

Nonetheless, the pharmaceutical industry has some characteristics which perceived to be fundamentally different from these industries. First, contrary to the electronics and telecommunications industries where each product involves a large number of patents, pharmaceutical products are rather discrete and the number of patents per one invention is smaller. The problem of patent thicket may not be as severe as those in electronics and telecommunications industries. Nevertheless, the problem of blocking patents can be quite severe for a particular drug's further R&D. [106]

Despite a smaller number of patents involved, getting all the necessary licenses can still take considerable time and resources, patents thereby can be barriers for further development of new and superior products. A single vaccine, for example, could include patents on 'the antigen

[106] See The Malaria Vaccine Initiative *supra* note 49

needed to produce the proper immune response, including its DNA sequence and particular expression; the adjuvant, which is used to facilitate a person's response to an antigen; the recipient, which is the substance and antigen and adjuvant are stored in; the vaccine itself; and finally, its method of delivery'.[107]

Second, while standards for interoperability of devices in the ICT sectors have been the main driving force for the establishment of a patent pool, such kind of standard does not exist in the field of pharmaceutical and biotechnology.[108] The absence of standard means there is no standard setting body to initiate a basis of norms on how companies should behave while companies acting on their own interests have little incentive to set up a pool despite the potential benefits of knowledge sharing the pool would bring to the companies and society. The pharmaceutical industry is, in fact, one of the few industries which are doing well financially with a strong protection under the current patent system.[109] The reason is a stronger patent protection lowers market competition in the industry. Hence, pharmaceutical companies not only have no incentive to set up a patent pool but also not willing license their products to competitors. The rationale of proprietary companies' unwillingness to license their essential patent to the other company can be illustrated using the following game theory example.

Suppose the production a fixed dose combination X (a combined of drugs A and B) requires patents of 2 drugs - for simplicity, assume that each drug has only one patent. These 2 patents are hold by 2 different companies named after their drug – A and B. The companies' market shares which dependent on their patent licensing decisions are shown in the following table.

[107] KAITLIN MARA, Experts Discuss Policy On Patent Landscapes For Life Sciences § December 5, 2009 (2008).
[108] Some authors, however, have suggested that a standard for genetic can be created too, not in term of technical specification but rather as a set of mutation recognized by international specific community or reflecting best practice guidelines for genetic testing for a specific disease. See e.g. GEERTRUI VAN OVERWALLE, et al., *Dealing with Patent Fragmentation in ICT and Genetics: Patent Pools and Clearing Houses*, 12 First Monday, (2007).
[109] See ELAHI, et al *supra* note 2

Table 2: Market share Matrix

(Company B, Company A)

		A	
		License	Not license
B	License	Scenario 1, (0.5, 0.5)	Scenario 2, (0, 1)
	Not license	Scenario 3, (1, 0)	Scenario 4, (0,0)

When making decision whether to license its patent to the other party or not, each company takes the other company's decision into consideration. Company B's decision to license or not, for example, depends on Company A's licensing decision. If Company A licenses its patent to Company B, Company B would have incentive not to license its patent to Company A because its market share would be higher if it does not license (1) than if it licenses (0.5). The reason is if it does not license its patent to Company A (Scenario 3), it will be the sole producer of X and can earn monopoly profit which is higher than oligopoly profit it would get from licenses to Company A and each shares half of the market (Scenario 1).

However, if Company A decides not to license, Company B will not be able to produce as a result its market shares are equal regardless of its licensing decision. Company A's market shares are, however, different. If Company B licenses its patent to Company A, Company A will be the only producer in the market. But if Company B does not license, no one can produce the product. From business point of view Company A prefers scenario 2 because it can earn monopoly profit. With the same reason Company B prefers scenario 3. The optimal scenario for the society is, however, scenario 4 as it gives the society the highest welfare (the price is lower in oligopoly market than in monopoly market). Though scenarios 2 & 3 are not optimal for the society, it is preferable than Scenario 4 when the product is not produced at all. Unfortunately, Scenario 4 is what the society would end up with. The reason is, although 'not license' decision from the other company does not affect the market share of X of a company that licenses but does not get the license in return, it affects its market share of A&B because X is a combination of A&B. The presence of X would reduce demand for A&B, the revenue of the sole provider of X will be

compensated by the sale of X but the other company will not get any compensation for the lost of its sales in A (or B) except license royalty.

