WORKING PAPER

From One-Stop to One-Stop-Shop:

Patent Pools and Clearinghouse Mechanisms as Pragmatic Solutions for Patent Thickets and Non-cooperative Patent Holders in Genetic Diagnostics?

Esther van Zimmeren[*]

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ABSTRACT

Scientists and legal practitioners have expressed concern about the emergence of "patent thickets" or the potential inhibitive "anticommons effect" in the field of (human) genetics. These two theoretical concepts refer to the proliferation of patents in genetics caused by the race on patents by private and public entities in the biomedical sector, which leads to difficulties in bargaining licenses to the patented inventions. Ultimately, this would result in "underuse" of the patents concerned. In addition, some patent holders refuse to grant licenses at all or license only to a (relatively) small number of licensees (often) under highly restrictive conditions. There are three major practical impediments practitioners are currently facing resulting from these phenomena. First, the rising level of transactions costs due to the number of licensing negotiations necessary to guarantee freedom to operate. Second, royalty stacking; the subsequent accumulation of royalties resulting from the required bundle of licenses. And third, patent holders on blocking positions unwilling to grant licenses, or imposing unreasonable licensing conditions. Patent pools and clearinghouse mechanisms have been suggested by various national, international, governmental and non-governmental organizations as useful models to cut through the patent thicket and to overcome the anticommons effect. However, one may wonder to what extent these models may be effective to respond to the three practical impediments mentioned above.

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[*] PhD researcher at the Centre for Intellectual Property Rights (CIR), University of Leuven, Belgium. LL.M. in European Union Law and Intellectual Property Law, University of Leuven, Belgium (2002); Master in Dutch Private International Law, University of Tilburg, Netherlands (2002) and Master in European International Law, University of Tilburg, Netherlands (2001). Legal assistant Court of First Instance of the European Communities (2002-2004). The author thanks Prof. Dr. Geertrui Van Overwalle, Dr. Birgit Verbeure, Prof. Dr. Gert Matthijs and the participants of the International Workshop Gene Patents and Clearing Models: From Concepts to Cases, Leuven, 8-10 June 2006 for the interesting discussions and valuable comments on an earlier paper on clearinghouses.

SUMMARY

Scientists and legal practitioners have expressed concern about the emergence of "patent thickets" or the potential inhibitive "anticommons effect" in the field of (human) genetics. These two theoretical concepts refer to the proliferation of patents in genetics caused by the race on patents by private and public entities in the biomedical sector, which leads to difficulties in bargaining licenses to the patented inventions. Ultimately, this would result in "underuse" of the patents concerned. Moreover, some patent holders refuse to grant licenses at all or license only to a (relatively) small number of licensees (often) under highly restrictive conditions. There are three major practical impediments practitioners are currently facing resulting from these phenomena. First, the rising level of transactions costs due to the number of licensing negotiations necessary to guarantee freedom to operate. Second, royalty stacking; the subsequent accumulation of royalties resulting from the required bundle of licenses. And third, patent holders on blocking positions unwilling to grant licenses, or imposing unreasonable licensing conditions. Patent pools and clearinghouse mechanisms have been suggested by various national, international, governmental and non-governmental organizations as useful models to cut through the patent thicket and to overcome the anticommons effect. However, one may wonder to what extent these models may be effective to respond to the three practical impediments mentioned above.

Especially in the US, patent pools have gained an impressive twofold reputation for on the one side solving the royalty stacking problem, but at the same time creating a risk of collusion. This reputation is based on a centenary experience with patent pools in industries varying from aircraft to sewing machines. More recent, various patent pools have successfully been established in the electronics and telecommunications industries, which have been cleared by the competition authorities in Europe and the US. Currently, the patent pool model is being put to test in the biomedical sector with the SARS genome patents with the support of the WHO and the NIH. The author suggests that the different characteristics of the biomedical market, its market players, their products, and the additional public interests involved, require an approach distinct from the way pools are dealt with in other industries. A decrease in transaction costs, the mitigation of royalty stacking and the development and management of an industry standard may have been sufficient reason to establish a patent pool in e.g. consumer electronics, but in addition patent pools in genetics warrant essential public health interests absent in the electronics sector. This public health interest should be taken into account in both the stakeholders' (biotechnology and pharmaceutical industry, universities, research institutes, clinical laboratories, etc.) balance of pros and cons of the establishment of a patent pool and the final assessment by the competition law authorities.

Whereas patent pools are still a rare phenomenon in the biomedical field, one can already observe an explosive growth of clearinghouses especially aiming at 'clearing' information in this area. Several types of clearinghouse mechanisms can be identified. On the one hand, the information clearinghouse and the technology exchange clearinghouse, which provide access to information on the patented inventions. However, these types of clearinghouses basically will not contribute to the solution of the problems presented above. On the other hand, the open access clearinghouse, the standard licenses clearinghouse and the royalty collection clearinghouse not only offer access to information but also provide an instrument to facilitate the use of the patented inventions. The last two clearinghouse models may significantly contribute to lowering the transaction costs and reducing the level of royalties to be paid. A special clause in the standard license or effective enforcement of "good licensing conduct guidelines" by the royalty collection clearinghouse will contend with

non-cooperative patent holders. Similar to the reasoning for patent pools, the author argues that an examination of the value of a clearinghouse model for human genetics should – next to the objective of controlling the three practical problems – include the need to guarantee access to public health care services as a common goal and major purpose of such a clearinghouse.

The emphasis on public interest, public health in particular, and the need to guarantee access to and use of patented genetic inventions imposes a certain social responsibility on the biomedical industry. The last decade, the biomedical industry has shown at several occasions to be favorably disposed towards such initiatives by establishing medicine patients' assistance programs and developing and donating treatments for rare diseases. This social engagement should however not place excessive burdens on industry. Besides and despite their public interest goal, patent pools and clearinghouse mechanisms may operate as platforms to negotiate reasonable, market-based licensing conditions. The role of governments should preferably be limited to, on the one hand, the stimulation of all the stakeholders to effectively cooperate and, on the other hand, the supervision of the licensing authorities. If the licensing authority of the patent pool/clearinghouse determines that a patent holder or technology user abuses his property rights or the collective licensing mechanism and the authority has no appropriate contractual instruments to enforce good licensing behavior it will notify the competent public authority. Only in exceptional circumstances governments will interfere either through their competition authorities or by putting a compulsory licensing scheme into operation.

The present paper thus explores to what extent and how the patent pool and/or clearinghouse model may respond to the call for reduction of transactions costs and royalty stacking, and for reasonable licensing behavior. This way opportunities for further R&D and access to and use of public health services will be guaranteed, while at the same time securing industry's interests to 'reap what they have sown'.

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I. INTRODUCTION: THE PROBLEMS DEFINED, THE GOALS PRESENTED

Mrs. P. Johnson, who lives in industrialized country A, is suffering from a disease which has the characteristics of disease X common in her family. Her doctor advises her to have a genetic test being done. Mrs. Johnson takes this advice and goes to the clinic. The head of the clinical laboratory concludes that indeed there are many indications that the lady suffers from disease X. Since long his laboratory carried out the test for disease X by way of home-brew methods (at operating costs) developed on the basis of a number of papers published in scientific journals on the relevant mutations and a testing guideline for disease X made public by the society for medical genetics. That week, however, he received a cease and desist letter from the patent holder/exclusive licensee in country A, who holds patents with regard to the most common mutations. The patent holder/exclusive licensee prohibits the laboratory from performing the respective home-brew test. In the same letter, the patent holder/exclusive licensee offers the test carried out by his company for a significantly higher price, including both the operating costs and a supplementary royalty fee. What to do now?

This imaginary case points toward a two-sided problem. First, the surge of companies and public entities to file patent applications in the area of genetics resulting in a proliferation of patents, also called a patent thicket (Chapter I.A). [1] The second phenomenon relates to the strategic licensing behavior adopted by patent holders. In some cases, such strategic behavior leads to exorbitant license fees (and subsequently high prices for diagnostic tests and medical treatment), restrictive licensing conditions and blocking positions (Chapter I.B). Whereas the first part of the problem is clearly the result of the patent granting policy of the patent offices, the second element is no core characteristic of patent law, but common tactical business policy [2].

Some scholars would argue that one should not address patent law problems outside the scope of patent law. In principle, I agree with this statement, but in addressing this problem, distinction should be made between, on the one hand, the grant of patents for genetic inventions and, on the other hand, the exploitation of patents, which is a post-grant-issue. Experience has shown that the omnipresence of patents in the fields of biotechnology and

[1] In the example, the relevance of the explosion of patents would become clearer if after the receipt of the first cease and desist letter, the head of the laboratory would be confronted with other cease and desist letters all related to the genetic test for disease X.

[2] Though it might be contended that such behavior is facilitated by the nature of the exclusive right; the monopoly granted on the basis of patent law

genetics cannot only be imputed to the (allegedly) loose application of the patentability criteria, but also to the pace of innovation in these areas of research. Moreover, reviewing and eventually amending the patent system is a time-consuming and challenging endeavor throttled down by political strategies. Some existing legal instruments included in patent acts, like the research exemption and compulsory licensing mechanism celebrated by politicians and legal scholars as instruments that safeguard access to patented inventions, appear to be relatively ineffective or unpopular in practice. In theory, the problems of access to patented inventions for research and of non-cooperative patent holders might be successfully addressed by invoking the research exemption or compulsory licensing provisions. However, the scope of the research exemption is debatable and varies considerably from country to country. [3] The compulsory license operates merely as a last instance threat to persuade patent holders to agree on a 'voluntary' bilateral license. Despite past cases in genetic diagnostics of highly restrictive licensing conditions, scientists and industry do not appear to be particularly taken with the latter quite vigorous device. The few cases in which reference was made to a compulsory license mostly relate to national emergencies, such as AIDS medicines for developing countries and tamiflu, the only available treatment for avian influenza [4]. [5] The scope of application of this instrument could however be extended to other fields of technology, like for example diagnostic testing, provided it would be applied carefully. A more pragmatic solution might be to continue the review of patent quality and the patent system, [6] and of complementary patent law mechanisms, such as the research exemption and

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[3] *See e.g.* CHRIS DENT, RESEARCH USE OF PATENTED KNOWLEDGE: A REVIEW, STI Working Paper, No. 2006/2 (OECD Directorate for Science, Technology and Industry, 2006), *available at* http://www.oecd.org/dataoecd/15/16/36311146.pdf.

[4] Tamiflu (oseltamivir) is an oral antiviral treatment (no vaccine) for avian influenza, which prevents the influenza virus from spreading inside the body. Roche has the worldwide exclusive rights to develop and market the drug. Due to the fears of avian influenza becoming a pandemic there is a high demand for tamiflu.

[5] See also: Esther van Zimmeren & Gilles Requena, Ex Officio Licensing in the Medical Sector: The French Model, *in* PROCEEDINGS OF THE CONFERENCE ON "GENE PATENTS AND PUBLIC HEALTH" (LEUVEN 27TH MAY 2005) (Geertrui Van Overwalle, ed., forthcoming) (on file with the author) (providing a number of examples of cases where compulsory licensing provisions have been invoked).

[6] In the EU and the US the patent system is currently extensively examined and reviewed. *See* for the EU: *European Commission, Public Hearing on the Future Patent Policy in Europe*, July 12, 2006, *available at* http://ec.europa.eu/internal_market/indprop/patent/hearing_en.htm; Charlie McCreevy, European Commissioner for Internal Market and Services, Public Discussion on Future Patent policy in Europe Closing remarks at public hearing on future patent policy, SPEECH/06/453 (Brussels, July 12, 2006), *available at* http://europa.eu.int/rapid/; European Commission, Questionnaire - On the patent system in Europe (Brussels, January 9, 2006), *available at* http://ec.europa.eu/internal_market/indprop/patent/hearing_en.htm and European commission, Preliminary findings: issues for debate, Public Hearing Future Patent Policy in Europe (Brussels, July 12, 2006), *available at* http://ec.europa.eu/internal_market/indprop/patent/hearing_en.htm. For the US: WENDY H. SCHACHT, PATENT REFORM: ISSUES IN THE BIOMEDICAL AND SOFTWARE INDUSTRIES, Report for Congress (Washington, D.C., Congressional Research Service (CRS), April 7, 2006), *available at* http://www.fas.org/sgp/crs/misc/RL33367.pdf; Patent Reform Act of 2005, H.R. 2795, *available at*

the compulsory license. But at the same time patent holder licensing behavior which might be triggered by extensive and strong patent portfolios, should be analyzed from a more holistic perspective. The protection by patent law closely interacts with various other sets of rules and legal frameworks, such as contract and competition law, which in turn complement and balance the system. Alternative solutions to be found in licensing policy and governed by competition law for dealing with large numbers of patents will offer a complementary, working solution for the transition towards a reviewed, integrated and optimally functioning patent system. Patent law advocates, blaming pragmatists who make way for a role for complementary solutions to patent problems supplied by other bodies of law, are invited to consider patent pools and clearinghouse with this in mind. A more holistic perspective needs to replace the often narrow focus favoring a stringent application of the divide between patent law and other areas of law. [7]

In this paper, two alternative licensing models will be examined that have been suggested at several occasions in highly regarded national and international reports: patent pools and clearinghouse mechanisms (Chapter III and IV). These models will be examined by referring to real-life examples in other technical fields and in genetics. These examples provide clarity on the strengths, some risks and a number of drawbacks of both models. Potential violations of competition law by a patent pool or clearinghouse constitute an important risk that should be taken into account. Therefore, the major 'stumbling-blocks' of competition law based on US and EU licensing guidelines and antitrust decisions will be highlighted. The role of industry standards for genetics, which has been questioned, will be separately analyzed for both models.

Patient groups and health care providers have expressed concerns regarding the patent thicket problem and the non-cooperative approach of patent holders, which may block further research and development and prevent patients from receiving the appropriate care. These interest groups have called up holders of patented genetic inventions to facilitate access to health care services. Lengthy bilateral licensing negotiations often frustrate the pace of

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http://thomas.loc.gov/cgi-bin/query/z?c109:H.R.2795:/; STEPHEN A. MERRILL ET AL., A PATENT SYSTEM FOR THE 21ST CENTURY (Washington D.C, The National Academies Press 2004), *available at* http://www.nap.edu and FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (October 2004), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf. *See* generally: TEKNOLOGI-RÅDET, RECOMMENDATIONS FOR A PATENT SYSTEM OF THE FUTURE – REPORT BY A WORKING GROUP UNDER THE DANISH BOARD OF TECHNOLOGY, No. 7, 13 and 24 (Copenhagen, Vester Kopi 2005), *available at* http://www.tekno.dk.

[7] *See also* TEKNOLOGI-RÅDET, *supra* note 6.

innovation. Hence, these interest groups have an incentive in the quest for substitutes for bilateral licensing negotiations. The interest of patent holders with a well-balanced patent portfolio and experienced staff at their licensing departments in patent pools and clearinghouse mechanisms will not immediately come to mind. One of the arguments in this paper will be that patent holders in the biomedical field bear a special social responsibility (Chapter I.C). They are not dealing with shoes or shavers, and should aim at an effective IP management policy with optimal opportunities for innovation and access to health care imposed by this responsibility. Additional reasons and legal instruments stimulating patent holder cooperation will be set out through Part III and IV.

A. Patent Thicket and Anticommons Effect

Research and development are taking place at an impressive pace today. In parallel, intellectual property rights proliferate in order to compensate innovators for these efforts and investments and to foster further innovation. Unfortunately, at the same time the proliferation of patents may have the effect of stifling innovation. The essence of innovation in genetics is cumulative investigation: each invention builds on many previous findings, researchers are standing on top of a huge "pyramid of blocks". [8] In order to scale the pyramid and place a new block on the top, researchers must gain permission of each person who previously contributed to the building of the pyramid. In fact, in many fields downstream innovators will need licenses from a large number of patent owners in order to continue research and in the end commercialize the new technology. Experts are increasingly expressing concerns that the current patent system is creating a "patent thicket" in key industries: a web of overlapping patents that a researcher or a company must hack its way through by obtaining licenses in order to actually develop and commercialize a new technology. [9] The high costs involved in locating the licensing partners ('search costs'), in negotiating the licensing conditions ('bargaining costs') and the enforcement of the licensing agreement ('enforcements costs') – in other words the transaction costs, may stand in the way of an agreement. [10] The presence of many upstream patent holders with regard to a specific product or process usually involves

[8] Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard Setting*, *in* INNOVATION POLICY AND THE ECONOMY, VOL. I (Adam Jaffe et al., eds., 2001), *available at* http://haas.berkeley.edu/~shapiro/thicket.pdf, 1.

[9] Frederic M. Scherer, *The Economics of Human Gene Patents*, 77 ACADEMIC MEDICINE 1348, 1348-1367 (2002).

[10] Ronald H. Coase, *The Problem of Social Cost*, 3 THE JOURNAL OF LAW AND ECONOMICS 1, 1-44 (1960) and Robert Cooter and Thomas Ulen, *Law & Economics*, International Edition, Boston-San Francisco-New York: Pearson Addison Wesley, at 91-96 (2004).

royalty stacking; multiple stacked license fees, which a downstream inventor has to pay to those upstream patent holders. Hence, too many patent rights on upstream inventions can block downstream research and product development by increasing transaction costs, stacking of royalties and the risk of bargaining failures. Consequently, similar to the way limited property rights leave communally held resources eligible to overuse in a "tragedy of the commons", [11] too many property rights can expose resources to "underuse" in what is called a "tragedy of the anticommons" [12].

In order to gather empirical evidence for this observation, several studies have examined the existence of a patent thicket and the consequences (on research) of the licensing behavior of patent proprietors in the area of genetics. [13] A recent study from the Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation (US National Research Council of the National Academies) shows that *at present* there is no substantial evidence for the existence of a patent thicket or a patent-blocking problem *in genetics in general*. [14] However, this study mainly focuses on the consequences of a potential patent thicket on genetic *research*. Reluctance of companies to pursue active licensing policies or litigate against universities and research institutes may partially explain why there is no blocking problem in this area (yet). Companies may not think shame for enforcing more vigorously in commercially competitive relationships. Additionally, several trends may lead to the emergence of a patent-blocking problem in genetics in the future: growing awareness among researchers, increased patent enforcement due to the strategic management of their rights by patent holders (also vis-à-vis universities, research institutes and clinical laboratories), and the proliferating complexity of biomedical research (requiring a broader range and greater number of inputs of which a growing number is patented). [15]

Several studies have, however, highlighted that in the field of gene-based diagnostics, patent holders are already more active in asserting their patents, which seems to be inhibiting

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[11] Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243, 1243-1248 (1968).

[12] Michael A. Heller, *The Tragedy of the Anticommons: Property in Transition for Marx to Markets*, 111 HARV. L. REV. 621, 621-688 (1998); Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998).

[13] NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES - COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN RESEARCH AND INNOVATION, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH, (Washington, DC, The National Academies Press 2005), *available at* http://www.nap.edu/catalog/11487.html [hereinafter Reaping the Benefits of Genomic and Proteomic Research] and John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285-340 (Wesley M. Cohen and Stephen A. Merrel eds., Washington, DC, The National Academies Press 2003).

[14] *Id.*, at 105 and 112.

[15] *Id.*, at 105.

research and clinical practice. [16] Indeed, it appears that some laboratories have – as a result of such patent enforcement policies – ceased to perform tests and/or refrained from test development. [17] Commentators have criticized this conclusion insisting that there is a need for more empirical studies to establish the actual existence of a patent thicket also in the area of genetic diagnostics. But even though the problem may turn out to be less urgent on the basis of future empirical analyses, [18] transparency and legal certainty may justify the search for alternative solutions, as practitioners may be under the (false) impression that intellectual property rights keep them from research and development. [19] In this respect, the attention for patents and licensing, especially with respect to genetic diagnostics, within the European Society for Human Genetics is significant. [20] Therefore, genetic diagnostics will be used in this paper as a case study for examining different clearing models as an instrument to facilitate access to and use of patented genetic inventions.

B. Non-Cooperative Patent Holder

After the proliferation of patents, the second potentially blocking phenomenon concerns the situation where a single patent holder controls all/the major patents relevant to e.g genetic testing for a particular disease. [21] Such a patent owner holds a dominant position

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[16] REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH, *supra* note 13, at 111; Ian R. Walpole et al., *Human Gene Patents: the possible impacts on genetics services health care*, 179 MEDICAL JOURNAL OF AUSTRALIA, 203, 203-205 (2003); Gert Matthijs & Dicky Halley, *European-wide opposition against the breast cancer gene patents*, 10 EUROPEAN JOURNAL OF HUMAN GENETICS, 783, 783-784 (2002); Jon F. Merz et al., *Diagnostic testing fails the test*, 415 NATURE 577, 577-579 (2003); Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 JOURNAL OF. MOLECULAR DIAGNOSTICS 3, 3-8 (2003); SHAPIRO, *supra* note 8; SCHERER, *supra* note 9, at 1348, 1438-1367; JOSEPH STRAUS ET AL., GENETIC INVENTIONS AND PATENT LAW, Max-Planck-Institüt für ausländisches und internationals Patent-, Urheber- und Wettbewerbsrecht & Bundesminsterium für Bilding und Forschung 6 (2002); WALSH ET AL., *supra* note 13, at 299-300 and ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD), GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES, EVIDENCE AND POLICIES 48 (2002), *available at* http://www.oecd.org/dataoecd/42/21/2491084.pdf [hereinafter OECD Report].