The fear of giving its technology to competitors and loosing its market is part of the reasons why there is not much cooperation among drug major companies. The AIDS/HIV fixed dosed combinations, for example, were originated and produced not by the patent holding companies but generic drug companies mostly in countries where there was no (product) pharmaceutical patent such as India. Nonetheless, there are many benefits that pharmaceutical companies can gain from a well-organized patent pool. The next section will show some potential benefits that companies will get from participating in patent pools.

1. Access to knowledge

Despite the absence of interoperability standard, access to technology and knowledge is as important in pharmaceutical industry as in electronics and telecommunication industries. Participating in the pool will allow companies to use knowledge of other companies against the payment of royalty which is relatively small compare to the investment companies would incur from undertaking the R&D process themselves. The following is a simplified example of the value of a company's access to patent pool knowledge.[110]

Consider a fixed dose combination X that consisted of 3 drugs from 3 companies. Let's us again assume that each drug is covered by one patent which is held by the company that produce it. Thus each company will have license to one another in order to be able to produce and commercialized X. If each patent has equal value and receives the same royalty, the royalties that each patent holder receives will be offset by the royalties they have to pay to the other patent holders.

The result is each company is using other companies' technologies free of charge. The economic value of using one patent in exchange for the use of 3 patents is a 3 folds increase in R&D efficiency. In the absent of a collective right management institution like a patent pool, each company will need to conduct at least 2 transactions in order to obtain the essential patents for

[110] Example adapted from HAJIME YAMADA, *Standardization and Patent Pools: Using patent licensing to lead the market*, IEC Century Challenge, (2006).

the production of X. A patent pool can lower companies' transaction costs by reducing the number of transaction each company has to make to one – that is instead of negotiating with the other two companies – each company is only required to transact with the pool. In practice there is more than one patent over one drug - possibly hold by different holders. As a consequent, the costs and time saved by the pool will be higher.

A patent pool does not only increase R&D efficiency which is important for companies' competitiveness but can also be used by multinational companies to keep out competition at the upstream level. In the absence of a patent pool, companies wishing to manufacture the product will have to invent around in order to avoid infringing the incumbent companies' patents. In this invent around process, it is possible that these companies come up with a better product than that of the patent holder. Such a superior, non-infringing product can take away the originating company's market share.

Even if the new product infringes patents hold by other companies, most patent laws allow compulsory license for dependent patent if the new product is patented. The improved product can be patent if the improvement meets the patentability criteria (under most laws these criteria are novelty, inventive step and industrial application). If the new product is patented, the holder of the incumbent patent on which the improved product is based on only entitled to receive royalties for the use of his/her patent technology.

In either case, the multinational companies are risked loosing their dominance position to the more attractive products. The sales of the original product will reduce as people opt for a newer and better product. From incumbent companies' perspective, it is best to keep other companies' incentive to invest in new invention low. A patent pool can reduce companies' incentive to invest in alternative technologies and limit competition from other companies as the same time as enable multinational companies to remain their leadership in the market by providing them with the access to knowledge necessary for further R&D.[111]

[111] See Id.

2. Royalty income

One prime reason why the proprietary companies do not want to participate in the pool is the fear of that competition from a pool's licensees will take away theirs existing markets and profits. However, participating in pharmaceutical patent pools that aim to mitigate the access to drugs problem in developing countries will not have much impact on multinational companies' sales revenue. The reason is the market for patented product in developing countries is small and only constitutes an insignificant part of multinational companies' total sales.