[17] *Id.*

[18] At present, several research groups are carrying out empirical research concerning the existence of patent thickets in the field of genetics by closely analyzing the scope of the relevant patents. *See e.g.* Birgit Verbeure et al., *Analysing DNA patents in relation with diagnostic genetic testing*, 13 EUROPEAN JOURNAL OF HUMAN GENETICS 1, 1-8 (2005).

[19] This last concern may, however, also partially be solved by proper education of biomedical scientists on IP, and patents in particular.

[20] The European Society for Human Genetics has created a panel of experts, which is preparing a report and guidelines for the Society's members. Its major aim is to explain the problems related to patenting and licensing in human genetics and provide workable solutions. *Cf* OECD, Guidelines for the Licensing of Genetic Inventions C(2005)149/Rev1 (2006), *available at* http://www.oecd.org/dataoecd/39/38/36198812.pdf [hereinafter OECD Guidelines].

[21] For example, one patent owner holds the different patents covering the diagnosis of hemochromatosis. MERZ ET AL., *supra* note 16, at 577–579. Bio-Rad acquired the patent on the Hereditary Hemochromatosis (HFE)

on the market for that particular test. If he would decide not to grant licenses neither for research [22] nor for test development, and to exploit the patent autonomously, this might have a number of serious consequences on both research and public health. It could impede research into complementary or alternative methods of diagnosis. The medical practice could be dictated by the single provider without procedures for ensuring quality control and peer review. Furthermore, testing will be quantitatively limited to the capacity of the patent owner, which under such circumstances does not necessarily meet the demands of the number of patients. Additionally, there would be no price competition which might lead to a substantial increase in genetic testing costs and thus a serious drain on funds of public health services. Finally, the close link between testing, clinical and counseling services could be disrupted.

The same applies to the situation where the patent owner would be 'more cooperative' and would issue exclusive licenses for a specific territory and/or a specific type of testing for a high licensing fee [23]: further research and the provision of clinical testing services could be seriously hampered. The OECD Guidelines for the Licensing of Genetic Inventions [24] may provide some guidance as to the legitimacy of specific licensing practices. However, they are not binding and no authority is closely supervising the observance.

C. Trend towards Social Responsibility

The two phenomena explained above may impede the access to health care by limiting the available tests and thus preventing patients from the appropriate care. Calls for 'access to medicines' are generally associated with developing countries' health care problems. It is acknowledged that the problems of developing countries are serious and mostly of a different nature [25] than those in industrialized countries. However, (part of) the problems related to

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gene after Mercator Genetics went out of business. The company offers to license laboratories to perform testing, but at a cost that makes Bio-Rads own, commercial test kit more economically attractive due to up-front payments and a per test fee of $ 20 (for 2 mutations).

[22] In some countries research is exempted from patent infringement. In principle, researchers would not be obliged to negotiate a license to allow them to carry out their research. However, the scope of those statutory/non-statutory exemptions varies considerably. *See e.g.* CHRIS DENT ET AL., RESEARCH USE OF PATENTED KNOWLEDGE: A REVIEW, OECD Directorate for Science, Technology and Industry, STI Working Paper, No. 2006/2 (2006), *available at* http://www.oecd.org/dataoecd/15/16/36311146.pdf.

[23] However, it is complicated to objectively determine whether a license fee is excessive or not and thus it may be hard to demonstrate an eventual infringement of competition law (abuse of a dominant position). This will depend on the circumstances of the case: the costs of research and development, the marginal costs of the diagnostic test, the upstream or downstream nature of the patent, the broad or narrow scope of the patent, the availability of substitutes, opportunities for (cross-)licensing, etc.

[24] OECD GUIDELINES, *supra* note 20.

[25] Developing countries often do not only lack medicines and medical facilities, but also educated health workers, and basic needs such as water and healthy food.

restricted access caused by patent thickets or unilateral blocking licensing practices could be approached globally. This paper will not focus on the particular problems of developing countries. [26] Also in industrialized countries access to diagnostic tests followed by the appropriate treatment cannot always be guaranteed to all patients. Public health insurance schemes encounter difficulties covering health care costs of their (low income) members due to the – from time to time – exorbitant prices of drugs, therapies and diagnostic tests. In some industrialized countries, patients will not be able to afford the franchise (co-payments) for the best available medicine. [27] Hence, they will not receive the most appropriate care.

The high prices can partially be explained by expensive ingredients and production processes, R&D costs, labor costs, transaction costs, royalties that have to be paid to holders of patents related to inventions that constitute the product, etc. However, it has been contended that some pharmaceutical companies are raising their prices, just because they can, because they are the only company selling the drug. [28] This pricing policy has had a very negative impact on the reputation of the pharmaceutical industry.

This does not mean that just 'bad' industry behavior is at the order of the day. For instance, in the US, many pharmaceutical companies have (had) patient assistance programs in place offering free medicines to patients who cannot pay the full costs of their medications. [29] With the introduction of the new US Medicare drugs plan [30] there was some

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[26] *See e.g.* COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS WITH DEVELOPMENT POLICY, Final Report, London: DFID (September 2002), *available at* http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf; CARLOS M. CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES (Geneva, South Centre; 2000), *available at* http://www.southcentre.org/publications/publichealth/publichealth.pdf and Frederick M. Abbott, *The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference*, 5 J. WORLD INTELL'L PROP. 15, 15-52.

[27] Currently, this phenomenon especially arises with regard to cancer treatment. *See* e.g.: Alex Berenson, *Cancer Drugs Offer Hope, but at a Huge Expense*, THE NEW YORK TIMES, July 12, 2005.

[28] In countries, with strict supervision on the price of medicines and health care services by the health care authorities, like Canada and the UK, pharmaceutical and biotech companies have obviously less freedom to set prices.

[29] *See* e.g. http://www.pparx.org/.

[30] The US health insurance scheme includes two health insurance programs, Medicaid and Medicare. Medicaid is a publicly funded, joint federal-state health insurance program for people with limited income (low-income children, seniors and people with disabilities; form of social welfare). Each state administers its own Medicaid program while the Federal Centers for Medicare and Medicaid Services monitors the state-run programs. Medicare is a publicly funded, federal health insurance program covering people who are either 65 and people with a disability (entitlement program). Medicaid and Medicare cover similar groups of people, but there are important differences between them. For example, Medicaid covers a wider range of health care services than Medicare and Medicaid does not have premiums, deductibles and co-payments like Medicare. The 'original' Medicare program had two parts: Part A for hospital insurance and Part B for medical insurance. Neither Part A nor Part B paid for all medical costs. Only in few cases, prescription medicines were covered, but as from January 2006 Medicare Part D provides more comprehensive coverage. Recent Senate Hearings on Part D prescription plans revealed, however, a sizable coverage gap, the so-called "Donut Hole", that requires seniors to pay the full cost of medicines when the cost run between $2250 and $5100.

uncertainty about the future availability of such programs. In November 2005 inspector general Daniel R. Levinson of the Department of Health and Human Services had expressed the view that the programs carried a high risk of fraud and abuse driving up costs for Medicare. He contended that manufacturers would try to increase their sales by tying patients to their products though cheaper alternatives were available. However, shortly after the taking into operation of Part D, the new Medicare drug plan, the plan appeared to lead to a coverage gap, the so-called "Donut Hole". The Medicare drugs plan provides a broad coverage for initial drug costs, but offer little or no coverage until the "out-of-pocket costs" for the year total $3600. From that point, Medicare will generally pay 95% of the costs. Several pharmaceutical companies were interested in paying the beneficiaries share of the costs of medication during the initial coverage period and all the costs during the coverage gap, provided that the medicines were manufactured by the company concerned. The inspector general approved two specific free drug programs, structured to reduce the risk of fraud and abuse. They operate entirely outside the Medicare Part D plan. [31]

Recent initiatives of pharmaceutical companies to invest in research for tropical diseases and to donate medicines, such as the creation of the Novartis Institute for Tropical Diseases in Singapore dedicated to the discovery of drugs for tuberculosis and dengue, Merck's HIV/AIDS partnership and Sanofi-Aventis' dengue vaccine project, are another example. These projects have a distinctively charitable aspect and do not generate financial returns. [32] They show a shift in attitude among pharmaceutical companies from exclusively seeking profits to accepting social responsibility for access to medicines.

I admit that drug manufacturers do not act out of pure altruism, but that it is fueled by a desire for good publicity as well. Companies are primarily self-interested and revenue-driven and will generally try to maximize economic benefits. However, I do not subscribe to the idea that this is their only concern. The above-mentioned examples show that pharmaceutical companies do take their responsibilities with respect to public health. Solutions for the access blocking problems that would entail the destruction of IP portfolios in the area of genetics are to my mind not within the realm of realistic solutions. The patent pool and clearinghouse model offer compromise solutions that address the issue of guaranteeing access to and use of patented inventions based on social responsibilities. Simultaneously,

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See SENATE DEMOCRATIC POLICY COMMITTEE HEARING, July 17, 2006, *available at* http://democrats.senate.gov/dpc/dpc-hearing.afm?A=35.

[31] Robert Pear, *Makers Get Limited Approval of Free-Drug Plans*, THE NEW YORK TIMES, April 19, 2006.

[32] Paul Herrling, *Experiments in social responsibility*, 439 NATURE, 267, at 267-277 (2006).

these models encourage investments in further innovation, and are within the realm of what may be accomplished by stakeholders on a voluntary basis.

D. Method of Analysis

In the analysis of the patent pool model and different clearinghouse models, I will refer to a test of three practical impediments to determine to what extent these models effectively address the access problems explained under Section I.A and I.B and may provide an adequate solution. The emergence of patent thickets involves (1) high transaction costs, caused by the number of licensing partners, including search, bargaining and enforcement costs. Bargaining with many licensing partners generally leads to the (2) accumulation of licensing fees. Patent holders unilaterally applying unreasonable licensing conditions or blatantly refusing to license at all may create blocking positions (3) impeding access to essential patents. For the patent pool model this analysis will be integrated in the Section on the strengths and weaknesses of patent pools in general, while the different clearinghouse models will each be subject to a brief examination on their aptitude to remedy these three obstacles.

II. CLEARING MECHANISMS

As long as the number of negotiating partners (patent holders) in order to obtain freedom to operate is limited, blocking positions might be dissolved by simple bilateral licensing negotiations. However, bilateral licensing negotiations may fail. Patent holders sometimes impose (extremely) restrictive licensing conditions on the licensee. Or a patent holder being the last licensing partner with a blocking patent essential for the activities of the licensee may play strategically. In patent thicket situations licensees may be overwhelmed by the number of relevant patent holders. All these factors may make it worthwhile for the licensee to consider alternatives for bilateral licensing.

At present, pharmaceutical companies, biotech companies, public and private laboratories and universities circumvent the need to (bilaterally) license-in all the required technology by means of “working solutions”, such as inventing around the major patents, conducting R&D in countries where the inventions have not been patented, developing and

using public tools (e.g. SNP Consortium), [33] infringing (informally referring to the research exemption), and challenging the validity of the patents in court or opposing the grant of the patent at patent office. [34] Cross licensing may be another solution for companies as long as they have something to offer in return. [35] Other companies (with a strong bargaining position) thread their way through the patent thicket by bargaining a reduced royalty provision or a cap on royalties by putting royalty stacking clauses in the license agreements. [36] Such provisions seek to allow a licensee to deduct all or some of the royalties or license fees payable to third parties to bring a product to the market.

The majority of these working solutions lack legal certainty and still require good negotiation skills and a fair amount of transactions costs. To overcome the high level of transaction costs and alleviate the royalty burden, while at the same time offering a secure and stable solution, two alternative mechanisms have been suggested. First, the establishment of patent pools has been proposed (Chapter III). A patent pool is an agreement between two or more patent owners to license one or more of their patents as a package to one another. Subsequently, the patents included in the pool will also be licensed as a package to third parties willing to pay the royalties associated, either directly, by patentees to licensees or indirectly, through a new entity specifically set up for administering the pool. [37] Second, a royalty collection clearinghouse model [38] has been put forward for facilitating access to and use of patented genetic inventions (Chapter IV). Such a licensing model would be administered by an independent collecting entity, which might be comparable in structure and

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[33] *See* Section IV.B.

[34] WALSH ET AL., *supra* note 13, at 285, 322-328.

[35] In many cases, cross licenses involve no running royalties, although they might involve balancing payments to reflect differences in the companies' patent portfolios. SHAPIRO, supra note 8, at 12.

[36] Frank Grassler and Mary A. Capria, *Patent pooling: Uncorking a technology transfer bottleneck and creating value in the biomedical research field*, 9 J. COMM. BIOTECHN., 111, 111-118 (2003); OECD Report, *supra* note 16, at 48.

[37] JOEL I. KLEIN, AN ADDRESS TO THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION ON THE SUBJECT OF CROSS LICENSING AND ANTITRUST LAW, *available at* http://www.usdoj.gov/atr/public/speeches/1123.htm (1997); JEANNE CLARK ET AL., PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? , White Paper 4 (2000), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf; Robert P. Merges, *Institutions for Intellectual Property Transactions: The Case of Patent Pools*, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY, 123, 129 (Rochelle D. Cooper et al. eds., 2001), also *available at* http://www.law.berkeley.edu/institutes/bclt/pubs/merges; EUROPEAN COMMISSION GUIDELINES ON THE APPLICATION OF ARTICLE 81 OF THE EC TREATY TO TECHNOLOGY TRANSFER AGREEMENTS [2004] *O.J.*, C 101/2, para. 210. I note that the European Commission refers to technology pools instead of patent pools, thus applying a somewhat broader concept.

[38] A distinction is made between the concept "*clearing mechanisms*" and "*clearinghouse*" mechanisms. The former encompasses the working solutions and patents pools and clearinghouses. "*Clearinghouse*" mechanisms, only refers to the last model.

function to the existing copyright collection societies. [39] Similarly, users of genetic inventions would pay an equitable royalty fee to the clearinghouse to use the relevant invention(s) patented. Preliminary research has shown that various types of clearinghouses may be distinguished, among which there are two that might fulfill the three purposes distinguished in Section I.D.

This paper deals more extensively with patent pools and clearinghouse mechanisms as they are either relatively unknown or completely new in the field of patents for genetic inventions.

III. PATENT POOLS

A patent pool is two-sided and thereby embodies two major licensing techniques. On the one side, the multiparty agreement between two or more patent owners by which their patents are licensed as a package to one another and form a pool. On the other side, the package is licensed out to third parties on a bilateral basis either directly by one of the partners of the pool or indirectly through an independent licensing authority. This is also-called the 'one-stop license'-function of the patent pool: licensees apply for a single license at the patent pool licensing entity and are authorized to use the bundle of essential patented inventions.

Because of the two-sided character of the patent pool, the pool will generally be carried out by a group of agreements. This group may consist of e.g. an Authorization Agreement, establishing the Licensing Authority, an agreement between the licensors themselves to organize the formation of the pool (the selection and retention of experts, the procedures to be followed, the royalties' allocation formula, etc.) and a Standard Out-Licensing Agreement. The establishment of a patent pool is a long, technically and legally complex, multi-step process. In view of the varied issues and interests at stake, expertise and joint collaboration of highly qualified patent attorneys, technical experts in the relevant field and legal advisors both in the field of patent law and competition law is required.

Personal communications with public and private entities active in genetics have indicated that they tend to be quite interested in the first element which they consider a safe

[39] E. Richard Gold, *Biotechnology patents: strategies for meeting economic and ethical concerns*, 30 NATURE GENETICS 359, 359 and AUSTRALIAN LAW REFORM COMMISSION (ALRC), GENE PATENTING AND HUMAN HEALTH, para. 23.53 (Discussion Paper No. 68, 2004), *available at* http://www.alrc.gov.au [hereinafter ALRC Discussion Paper].

harbor for licensing agreements to cut through a web of patent rights. However, most actors do not immediately fancy *the obligation* imposed by competition law to license the patents included in the pool to third parties. In addition, these licenses have to be *non-exclusive* and the royalties *fair, reasonable and non-discriminatory* (Section III.D). Hence, this will rule out their chance to adopt a strategic licensing policy having to put all their cards in the game with respect to exclusivity, royalty rates and other licensing conditions on the table. Therefore, it is important for the promotion of this model to present additional advantages and incentives to get the multi-step process of setting up a pool started.

As stated above, out-licensing can take place either by one of the partners in the pool (although some safeguards as to its independence and the confidentiality of business information should be built in) or by a separate independent licensing authority. The first alternative will generally be selected by patent pools with a relatively limited number of participating patent holders and potential licensees, manageable by a small number of people (Section III.A.2). Pools established on the basis of or in preparation of industry standards (often in the field of consumer electronics or telecommunications) have a large market of potential licensees within reach. This would put a heavy burden on the partner administering the licensing activities. Therefore this kind of pool will generally be submitted to the second licensing structure; the independent licensing authority. MPEG-LA is the classic example in this respect (Section III.A.1).

Patent thickets have arisen in technical fields other than genetics and patent pools have emerged to cut through the overlapping patents in many of those cases, especially in the US. In 1856, a first successful patent pool of sewing machine patents emerged. In 1917, an aircraft pool was formed encompassing almost all aircraft manufacturers. This pool was instigated by the US government as it was crucial to the US government entering World War I. In 1924, a patent pool was established for radio parts. [40] In the late 1990's several patent pools with worldwide coverage were formed in the electronic and telecommunications sectors.

[40] CLARK, *supra* note 37, at 4; MERGES, *supra* note 37, at 123, 125-146; Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1341-1349 (1996).

A. Patent Pools & Electronics and Telecommunications

1. 'MPEG-Pools'

In 1997 the MPEG-2 pool was formed for inventions relating to the MPEG-2 standard. [41] This pool is being administered by the MPEG Licensing Administrator (MPEG-LA). Since then various other pools related to a specific technical standard have been established under the management of MPEG-LA. MPEG-LA regularly announces essential patent holders starting to structure joint licenses for a new pool (primarily in electronics and telecommunications). [42] It is even seriously considering setting up pools in the biotechnology sector. [43]

An example of one of the MPEG-LA managed pools is the "1394"-pool which was established in 1999. [44] The numerals refer to the "1394 standard" which is applied in the high-speed transfer digital networking (serial bus) technology, better known as *FireWire* (Apple's trademark) and *iLink* (Sony's trademark). The major incentive to create the pool was the adoption of international standards relating to a high speed data transfer digital interface, known as the 1394 Standard, by the Institute of Electrical and Electronics Engineers and the International Electrotechnical Commission. The pool offers worldwide, non-exclusive, non-discriminatory and reasonable licensing of the 1394 technology's essential patents. Non members of the pool pay a royalty of 0.25 US$ upon the manufacture or sale of each finished product they produce (e.g. a camera, a photocopier, a medical device) in which the 1394 technology has been implemented, regardless of the number of components in the product that incorporate the standard. The 1394 pool allocates a portion of the licensing fee to each member of the pool, according to a pre-set formula. All patents carry equal weight.

At present, this mega-type of pool includes about 90 patent families from 9 patent holders, including Apple, Canon, Hitachi, Philips, Panasonic, Samsung, Sony, ST Microelectronics and Toshiba. All patents in the pool are evaluated by an independent expert and deemed to be essential for implementing the 1394 standard, because "one or some of the

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[41] MPEG: "MPEG" stands for "Moving Picture Experts Group". As used in the trademark MPEG LA, MPEG does not stand for anything in particular but is simply part of the name MPEG LA. JOEL I. KLEIN, BUSINESS REVIEW LETTER TO GERRARD R. BEENEY (1997), *available at* http://www.usDoJ.gov/atr/public/busreview/1170.htm.

[42] These pools relate for instance to the DVB-H standard for carrying multimedia services over digital terrestrial broadcast networks to handheld terminals and the ATSC digital television standard, more information *available at* http://www.mpegla.com/pid/.

[43] LAWRENCE HORN, NOVEL APPROACHES TO IP MANAGEMENT: ONE-STOP TECHNOLOGY PLATFORM LICENSES (Presentation at the OECD Workshop on Genetic Inventions, Intellectual Property Rights and Licensing Practices, Berlin, January 24, 2002), *available at* http://www.oecd.org/dataoecd/16/32/1817882.pdf.