The patent pool, in contrast, can generate addition revenues for proprietary companies. The patent holders in the example above do not earn any license revenues because royalties received canceled out with the royalties paid. In practice the number of licensees is higher than the number of patent holders. As a result the patent holders of the essential patents can earn royalties from other licensees who do not have any patent in the pool. The total amount of royalties that the licensors will receive can be very large. The patent pools for DVD6C, for example, has been estimated to have collected the royalties of US$ 655 millions to be shared among the patent holders.[112] This is income that holders of essential patents can earn without having to manufacture which implies a large financial efficiency.

However, the increased transaction costs resulting from more patenting activities affect not only the potential producers/researchers but also patent holders who wish to license their patents. The reasonable and standardized license terms of the pool can reduce transaction costs and uncertainty by providing the patent holders with a predictable and fair system of remuneration.

Given the absent of products in developing countries, the potential market for the generic drugs produced under licenses from the pool is large. Competition among the licensees will drive the prices down. As prices decrease, quantities demanded from the public increases. Companies that engage in production and commercialization of the products, including the patent holders, can enjoy the economies of scale (and possibly economies of scope) resulting from these larger markets. Since royalties are generally connected with sales, the higher the sales the better the revenues for the pool's patent holders. The lost of revenues in the patented market will be more than compensated by the license fees.

[112] See Id.

Moreover, the presence of a pool that consisted of all patents essential for a production of a particular product makes it easier to identify infringement. Generic companies that selling products that contained essential patents cannot deny that the patented technology has been used. The holder of essential patents can therefore identify generic companies that have used their patented technologies easily. In order to avoid the costly litigation generic companies would license from the pool and the licensors' income increases as a consequent. Multinational companies should, therefore, join patent pools to earn more income.

3. Reputation

In addition to the financial benefits, participating in a patent pool can affect companies' reputation positively. Given the serious access to essential drugs problems developing countries currently face and the current situations in the pharmaceutical industry, a pharmaceutical patent pool seems to be inevitable. The incumbent pharmaceutical companies, on the one hand, need access to others' technology in order to survive in a world of complex and cumulative innovation. On the other hand, high patented drug prices have been claimed as a main cause for the access to drug problem in developing countries. Facing with increasing severity of the problem; it seems like companies cannot avoid the overriding of their patents. Already countries have used compulsory licenses to solve their access to drug problem and the proposals for a pharmaceutical patent pool that have been proposed have stated clearly that compulsory licenses will be seek should multinational companies refuse to join the pools voluntarily. From a financial point of view, voluntary or involuntary participation does not make any difference to companies' income. The effect on companies' reputation is, however, quite different. Voluntary participation gives the companies positive images as a good member of the society while forced participation via compulsory licensing will just reinforce the already negative images as a greedy, heartless industry. Thus, the multination companies should join the pool voluntarily to gain better reputation.

E. Pharmaceutical Patent Pools: the feasibility

The last section has described the potential benefits of pharmaceutical patent pools to the society, why pharmaceutical companies acting on their own interest may not have the incentive to set up or participate in a patent pool and explained the reason why these companies should participate

in the patent pool. This section will then examine the possibility for establishing a pharmaceutical patent. Major issues to be considered include 1) a patent pool's formation – if the pharmaceutical industry is not taking the initiative to set up the pool, who will take the initiative to set up and run the pool, 2) getting all the essential patents into the pool and 3) the pool's operating costs.

At present there are several proposals for a biomedical or pharmaceutical patent pools. In the field of biomedical, the SARS patent pool has been proposed to avoid complications and delays associated with the development of SARS vaccine and treatment by pooling all relevant patents together. The objective of the proposed pool is to make SARS vaccines and drugs readily available in case of a pandemic outbreak.[113]

With regard to pharmaceutical patent pools, GlaxoSmithKline (GSK) - one of the world's biggest pharmaceutical companies - has established its own patent pool in March 2009. The company has donated over 500 granted patents and over 300 pending applications into the pool. [114]According to Andrew Witty, Chief Executive Officer of GSK: "The key objective of the pool is to make it easier for researchers across the world to access intellectual property that may be useful in…the discovery and development of new medicines for the treatment of 16 neglected tropical diseases…in the world's Least Developed Countries"[115]

One important feature about the GSK pool is it aims to stimulate research on 16 neglected tropical diseases in the least developed countries where there is little or no drugs available (they are called 'neglected diseases' because pharmaceutical companies have no interest in developing treatment for them). Hence the target of the pool is innovation, in other words, new drugs.

This paper, however, is focusing on the pharmaceutical patent pool that intends to solve the problem of innovations and access of the existing drugs caused by blocking patents and patent thickets. At present there is no pharmaceutical patent pool in this respect has been set up.

[113] More on the SARS patent pool study see e.g. JAMES H.M. SIMON, et al., *Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling*, 83 Bulletin of the World Health Organization, (2005).
[114] More information about the pool is available at the company's website at http://www.gsk.com/collaborations/contribution.htm.
[115] GLAXOSMITHKLINE, *Press release: Alnylam joins GSK in donating intellectual property to patent pool for neglected tropical diseases at* http://www.gsk.com/media/pressreleases/2009/2009_pressrelease_10071.htm.

However, several proposals have been put forward. These proposals include 1) **Essential Patent Pool for AIDS (EPPA)** proposed by Essential Inventions, Inc aims to provide acceptable quality and sustainable supply of ARVs medicines, medical device and testing regimes by providing open licensing of the pooled patents;[116] 2) **Essential Medical Inventions Licensing Agency (EMILA)**. This proposal aims to establish the EMILA a non-profit organization that support the creation and manage a licensing program or patent pool that increase generic competition and access to patented vaccines and pharmaceutical products in developing countries;[117] and 3) **UNITAID pool for AIDS medication** proposed in 2006 by the Knowledge Ecology International (KEI) and Medécins sans Frontières (MSF, Doctors Without Borders). The proposed pool aims to facilitate the development and production of new fixed dose combinations and drugs for children by providing access to intellectual property relating to these products. [118]

Of all these proposals, the UNITAID proposal is the only one closest to be implemented. The UNITAID's Executive Board has decided on December 14, 2009 to establish the proposed pool and plans to start operating in mid-2010.[119]The analysis in the following part will, therefore, use this proposal as a point of reference.

1. Pools' formation and administration

A patent pool has to be formed and administered by an entity. The absent of a standard setting organization and the pharmaceutical industry's lack of incentives to participate in patent pools imply that the initiative for setting up a pool need to come from other sources.

In pharmaceuticals, the chief beneficiaries of a decrease in drug prices are health care providers or drug purchasers. The major drug purchasers are national governments and international organizations and non – government organizations (NGOs) that provide drugs in developing countries such as the WHO, UNISEF, MSF, UNITAID, Clinton Foundation, etc. These

[116] ESSENTIAL INVENTION INC, *Essential Patent Pool for AIDS (EPPA): Background Information*. (2005), available at http://www.essentialinventions.org/docs/eppa/whatisapatentpool.html.
[117] KNOWLEDGE ECOLOGY INTERNATIONAL, *EMILA Working Plan* available at http://www.keionline.org/content/view/64/1.
[118] UNITAID is a drug purchasing facility hosted by the WHO, designed to support organizations such as WHO, UNAIDS and UNISEF. More information about its pool is available on its website at http://www.unitaid.eu/en/The-Medicines-Patent-Pool-Initiative.html
[119] UNITAID, *UNITAID Executive Board approves breakthrough plan to make AIDS treatment more widely available at lower cost*. (2009), at http://www.unitaid.eu/en/20091215237/News/UNITAID-APPROVES-PATENT-POOL.html.