[44] 1394 Licensing Agreement, status on January 1, 2005, *available at* http://www.mpegla.com/1394/ and personal communication.

patent claims will necessarily, unavoidably and literally be infringed by implementation of any portion of the 1394 standard". Currently, the patent pool embraces about 350 licensees worldwide. [45]

2. DVD-pools

As with MPEG-2 and the 1394-technology, a multi-firm standards group declared a standard for DVD technology. Several enterprises hold relevant patents regarding this standard. Late 1995, 4 core DVD-developers (of a DVD consortium consisting of 10 members), Philips, Sony, Matsushita and Toshiba, started negotiations on the establishment of a patent pool in view of manufacturing DVDs and players in compliance with the DVD-ROM and DVD-Video formats. In August 1996, Sony and Philips announced that they would form their own DVD-pool due to the failing negotiations among the core members. Pioneer Corporation subsequently joined this 3C-pool. The Department of Justice cleared the pool in 1998. [46] Philips serves as joint licensor on the basis of bilateral agreements with Sony and Pioneer. The patents in the pool should be "necessary (as a practical matter) for compliance". A qualified independent expert retained by Philips (!) determines which patents are considered essential. Philips is obliged to license non-discriminatorily to all interested third parties. All three licensors, however, remain free to license their essential patents independently including for other uses. The royalty rate is set at 3.5% of the net selling price for each player sold and $0.05 for each disc sold. Additionally, the portfolio license requires an initial payment of $10,000 half of which is creditable against the per-unit royalties. The allocation of the royalties to the licensors is determined on a per-unit sold basis and not on the number of patents contributed to the pool. Licensees must grant back the licensors and fellow licensees a license on any patents they own or control that are "essential" on reasonable, non-discriminatory conditions. In 2003, the accession of LG Electronics allowed the pool to grow into the DVD4C pool.

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[45] This includes member-licensees such as Apple, Canon, Sony, Toshiba and non-member licensees such as Agfa-Gevaert, Barco, Bell, Epson, Fuji, Kodak, Leica, Linux, Motorola, Nokia, Pioneer, Ricoh, Xerox and Yamaha. All information derived from the MPEG-LA-website, *see* http://www.mpegla.com/index1.cfm (last visit 25/10/2005).

[46] JOEL I. KLEIN, BUSINESS REVIEW LETTER TO GERRARD R. BEENEY (1998), *available at* http://www.usDoJ.gov/atr/public/busreview/2121.htm (last visit 28/07/2006). *See also* http://www.licensing.philips.com/licensees/conditions/dvd/ (last visit 28/07/2006).

In 1997, Hitachi, Matsushita, Mitsubishi, Time Warner, Toshiba and JVC established the DVD6C pool, which was cleared in 1999.[47] Toshiba agreed to assemble the essential patents in a portfolio and to license the portfolio to all makers of DVD products by way of non-exclusive, non-transferable license and to distribute the royalties to the other licensors. A patent is "essential" if it is "necessarily infringed" or, there is no "realistic alternative" to it in implementing the DVD standard specifications. An independent expert will review the essential character of the included patents. His determinations are "conclusive" and non-appealable". The multilateral agreement gives detailed arrangement concerning the expert's remuneration, prohibition on economic affiliation with individual licensors, etc, in order to safeguard his independence.

Toshiba will charge royalties of $.045 per DVD disc and 4% of the net sales price of DVD players and DVD decoders, with a minimum royalty of $4.00 per player or decoder. It will distribute the royalties pursuant to an agreed allocation formula set forth in the patent pool arrangement, which takes into account how often a licensor's essential patents are infringed by manufacture or sale of licensee's products, the age of the patent and whether the patents relate to optional or mandatory features of the standard. Each licensor agrees to offer its essential DVD patents also on an individual non-exclusive basis to interested third-party licensees pursuant to separate negotiations. Licensees are obliged to grant back any essential patents it may own or control during the term of the license. Toshiba may have an independent auditor review the licensees books with respect to sales, other transfers and royalties, but will erect internal firewalls to protect competitively sensitive information it receives from licensees. In the meantime IBM (June 20, 2002) Sanyo and Sharp (April 15, 2005) have joined the DVD6C pool.

A company that intents to enter the DVD market is to seek licenses from both patent pools.

3. 3G Patent Platform Partnership (3G3P)

The 3rd Generation Partnership Project (3GPP)[48] is a collaboration agreement established in December 1998 for the production of a complete set of globally applicable technical specifications and reports for third generation wireless communication systems involving the use of digital transmission technologies. Following the establishment of 5 major

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[47] JOEL I. KLEIN, BUSINESS REVIEW LETTER TO CAREY R. RAMOS (1999), *available at* http://www.usDoJ.gov/atr/public/busreview/2485.htm (last visit 28/07/2006). *See also* http://www.dvd6cla.com/ (last visit 2006/08/25).

[48] *See* http://www.3gpp.org/.

technical standards, the 3rd Generation Patent Platform Partnership was developed in order to clear the patent thicket and secure independent valuation of essential patents and flexible but fair, reasonable and non-discriminatory licensing. 3G3P is not a "classical" pool, but a platform offering a range of different license options. Unlike MPEG, and the DVD-pools, it was not thought feasible to produce a simple patent pool arrangement with a bundle including all 3G essential patents, because of the great number of essential patent holders and because any user might need only a small portion of the patents involved.

Although the Japanese Fair Trade Commission approved the initial 3G3P-proposal already on December 14th, 2000, the US DoJ only endorsed the proposal after the 3G3P agreed to make substantial modifications. These modifications involved the separation of the original proposal's single patent platform into five largely independent platforms for each of the five 3G radio interface technologies. [49]

The 3G Patent Platform Partnership is limited to coverage of essential patents mandatory to standards for 3G Systems. A patent is deemed to be "essential" if it is "claiming an apparatus, a method or a process necessary for compliance for the 3G standards" and is "technically essential". In order to be found essential to a particular 3G Standard at least one claim under the patent must be found to be essential. The essential character will be reviewed by an expert, who will not be directly paid nor selected by the licensors to safeguard his independence.

3G3P also differs from the other pools in that the actual license is between the licensor and the licensee and not with the platform, which neither collects nor remits the license fees. Potential licensees thus do not have the benefit of a one-stop license. A licensee enters into a default Standard License separately with each essential patent licensor on the terms established for that platform, or enters into an Interim License, on terms similar to the Standard License, while negotiating terms bilaterally with the essential patent licensor for a final license that may vary from the standard license. Indeed, the patent holder can decide to seek an alternative arrangement with the licensee outside the platform. However, the essential patent holder's demands should be fair and reasonable. If the parties do not reach an agreement, they can resort to the internal dispute resolution procedures to facilitate the

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[49] CHARLES A. JAMES, BUSINESS REVIEW LETTER TO KY P. EWING (2002) *available at* http://www.usdoj.gov/atr/public/busreview/200455.pdf (last visit 28/07/2006). The European Commission approved the proposal by way of an (informal, unpublished) comfort letter provided it would be modified conform the indications of the DoJ (November 11, 2002). *See* Ky P. Ewing, EC and DoJ approval of the 3G Patent Platform, 6 GLOBAL COMP. REV., 12, 14 (2003).

negotiations. In case of disagreement, the Licensing Administrator [50] is authorized to issue the (default) Standard License subject to the so-called Maximum Cumulative Royalty Rate. [51] This option offers optimal flexibility, but may attenuate the transaction cost savings common for patent pool arrangements.

Licensees are obliged to submit all of their 3G-related patents for evaluation of essentiality and to make such patents available under the platform terms if they are found to be essential. This grant back obligation is specific to each individual platform company.
The royalty to be paid by the licensees and the allocation formula for the distribution of the royalties between the licensors will be set by each platform separately.

The 3G3P is perceived as less successful than the pools described above. At present it only involves 9 essential patent holders [52] and many major players in the telecommunications sector could not be convinced to join the partnership (yet).

B. Patent Pools & Biotech

To what extent can patent pools as they have been designed for electronic and telecommunication industries, be used as a template for patent pools in the biomedical sector? The OECD considers the patent pool concept to be interesting for biotechnology but has some doubts as to whether the technologies and markets for genetic inventions are amenable to pools. The biomedical industry is perceived as fundamentally different from the electronics and telecommunication sectors. Especially the generation of industry standards as used in electronics and telecommunications for interoperability of electronic devices is seen as a strong incentive for setting up a patent pool in those sectors (Section III.F). In the absence of this type of standard driven incentive for the setup of a patent pool, [53] the OECD highlights that dominant players might be reluctant to join the pool because there is no apparent gain. Additionally, according to the OECD, biotech companies rely heavily on their IP and foster what has been called a "bunker mentality", a defensive attitude focused on self-protection and secrecy. Furthermore, there are likely to be disagreements over the value of patents in a pool

[50] 3G Licensing Ltd., established January 2004, *see* http://www.3glicensing.com/.
[51] Maximum cumulative royalty rate that a licensee of the platform will pay for all the licenses needed for that 3G standard.
[52] May 2006, 3G Licensing presented the W-CDMA Patent Licensing Program. ETRI, DoCoMo, Fujitsu, KPN, Mitsubishi Electric, NEC, NTT, Sharp and Siemens are the licensors within this program. *See* http://www.3glicensing.com/articles/News%20ETSI.pdf.
[53] In this paper, it will however be argued that also in the field of genetics industry standards might play a role, although these standards do not fulfill the same 'interoperability-function' as in electronics and telecommunications, but act as best practice guidelines. *See* below Section III.F.

which may block the creation of the pool. [54] In view of all these elements, the OECD is calling for further study. [55]

There is hardly any literature on how companies have resolved patent thicket problems in the biotechnology sector. This is probably because these solutions have an element of commercial secrecy. However, one instructive case on patterns of protection and on the negotiation through the patent thicket was published in the field of agricultural biotechnology, the Golden Rice case. A fairly recent case where genetic laboratories are trying to remove the bundle of patents by way of a pool relates to the biomedical field; the SARS corona virus. [56] The GFP 'pool' does not completely meet the definition provided above, but will be described anyway because it shows a common practice sometimes referred to as 'pooling portfolio's' or 'aggregation of exclusive rights'. [57]

1. Golden Rice

Potrykus succeeded in genetically enriching rice grains with β-carotene, the precursor to vitamin A [58], as a result of which the grains are yellowish in color and called "golden rice". Potrykus wanted to transfer the golden rice materials to developing countries for further breeding in order to introduce the trait in local varieties consumed by poor people. However, a freedom-to-operate survey uncovered 70 patents belonging to 32 different companies and universities embedded in golden rice. [59] The 6 key patent holders were invited for negotiations and agreed to allow Potrykus to grant non-exclusive licenses, free of charge, to developing

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[54] This is a common problem for patent pools. Also pools in electronics and telecommunications have been faced with this problem. Arguably, it was one of the reasons why the DVD-pool failed and the DVD-Consortium fell apart in two smaller pools and one separate licensing entity. One solution might be expert valuation and alternative dispute resolution mechanisms to settle disagreements on the value of the patents.