organizations have very incentive to lower the drug prices in order to increase their access and coverage. Two major benefits of the pool for the developing countries include:

a. **Improved health care**. The main components of health care expenditures consists drug expenditures which, in turn depend on drug prices. Competition from the pool's licensee(s) will not only reduce drug prices and increase product availability but also improve the product quality. All these factors work toward a more effective and efficient treatment. The end result is an improvement of health care situation which is very important for social and economic development especially in developing countries which have limited resources.
b. **Development of local industry**. R&D is costly and developing countries usually do not have the infrastructure and technological base necessary to develop a pharmaceutical industry. With patent pools developing countries can import the technology and knowledge found in other countries against the payment of royalty which is only a fraction of the total investment costs they would incur should they need it themselves. Depending on their national law, local companies that license from the pool may produce the licensed product to serve local market and/or export to other countries as the same time as searching for ways to improve the patented technology.

   Although it is possible for local inventors to first use the experimental exception available in most national laws for research for an improved product or process and obtain a compulsory license from the original patent holder once the new product or process is patented. Compulsory license for dependent patent is, however, possible only for a patented improvement. Hence, inventors that choose this path are running the risk that they may not be able to manufacture and commercialize the product even after a lot of investment has been made because the improvement does not meet the patentability criteria. By allowing its licensees to produce and commercialize their product regardless of the degree of improvement they have made, patent pool reduces inventors' risk and encourages local innovation.

Governments may, however, not be a viable solution for the setting up and administration of the pool. There are several reasons for this. First, setting up a pool requires management expertise

and resources which most governments do not have. Second, a country's incentive and the pool's scope. A single country pool will not generate benefits required to cover its costs because local markets in developing countries are usually too small for drug companies to benefits from economies of scale. On the one hand, the proposed pool should be regional or global in scope and include both the manufacturing and importing countries. On the other hand, countries will look at their own costs and benefits and for most of the pool's beneficiary countries, the costs of setting up and run a pool outweigh the benefits that the country will receive. As a result no country would be interested in setting up a pool and the market failure that happens at the company level will also happens at the country level. Third, even if governments are capable and willing to set up and administer the pool, governments are subject to politics and interest groups. The pool's administration will have to decide on the drugs and the essential patents to be include in the pool. If a patent pool is managed by a government or its agency, there is a possibility for political capture and opportunism.[120]Countries may, for example, may select the drugs and the essential patents according to their own interest which can be contradict to the objective for having a pool in the first place.

Another possible solution is international organizations or NGOs -either a new established agency or the existing one. The EMILA proposal, for example plans to create a new organization to set up a pool. But creating a new organization is as complicate as creating a pool and the problems of a pool set up can be found here as well.

In this regard existing international organizations or NGOs that are dealing with health care issues such as the WHO, UNISEF or MFS can be a better option. Some important features of these organizations are first, they have the background knowledge about the situation. Second, these organizations operate on a global basis and have worked with various stakeholders including proprietary drug companies, generic drug companies, governments, other international organizations and NGOs. As already mentioned, the pool should be regional or global in scope to be efficient. Such expertise and networks are necessary for the pool's administration. Most of

[120] Opportunism is the conscious policy and practice of taking selfish advantage of circumstances, with little regard for principles. The pool's management, for example, may decide to include drugs and patents that suit its (national) interests rather than the public (global) interests. Such opportunistic behaviors can have negative impact on the industry and the system as a whole. For definition of opportunism see http://www.thefreedictionary.com/opportunism

these organizations are supplying drugs for the poor in developing countries. As a result it is in their interests that the pharmaceutical industry remains innovative for they can have new and better drugs and prices are affordable so access can increase. Therefore there will be less conflict of interests since these are exactly the objectives of the proposed pool.

Like governments, these organizations also subject to politics. But they operate in many countries as a result they will make decision based on the overall the costs and benefits rather than that of an individual country. Hence, compare to national governments that subject to both international and domestic politics, they are more secured and the possibility that they will act opportunistically or being captured by interest groups is lower. Although in the future we might come up with other form of institution that is better in forming and operating the pool, at this moment international organizations and NGOs seem to be the most appropriate answer. In practice, all pharmaceutical patent pool proposals are in fact initiated from these international organization and NGOs. In case of the UNITAID patent pool, UNITAID has committed to operate the pool.

2. Patents

The essence of a patent pool lies on the patents it has for license. The pharmaceutical industry has no standards that determine patent essentiality. Nevertheless, essentiality can be determined from the pool's objective. The UNTAID pool, for example, aims to pools patents on fixed dosed combinations and new formulations of existing medicines adapted to the developing countries.[121] Hence, essential patents in this case can be identified as any patent that block the development and production of the ARVs. The essential patents for a production of a fixed dose combination of Atazanavir (Bristol-Myers Squibb) and Ritonavir (Abbott Laboratories), for example, would encompass all patents necessary to produce Atazanavir and Ritonavir.

For the proposed pool, the problem of essentiality determination can be solved by working in corporation with other international organizations dealing with access to essential medicines such as the WHO Essential Medicines and Pharmaceutical Policies Department.

[121] SERAFINO. *supra* note 65

But more important than identifying essential patents is trying to get them into the pool. In this regard there are 2 possible methods to this - to have the patent holders license to the pool voluntarily or to force them to license to the pool.

First, voluntary license. It will be best if the patent pool is established with voluntary licenses from the patent holders. The reason is such a pool will not raise any significant international or national legal issues.[122] Although government agencies and other entities may hold some patents, most pharmaceutical patents are hold by multinational companies which, as the previous section has shown, have no incentive either to form or participate in the pool.

However in practice companies' initial responses to the pharmaceutical patent pool proposals, especially the UNITAID patent pool, are positive. GSK, for example, has been in discussion with the UNITAID regarding the former AIDS/HIV patent pool proposal. GSK has not agreed to put its patent on AIDS/HIV drugs into the UNITAID patent pool yet, claiming that it has already granted eight voluntary licenses to African generic companies. However, according to the company, it has not ruled out the possibility of participating in the pool but has yet to see any real proposal that provide benefits beyond its' existing approach.[123]

Gilead, another major pharmaceutical company, has entered into partnerships with 13 Indian generic drug companies where it provides 'a full technology transfer to enable them to produce and distribute quality, low-cost generic versions of Gilead's HIV medication in 95 developing countries".[124] These companies are free to set the prices for their products and Gilead receives 5 % royalty on sales. These license agreements are similar to the UNITAID proposal; as a result, there is no reason for Gilead to not participate in the pool. According to Gilead's Executive Vice President, Corporate and Medical Affairs Gregg Alton, "Gilead looks forward to continuing to work with the UNITAID and other partners in meeting the urgent need for expanded HIV

[122] E. RICHARD GOLD, et al., *Preliminary Legal Review of Proposed Medicines Patent Pool at* http://www.theinnovationpartnership.org/data/documents/00000003-1.pdf.
[123] See CHRIS STRUTT, *GSK is in talks on patent pools*, The Guardian 10 September 2009
[124] GILEAD, *Gilead Sciences: Advancing Sustainable Access to HIV/AIDS Medicines in the Developing World*. (2009), at http://www.gilead.com/pdf/access_fact_sheet.pdf.

treatment access, and we welcome the opportunity for future discussions about patent pools and other access-related topics".[125]

Another positive response comes from Alnylam Pharmaceuticals, Inc. who has joined GSK's patent pool. The company has contributed more than 1,500 issued or pending patents on RNA interference (RNAi) technology – a technology which provides an innovative approach to drugs discovery and development.[126]Optimistically it is expected that should any patent of Alnylam Pharmaceuticals, Inc be required for the proposed pool, the company should be keen to participate. These companies' willingness to participate in the pool and, hopefully, their actual participation in the future should put pressure on other companies to take part in the pool.