[55] OECD REPORT, *supra* note 16, at 67. Also the Australian Law Reform Commission (ALRC) recommends further examination of the feasibility of patent pools for particular types of patented genetic materials or technologies. AUSTRALIAN LAW REFORM COMMISSION (ALRC), GENES AND INGENUITY: GENE PATENTING AND HUMAN HEALTH, (Final Report 99, 2004), *available at* http://www.alrc.gov.au, at paras. 22.75-22.76 and 24.86-24.87 [hereinafter ALRC Final Report].

[56] JAMES SIMON, HOW PATENTS MAY AFFECT THE DEVELOPMENT OF A SARS VACCINE: THE POSSIBLE ROLE OF PATENT POOLS, (Presentation at Seminar Commission on Intellectual Property Rights, Innovation and Public Health (Geneva, World Health Organization, CIPIH, October 22, 2004), *available at* http://www.who.int/intellectualproperty/seminar2/en/.

[57] The SNP Consortium has been referred to as an "intellectual property pool". In this paper the SNP Consortium is labeled an open access clearinghouse. It provides free access and use to *public data* on SNPs without any third party encumbrances or obligation to take out licenses or pay royalties to a licensing entity. *See* below Section IV.B.

[58] Peter Beyer et al., *Golden Rice: introducing the beta-carotene biosynthesis pathway into rice endosperm by genetic engineering to defeat vitamin A deficiency*, 132 J. NUTR. 506S, 506S-510S (2002).

[59] R. DAVID KRYDER, THE INTELLECTUAL AND TECHNICAL PROPERTY COMPONENTS OF PRO-VITAMIN A RICE (GOLDEN RICE TM): A PRELIMINARY FREEDOM TO OPERATE REVIEW, (ISAAA Briefs No. 20, ISAAA, Ithaca, 2000), *available at* http://www.isaaa.org.

countries, with right to sub-license. [60] A Humanitarian Board ("HumBo") assists in governance and decision making. [61] Around 20 "master licenses" have been granted by Potrykus, the chairman of Humbo since its inception, to developing country institutions in Asia. [62]

The Golden rice case is an example of how private and public organizations in life sciences in a combined effort may deal with a patent thicket by creating a patent pool in the form of a single, neutral licensing authority. However, it is important to take into account the non-profit nature and the humanitarian objective of the pool signaling the uniqueness of this initiative. Nevertheless, this experience triggered further reflection and action with regard to other circumstances where the patent pool model might be applied [63] and other clearing models for (agricultural) biotechnology, such as the clearinghouse (Chapter IV). [64]

2. *SARS Pool*

In response to the outbreak of Severe Acute Respiratory Syndrome (SARS), the World Health Organization (WHO) set up a network of laboratories to assist in controlling the disease. This led to the isolation of the causative virus, the sequencing of its genome, and its containment. Two groups discovered the SARS genome independently from one another. [65] Several of the contributing laboratories filed patent applications incorporating SARS genomic sequence data. Further research led to the filing of additional patent applications by a multitude of public and private sector entities. [66] The WTO set up a SARS consultation group

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[60] *See* the Zeneca (now Syngenta) press release at the time for more details: Golden Rice collaboration brings health benefits nearer, (May 16, 2000), *available at* http://www.syngenta.com/en/media/article.aspx?pr=051600&Lang=en. For the follow-up, see two other press releases: International Rice Research Institute begins testing Golden Rice, (January 22, 2001), *available at* http://www.syngenta.com/en/media/article.aspx?pr=010122b&Lang=en; Syngenta to donate Golden Rice to Humanitarian Board, (October 14, 2004) *available at* http://www.syngenta.com/en/media/article.aspx?pr=101404&Lang=en.

[61] *See* ADRIAN C. DUBOCK, PRESENTATION AT CONFERENCE ON PUBLIC GOODS AND PUBLIC POLICY FOR AGRICULTURAL BIOTECHNOLOGY (7th ICABR International Conference, Ravello (Italy), June 29 to July 3, 2003) (manuscript on file with the author).

[62] Personal communication Anatole F. Krattiger (December 14, 2004).

[63] Randall Parish & Reiner Jargosch, *Using the Industry Model to Create Physical Science Patent Pools among Academic Institutions*, J. AUTM 65, 65-79 (2003).

[64] Gregory D. Graff & David Zilberman., *Towards an Intellectual Property Clearinghouse for Ag-Biotechnology. An Issues Paper*, IP STRATEGY TODAY 1, 1-12 (2001-3); Gregory D. Graff et al., *The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology*, 21 NAT. BIOTECHN. 989, 989-995 (2003).

[65] Paul A. Rota et. al., *Characterization of a Novel Coronavirus Associated with Severe Acute Respiratory Syndrome*, 300 SCIENCE 1394, 1394-1399 (2003) and Marco A. Marra et. al., *The Genome Sequence of the SARS-Associated Coronavirus*, 300 SCIENCE 1399, 1399-1404 (2003).

[66] Patent applications incorporating the fundamental SARS genomic sequence are (patent search of 09/12/2004): WO2004096842A2 (Cancer Agency), WO2004092360A2 (Chiron Corporation), WO2004092332A2 (Ciphergen Biosystems, Inc.), WO2004089983A2 (Vironovative B.V.), WO2004085633A1 (University of

which stretched the social responsibility of the patent applicants proposing "that a strategy be developed, in consultation with stakeholders, to address potential SARS corona virus related IP issues and thus enhance development of intervention approaches". [67]

The relevant parties have been identified and principal agreement has been gained on the creation of a patent pool by the signing of a letter of intent. Should the parties conclude a full agreement the pool will be set up in the US. One of the patent holders is affiliated with the NIH. The NIH has been proposed as the future licensing authority of the SARS pool. Arguably, the management of the pool could be transferred to a well-experienced patent pool managing authority, such as MPEG-LA or Via Licensing. Larry Horn, the managing director of MPEG-LA has expressed at various occasions his interest in extending MPEG-LA's area of working to biotechnology.

At present, the initiators of the SARS pool have negotiated on the essential patent applications to be included in the pool and patent attorneys are in the final phase of evaluating the patents. They are about to start discussions with the US federal antitrust agencies. The agencies appear to be willing to take a quite favorable stance with respect to the pool. Afterwards, the initiators will probably try to set up pools elsewhere. [68]

Highly qualified technical and legal experts assist the parties during the chain of negotiations. Attorneys and academic advisors are working pro bono to prevent the creation of the pool from becoming prohibitively expensive. This underlines the special nature of the pool strongly supported by the WHO and the public health interests involved. The SARS pool has some other noticeable features as well, such as the fact that it concerns patent applications instead of granted patents; the licensors are universities and public institutions instead of profit maximizing companies; and, the commercial products in which the licenses technology will be embedded are still to be developed by extensive R&D activities. This last characteristic creates uncertainty as to whether any potential revenue of the pool will justify the time and costs of setting up the pool.

If all goes well, the SARS initiative might set a key precedent for patent rights management in genetics by the establishment of a patent pool. However, it should be emphasized once more that just as the Golden Rice pool the SARS-pool had the advantage of

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Hong Kong). Probably many additional patent applications related to the SARS genome are or will be filed, e.g. reverse genetics, diagnostics, vaccines, antiviral protein (e.g. soluble Spike), antibodies (e.g. anti-NP).

[67] WORLD HEALTH ORGANIZATION SARS CONSULTATION GROUP, EXTRACT FROM RECOMMENDATIONS (November 2003).

[68] Personal communication, James H.M. Simon (August 2005); James H.M. Simon et al., *Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role for patent pooling*, 83 WHO BULLETIN 707, 707-710.

being supported for public health/humanitarian reasons, it remains to be seen whether patent pools in the biomedical field will arise voluntarily without such assistance.

3. GFP 'Pool' [69]

Green Fluorescent Protein (GFP) is a fluorescent reporter protein with a wide spectrum of applications in life science research. By using GFP to label target proteins researchers can track proteins in living cells and screen from compounds that affect cellular signaling pathways. This improves the biological relevance of drug screening and helps increase the speed and accuracy of drug discovery and development. The so-called *Aequorea victoria* GFP (AvGFP) is the most characterized and best understood reporter fluorescent protein. The AvGFP IP landscape is complex. Via a series of strategic alliances, GE Healthcare aggregated rights in order to offer sub-licenses to GFP patents and patent applications [70] thus enabling users to obtain these rights from a single source.

The "GFP License" offered by GE Healthcare includes the rights covered by European, US and Japanese patents covering different mutations that greatly enhance the performance of AvGFP. GE Healthcare offers a wide range of licenses starting at a technology evaluation license for smaller biotechs and startups who are considering adopting GFPs for just one application through to full life of patent screening licenses for global pharmaceutical companies. This ensures considerable flexibility and a cost-effective solution, by having licensees purchase only the rights they need. With the purchase of a GFP product, the user automatically acquires a license for use of the technology for the application for which the product is intended. GE Healthcare is also allowed to grant a "Columbia GFP License" in addition to the GFP License or as a stand alone agreement for the basic AvGFP claims held by Columbia University.

Thus, GE Healthcare acquired all the relevant rights through without multiparty patent pool arrangement, but through bilateral in-licensing. Although, this acquisition allows GE Healthcare to provide one-stop access to a bundled patent portfolio, it is no classical patent pool arrangement.

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[69] All information is derived from GE Healthcare's website via http://www.amershambiosciences.com.

[70] The pooled patent portfolio includes granted US, European and Japanese patents from Invitrogen IP Holdings and BioImage. A number of patent applications from Aurora Biosciences, BioImage and Amersham Biosciences can also be included in the license.

C. Strengths and Weaknesses Patent Pools

The experience with existing pools in the electronics and telecommunications industries has learnt that the establishment of patent pools may have significant benefits. [71] A first benefit of a patent pool is the reduction of transaction costs. [72] The search and bargaining costs will be reduced through the introduction of a system of one-stop licensing for third party licensees. Licensees no longer have to bargain separate licenses with multiple individual patent holders, but apply for one single (standard) patent pool license. Despite the transaction costs reduction, the initial costs of setting up and negotiating a pool agreement are not negligible. As these costs are (primarily) born by the patent holders, the establishment of a patent pool has an important redistribution effect. This is where the shoe may pinch. A cost-benefit analysis by a profit-maximizing enterprise requires that the economic benefit outweighs the costs. This element will be further elaborated below.