Second, involuntarily license. Even if pharmaceutical companies do not license voluntarily, it is possible to get all the required patents with use of compulsory licensing. Compulsory licensing is one of the flexibilities provided under the TRIPS Agreement which allows a government to issue license to a third party without having consent from the patent holder. In the past developing countries have been reluctant to use compulsory licensing mainly because the U.S. government has a long history of using trade retaliation or the threat of using it to flight developing countries' initiative to use compulsory licenses for generic drugs.

The ground has shifted in 2001 when the U.S. Health and Human Services Secretary Tommy Thomson threatened to override Bayer's patent on ciprofloxacin (Cipro) after the exposure of anthrax cases.[127] Developing countries saw that the U.S. too wished to use compulsory license to prioritize health when patent impede access to medicines and they too should have the same rights. Uncertainties about member country's legal authority to use compulsory license were resolved in the 'Doha Declaration on the TRIPS Agreement and Public Health' reached during the WTO Ministerial Meeting in Doha in 2001.

[125] GREGG ALTON, UNITAID Patent Pool Summary Statement (2009).
[126] The technology works through 'gene silencing' which is "a technology that targets the cause of diseases by potently silencing specific messenger RNAs (mRNAs), thereby preventing disease-causing proteins from being made". See GLAXOSMITHKLINE.
[127] ASIA RUSSELL, *Victory and betrayal: the third world takes on the rich countries in the struggle for access to medicines at* http://www.healthgap.org/press_releases/02/060102_HGAP_BP_Doha.html

The Declaration reaffirmed the rights of member states to use the TRIPS flexibilities, compulsory licenses included, to circumventing patent rights for better access to essential drugs. Paragraph 4 of the Declaration states that:

> *"The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose".* [128]

In addition, the political momentum is changing. President Obama and Vice President Biden believe that "people in developing countries living with HIV/AIDS should have access to safe, affordable generic drugs to treat HIV/AIDS. They will break the stranglehold that a few big drug and insurance companies have on these life-saving drugs. They support the rights of sovereign nations to access quality-assured, low-cost generic medication to meet their pressing public health needs under the WTO's Declaration on Trade Related Aspects of Intellectual Property Rights (TRIPS)".[129] Increase access to affordable drugs is one of their agenda to combat global HIV/AIDS and they support "the adoption of humanitarian licensing policies that ensure medications developed with U.S. taxpayer dollars are available off-patent in developing countries".[130]

Nevertheless, countries may still hesitate to issue the needed compulsory license in hope to free ride other countries' effort at the same time as avoiding any possibility of trade retaliation. In such case the strategic behavior that leads to market failure at the corporate level can also happen at the national level as well. However, over the last few years Thailand and Brazil have already issued compulsory licenses in response to the high prices of newer HIV/AIDS drugs. Since the

[128] WORLD TRADE ORGANIZATION, *Declaration on the TRIPS agreement and public health*. at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
[129] THE OFFICE OF PRESIDENT-ELECT, *Agenda: The Obama-Biden plan to combat global HIV/AIDS*. (2009), at http://change.gov/pages/the_obama_biden_plan_to_combat_global_hiv_aids.
[130] See Id.

benefits and support they would get from issuing compulsory license for the pool are higher than the traditional compulsory license, it is very possible for the pool to get the compulsory licenses for the patents it needs from these countries as well as other countries with manufacturing facilities which stand to be gain the pool's license like India.

Although the current situations may support developing countries' effort to use compulsory licensing more and it is likely that the UNITAID will be able to find countries that are willing to issue the required compulsory licenses for the pool, it is best if the holders of all essential patents agree to join the pool voluntarily (possibly with the threat of a compulsory license).

Given the initial positive response from some major companies, it is also possible to have a pool that is mixed with voluntary and compulsory licenses. The issuance of one or more compulsory licenses at the beginning can create pressure for some patent holders to license voluntarily. If such pressures work a fully voluntarily licenses pool can be achieved at the end.

3. Operating costs

Setting up and operating a patent pool is not cheap. The UNIAID patent pool, for example, has been estimated tot have an initial start-up costs for the first 3 years of $ 4.5 million in total or $ 1.5 million per year. The annual $ 1.5 million budget is estimated to sufficient to pay for office expenses, the hire of at least 2 senior and 2 support staff, travel expenses, insurance, legal, consulting as well as public relations services.[131] The UNITAID has committed to provide for these necessary set up costs.[132] In term of potential benefits, the UNITAID patent pool is expected to save more than one billion dollars a year and would help scaling up treatment access.

Some patent pool proposals plan to set up a new organization to administrate patent pools. In practice one organization is capable of administrating several pools at the same time. MPEG LA, the administrator of MPEG-2 patent pool for example currently has 8 pools under its administration. As a result, if the UNITAID patent pool operates well, there may be no need to set up a new entity for each and every pool. Pools' administration too can benefit from economies of scale.

[131] See UNITAID *supra* note 25 at 16
[132] See Id.

In sum it can be say that pharmaceutical patent pools are possible and feasible under the current situation.

CONCLUSION

The increase protection and complexity of innovation process have resulted in patent thicket and blocking patent not only in the electronics and telecommunications industries but also in biotechnology and pharmaceutical industries as well. The advantage of a well designed pool is it provides patent holders with financial incentive to commercialized their existing knowledge and undertake new potentially patentable innovation. Patent pools that have been used to solve the problem of blocking patents in the electronics and telecommunications industries can also be used in the biopharmaceutical industry as well. Knowledge sharing and increase competition resulting from such pools can boost innovation and access which raise social welfare. However, several adjustments may have to be made in order to make the proposed pools more suitable to the particular characteristics of the biopharmaceutical industries.

First, the biopharmaceutical industry does not have a common standard as a result the extent that blocking patents prevent companies from making the product is lesser than in case of standard. The result of this is despite the potential benefits of the pool to the society and individual company, companies acting on their own interests will have little incentive to set up the pool. The initiative therefore would have to come from other sources i.e. at the industry level or from the government. Nevertheless, there is much to be gained from setting up such pools and the report by U.S PTO in 2000 is a significant endorsement of and impetus for further consideration and development of patent pool for biotechnology.[133]

Second, unless companies join the pools initiated by other party such as the government, international organization, etc voluntarily; mechanism likes compulsory licensing may be needed. Consequently both national laws and international laws on this aspect will have to be considered. Third, in case of patent pools aim to increase access to medicines in developing countries, the territorial dimension will have to be consider carefully because the impact of the patent pools on the patent holders' market in developed countries may affect their incentive to invest in R&D.

[133] ED LEVY, et al., *Patent Pools and Genomics: Navigating a Course to Open Science?*, BU Journal of Science & Technology Law, (2009).

Given the access crisis developing countries have, a pharmaceutical patent pool seemed to be inevitable. Proprietary companies, on the one hand, should participate in such a pool voluntarily as such participation can improve companies' reputation and unlikely to have negative impact on their financial. Developing countries, on the other hand, will be the major and direct beneficiary of the pool. Hence, they should cooperate with international organization to establish a patent pool and issue compulsory license(s) when necessary.

A pharmaceutical patent pool seems to be an ideal tool to solve patent blockages. However, it setting up a patent pool in practice can be very difficult. This is evident by the fact that the idea of a pharmaceutical patent pool was first originated in 2006 but no pharmaceutical patent pool has been set up yet despite the efforts various parties have put. The fact that there are many stakeholders, with various and sometime contradicting agendas involve, make it very difficult to come up with an ideal pool. Nevertheless, an imaginative institution design is going to become increasingly important as the patent crisis is deepened.

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