Second, patent pools rule out royalty stacking. The patent pool will set a price for the package of patents included in the pool. The price may be an upfront payment, a percentage of the net sales price or a fixed amount per product with the understanding that it has to be fair, reasonable and non-discriminatory. The risk of accumulating royalties while bargaining access through the thicket of patents is thereby overcome. A patent pool is thus an effective instrument to fight the (second) practical impediment for further research and commercialization, mentioned in Section I.D.

Third, patent pools offer a welcome instrument for government policy to the extent that it is better to encourage companies to establish patent pools than force them into a compulsory licensing scheme. However, this argument seems to ignore the fact that the major prerequisite for establishing patent pools is the voluntary participation of all patent holders, whereas the compulsory licensing mechanism is the last resort instrument for patent holders who refuse to enter into (reasonable) licensing negotiations. Patent pools in principle only offer a solution for patent thickets (transaction costs) and royalty stacking if the patent owners *voluntarily* engage in the one-stop licensing scheme. Patent pools do not offer a solution in cases where patent holders unduly exploit their patents and refuse to grant (reasonable) licenses. Therefore, at first glance, patent pools are not apt at responding to the concern for the third practical impediment, included in the 'Method of Analysis' of this paper, which is non-cooperative patent holder behavior. However, if such a case arises thereby causing serious public health risks, it is worth considering applying for a compulsory license within

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[71] *See* e.g. MERGES, *supra* note 37, at 123, 131-156 CLARK, *supra* note 37, at 7-8 SHAPIRO, *supra* note 8, at 6-18.
[72] First practical impediment, see Section I.D.

the limits of national legislation [73] as a deterrent to force uncooperative patent holders into reasonable negotiations and possibly the pool. In both the Golden Rice and SARS case, voluntary negotiations were successful. One can only hope that the same will be true in future attempts to establish pools.

In addition to these three major benefits, some other advantages can be highlighted. Pools may overcome patent disputes leading to a decrease of patent litigation, which will save companies time and money. They may support institutionalized exchange of technical information relative to the patented inventions not covered by the patents, which would otherwise be kept as a trade secret. For now, it is not clear to what extent this favorable aspect may play a role in setting up a pool in genetic diagnostics. Furthermore, for molecular diagnostic labs a patent pool comprising the scattered rights in genetic diagnostics can help to adjust to the emerging phenomenon of patents in their practice. A pool may accommodate the regularization of their service by creating clarity and legal certainty as well as by lowering the barrier of entry. Similarly, a pool can remove the reluctance to enter into specific realms of research and incite innovation and test development.

Commentators point to some potential risks and weaknesses as well. [74] A first objection which has been put forward is that pools should not be encouraged because they might shield invalid patents. Companies which fear that their patents will be invalidated in court may be eager to settle by entering into a patent pool. A second danger is the risk of inequitable royalty fees. A solution here might be expert valuation to set a reasonable royalty rate and settle any disagreements on the value of the patents. The major risk which has been highlighted is the danger of patent pools covering for a cartel and subsequent anti-competitive effects. Patent pools need to comply with competition law and withstand the checklist mentioned in the following Section.

Patent pools are not apt to solve all varieties of 'patent access problems'. Patent pools are designed to settle the stacking of *multiple* patents *and multiple* patent holders. Pools do not offer a well-tailored solution for cases where *one* paramount patent, belonging to a *single* patent holder, is hindering downstream research and commercialization. In genetics often one

[73] The national provision on compulsory licensing should comply with the restrictions imposed by Article 31 of the TRIPs Agreement. Article 31 prescribes for instance an assessment of the individual merits of the case, prior failed negotiations with the patent holder, a non-exclusive, non-assignable license, adequate compensation of the patent holder, etc. It is debatable to what extent the requirement that the license should be non-assignable would conflict with the idea to apply the compulsory licensing mechanism in the framework of the patent pool.

[74] *See e.g* MERGES, *supra* note 37, at 123, 156-164; CLARK, *supra* note 37, at 7-8; SHAPIRO, *supra* note 8, at 6-18; OECD REPORT, *supra* note 16, at 66.

gene encompasses all opportunities for diagnostic testing for a particular disorder. Subsequently, a patent on that dominant gene might block all diagnostic services for that disorder. [75] In a similar way, pools will neither offer an effective remedy for cases where *several* patents, belonging to *one*, single patent holder are present. [76] The fact that all three biotech cases discussed – Golden Rice, SARS and GPF – encompass multiple patents belonging to a series of patent holders, nicely illustrates this aspect. Obviously, patent pools will not respond to problems inherent to the patent procedure, like the risk of "hold-up" [77], which inevitably arises when patents are granted long after the application date. As long as the patent application for a specific gene (or a particular mutation) and the diagnostic test related to that gene is under examination, genetic kit manufacturers and laboratories may be inclined to refrain from developing and performing tests until the grant or rejection of the application. In case they choose not to postpone the implementation and start using them, they will – once the patent is granted – either have to negotiate licensing terms (in a rather weak negotiating position), or stop testing. The hold-up problem is salient in the field of genetic diagnostics where the time lapse between the moment of the invention and putting it into practice is naturally short, much shorter than for therapeutics; and the granting procedure lengthy.

Neither will the establishment of a pool be very useful for a combination of different types of genetic inventions. Here I distinguish between, on the one hand, technology specific inventions, and on the hand, diagnosis specific inventions. Individual molecular biological technologies, such as amplification, labeling or detection of nucleic acid fragments can be identical for different diagnostic tests. Various technologies may be used to perform a particular diagnostic test. For instance, if amplification is needed, this can be carried out by Roche's PCR or a number of alternative methods. The technologies are substitutes and may therefore not be included in one pool. [78] These technologies have to be integrated into an apparatus or platform by specialized manufacturers before they can be offered to the users as commercial products. Hence, IP issues are at present largely dealt with by bilateral agreements. In the case of PCR, over time a fully functional license program has been set up for both technology as such and PCR products, including instrumentation and enzyme preparations. In contrast, it would be more logical to include diagnosis specific inventions in a

[75] This risk was present with the Huntington disease gene and the characteristic disease causing (CAG)-repeat mutation. However, the patent owner did not enforce his rights in an excessive manner.
[76] One example is Hemochromatosis, where several patents covering Hemochromatosis diagnosis, are held by one patent owner.
[77] SHAPIRO, *supra* note 8, at 6-8.
[78] Hereinafter Section III.D sub 2.

pool. The latter are specific for diagnosing a certain genetic defect or disease. Examples are the specific nucleic acid sequences, mutations, or polymorphisms correlated with the respective defect or disease. They differ for each diagnosis and are essential for the diagnosis of the related disease, as there is no alternative available to circumvent an eventual blocking patent.

Successful patent pools presume the *recurrent* application of the protected technology by multiple users. Pools do not offer a reasonable alternative for negotiating access to patents for a single use or application, or for a single user because in such a case the establishment costs largely outweigh the potential benefit. Worldwide steady demands for genetic tests for all kinds of disorders, developments in chip manufacture and pharmacogenetics seem to ensure that this requirement will be met in genetic diagnostics.

The major incentive for most patent pools [79] is *economic benefit*. The basic presumption underlying the patent system is to offer an award for innovative research through revenue obtained from the commercialization of the invention. In order for a patent pool to be cost-effective, a right balance has to be achieved between the cost of creating a pool and the prospect of revenue generated through commercialization of the end product. In the electronics and telecommunications mega type of pools, dozens of patents were involved guaranteeing considerable benefits, whereas in the SARS and other future biomedical pools, generally only a few patents will be at stake. It has to be seen to what extent small size (diagnosis specific) pools will prove to be viable. Nevertheless, patent pools in genetic diagnostics may trigger growth of the patent holder's licensing revenue by clarifying the patent landscape and signaling the availability of patents for licensing to potential licensees. At present, owners of gene patents mainly license their patented inventions to companies developing commercial kits and to large diagnostic laboratories. Patent pools may raise visibility and accessibility towards smaller or public genetic laboratories and thus may increase the actual amount of collected royalties – provided those laboratories are willing to cooperate. For example, several laboratories are still using 'home brew' methods for cystic fibrosis testing, although several appropriate kits are commercially available. For other genes the diagnostic method is less amenable to a commercial product in the format of a kit for detection of a selected number of mutations. This is presently the case for e.g. the breast- and ovarian cancer. In both instances, litigation is difficult since data about the number of tests being performed are hard to find, litigation is costly and the amount of money to grasp

[79] For the SARS-pool this might be different. The pool is being established after interference of the WHO and its goal is primarily to guarantee freedom to do research in this extremely important field.

relatively small. If the users of the patented inventions expect patent owners to take up their social responsibility and adopt open licensing policies, users face the prospect of showing their goodwill in return. Hence, – although I admit that it may be perceived as highly idealistic – the introduction of a one-stop license platform may promote a spontaneous registration by the users, and ease the collection of license fees.

Although not a real risk or a weakness of patent pools, I note that pools should be *flexible* instruments, both with regard to their size and their use. As to their size, the pool will develop over time: patent applications, once granted, will enter; granted patents, once revoked or expired, will disappear. As to their use, licensees should be able to apply for a license to a subset of patents, if they do not need access to the complete package offered by the pool. Some genetic laboratories, offering testing for a certain clinical condition as a whole, might be interested in the entire pool. Other laboratories might only be interested in a license to a subset of patents in the pool: a subset of disease causing genes, which are of specific interest in view of the geographical heterogeneity of the distribution of mutations; a specific gene, or even a particular mutation for the development of an antibody or another therapeutic or research tool.

D. Competition Law & Patent Pools

In an attempt to deal with potential anti-competitive effects of licensing agreements, the Federal Trade Commission (FTC) and Antitrust Division of the Department of Justice (DOJ) developed Antitrust Guidelines for the Licensing of Intellectual Property *(IP Licensing Guidelines)* [80]. The IP Licensing Guidelines state that patent pool agreements may provide pro-competitive benefits "by integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation" [81]. Both multiparty licensing agreements to set up a pool and bilateral licensing agreements between the pool and third parties are governed by the principles laid down in the Guidelines. Upon request, the federal antitrust agencies may review both types of licensing arrangements. In general, they will apply the "rule of reason", a legal doctrine balancing pro- and anti-competitive effects of licensing arrangements.

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[80] UD DEPARTMENT OF JUSTICE AND THE FEDERAL TRADE COMMISSION, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (April 6, 1995), *available at* http://www.usDoJ.gov/atr/public/guidelines/ipguide.htm).

[81] *Id.* § 5.5.

In the European Union, the major competition rules related to technology licensing are laid down in block exemption regulation No. 772/2004 on the application of Article 81(3) to technology transfer agreements (often referred to as the TTBER) [82] and the Technology Transfer Guidelines (hereinafter TTG) [83]. Multiparty licensing arrangements creating a patent pool are only subject to the TTG, whereas bilateral technology transfer agreements between the pool and a third licensee fall within the scope of both the TTBER and the TTG.

Until recently, undertakings were obliged to notify their licensing agreements to the European Commission, which would then provide an official individual exemption decision or an administrative clearance letter approving the agreement. Under the new system imposed by Council Regulation (EC) No. 1/2003 of 16 December 2002 [84] in most cases no longer a prior decision from the Commission can be obtained. Companies establishing a patent pool arrangement and developing standard bilateral out-licensing agreements should carry out a self-assessment as to their compliance with the TTG and TTBER.

Close examination of the US IP Licensing Guidelines, the business reviews from the Department of Justice, the European TTBER & TTG, and the clearance letters from the European Commission over the past fifteen years, provides valuable information on the future attitude of US and European authorities towards patent pools. In short, patent pools will avoid anti-competitive restraints and will most likely be accepted if they meet the criteria of the following checklist:

1. Validity

The patents in the pool should be valid. A patent is valid from the date of grant until the date of expiration defined by law (usually 20 years from the date of filing), on the condition that renewal fees are being paid annually. The patent remains valid, even when the patent is under opposition or appeal, as long as the patent office or (patent) court has not rendered a final decision in revocation or invalidity proceedings. It follows that patent applications in principle cannot be part of a pool. However, negotiations to establish a pool can start before the patent is granted and a letter of intent can be signed prior to the final pool agreement. The validity requirement might raise serious problems in the genetics field. At

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[82] EUROPEAN COMMISSION REGULATION (EC) NO. 772/2004 OF 27 APRIL 2004 ON THE APPLICATION OF ARTICLE 81 (3) OF THE TREATY TO CATEGORIES OF TECHNOLOGY TRANSFER AGREEMENTS, [2004] *O.J.* L 123/11. This Regulation replaces EUROPEAN COMMISSION REGULATION (EC) NO. 240/96 OF 31 JANUARY 1996 ON THE APPLICATION OF ARTICLE 85 (3) OF THE TREATY TO CERTAIN CATEGORIES OF TECHNOLOGY TRANSFER AGREEMENTS, [1996] *O.J.* L 31/2.

[83] EUROPEAN COMMISSION GUIDELINES, *supra* note 37.

[84] EUROPEAN COUNCIL REGULATION (EC) NO. 1/2003 OF 16 DECEMBER 2002 ON THE IMPLEMENTATION OF THE RULES ON COMPETITION LAID DOWN IN ARTICLES 81 AND 82 OF THE TREATY, [2003] *O.J.* L 1/1.

present, patent offices are faced with a substantial backlog in the biotech sector. [85] The resulting delay in granting genetic patents might postpone the final conclusion of the patent pool agreement and hinder the swift implementation of emerging genetic pools.

With regard to the validity requirement, the SARS-pool currently does not abide to the rule, as the patents are still pending. By the time the pool comes under scrutiny of the antitrust authorities, in principle those patents should have been granted, in order to be accepted within the framework of the pool. The special nature of this pool, which might have a positive impact on public health care and imposes a certain social responsibility on the patent holders, may however leave room for a more flexible approach by the antitrust authorities.

2. Essential Patents

The technologies and patents in the pool should be essential and complementary. A technology or patent is deemed to be essential if there are no substitutes for that technology inside or outside the pool and the technology in question constitutes a necessary part of the package of technologies for the purposes of producing the product(s) or carrying out the process(es) to which the pool relates. In the MPEG-LA, DVD and 3G3P pools the essential nature of the patents is evaluated in the light of the respective industry standards. Technologies that are essential are by necessity also complements. In a genetic context, essential patents might encompass pioneer gene patents, as well as patents on later revealed but equally important mutations within those genes. [86]

Passing the strict examination of the essential nature of the patents by the antitrust authorities in the absence of a commercial end product and the guidance of an industry standard, may appear a thorny and delicate issue for the SARS pool.

3. Independent Expert

An independent patent expert evaluates which patents are essential and their weight in the package of patents, both when the pool is being established and afterwards. Some of the pool arrangements contain detailed provisions regarding the expert's remuneration and legitimate affiliations with the patent holders to guarantee the independence and neutrality of his evaluation.

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[85] Alison Abbott, *Pressured staff 'lose faith' in patent quality*, 429 NATURE 493, 493 (2004).

[86] Ted J. Ebersole et al., *Patent pools as a solution to the licensing problems of diagnostic genetics*, 17 INT'LL PROP. & TECHN. L. J. 1, at 4 (2005) (providing a number of examples of essential and complementary patents in the field of genetic diagnostics).

4. Non-exclusive Licenses to the Pool

Licensors should grant non-exclusive licenses to the pool. A license is non-exclusive when one or more licensees are granted the right to use the licensed technology covered by the patent(s) during the term of the license and when the licensor retains the right to use the licensed technology and associated patent(s) as well. Potential licensees not interested in the whole package or a subset offered by the patent pool will thus not be prevented from applying for a license directly from the patent holder involved outside the framework of the pool.

5. Allocation Formula

Royalties are generally distributed amongst the licensors pursuant to a fixed allocation formula set forth in the patent pool arrangement. If the patent holders disagree on the weight of the identified patents, the independent expert will be invited to settle the dispute.

6. Use of Alternative Technologies

Licensees are free to develop and use alternative technologies (and develop industry standards related to these technologies). If not, such a prohibition would have an adverse effect on innovation.

7. Licensing Fees & Conditions

Royalties and other licensing terms should be fair, reasonable and non-discriminatory (the so-called "FRAND-terms") and licenses should be granted on a non-exclusive basis. This is all the more true, when the patent pool has a dominant position on the relevant market. Patent pools tend to be the single entity offering a one-stop license for such an extensive patent package, and therefore almost automatically occupy a dominant position. As long as (independent) licensing authorities do not offer competitive, substitute patent pool packages, this will probably remain unaltered. The only other situation I can think of is where the patent pool exists side-by-side with the royalty collection clearinghouse (Chapter IV).

8. Improvements

When a licensee improves the licensed technology the licensee may be obliged to extend to the licensor and the other licensees of the patent pool the right to use the licensee's improvements to the licensed technology. This obligation should be non-exclusive, limited to essential patents, and settled on reasonable terms in order not to discourage further innovation. From the patent holder/licensor's point of view this is a major provision ensuring

that he will not be prevented from competing with his licensees, because otherwise he would be denied access to improvements developed on the basis of his own technology.

9. Confidential Information

In general, the licensing authority will set up an auditing mechanism for the management of the royalties. Competitively sensitive information on the licensees' business provided in the framework of the audit will be safeguarded by the involvement of independent accountants or a separate department of the licensing authority. Another instrument to guarantee the protection of confidential information might be the establishment of so-called "internal firewalls" in cases where one of the patent holders/licensors fulfills the role of the licensing entity. In the DVD6C pool [87], where Toshiba was one of the licensors and acted as the joint licensor, such internal firewalls were erected.

10. Dispute Resolution Mechanism

The European Commission suggests in its TTG that an independent and therefore neutral dispute resolution mechanism in the agreements setting up the pool is established. Arbitration and mediation are two increasingly popular 'alternative' (outside the court system) dispute resolution mechanisms. This may not be useful for small pools, for which *ad hoc* dispute resolution mechanisms will do, but for institutionalized licensing authorities such as Via Licensing and MPEG-LA there might be all the more reason to create an arbitration board and provide mediation services.

11. Health Care Concerns

[This Section is still under construction and will be finalized after the discussion at the IPSC 2006

Should competition authorities in their (economic) analysis of the pro and anticompetitive effects of the pool consider the health care concerns which may be (partially) relieved by the establishment of the pool? Are competition authorities competent to take such interests into account? Is this different for the European Commission and the US antitrust authorities? Are there examples of cases where public interest played a crucial role in the assessment of the patent pool by the competent authorities? E.g. US aircraft pool? Could these public interests

[87] KLEIN, *supra* note 47.

influence their assessment in such a way that a pool otherwise violating competition law would be allowed for reasons related to public health?

E. Case Study Patent Pool

Genetic diseases are caused by mutations in genes. In some cases, the disorder is caused by the same mutation in one gene for all patients, e.g. Huntington disease. In other cases, the disease can be caused by a variety of mutations in one gene or by one or more mutations in one of several genes, e.g. Hereditary non-polyposis colorectal cancer (HNPCC). HNPCC is an example of a polygene disorder characterized by mutations in one or more of several mismatch repair (MMR) enzymes. Typically, patients are commonly being tested for two or more of four genes. [88] Other genes involved in the mismatch repair pathway have been reported to be associated with HNPCC. [89] The number of identified genes involved in HNPCC etiology is expected to grow even more. Some of these newly identified genes may soon be on the 'shortlist for routine testing'. It is most likely that a patent thicket will emerge on the genetic data necessary in testing for HNPCC as various patents were filed or granted, scattered over several patent holders [90]; a situation of *multiple* patents (patent applications) held by *multiple* patent owners.

Analogous to the SARS case, an HNPCC pool encompassing disease specific essential genomic patents (or patent applications), might help to eliminate the patent thicket and render proprietary genomic data more accessible for use. Either a national or international public authority or one of the patent holders should take the lead and invite patent owners with potentially essential patents to participate in the pool. The patent pool arrangement is to be developed according to the 'competition law-checklist'. Neutral patent experts should be retained to value the essential patents in the light of the internationally acknowledged shortlist for routine testing.

This candidate case illustrates, just as the SARS pool that a patent pool should not necessarily be set up in response to a call for a licensing tool to cut trough the overlapping thicket of patents, but is preferably created prior to the pressing demand, thereby creating an attractive environment for third parties to join the pool.

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[88] MLH1, MSH2, MSH6, and PMS2, *see* review of HNPCC at http://www.genetests.org.

[89] E.g. MLH2, MLH3, PMS1, MSH3, MSH5, MYH, *see* OMIM entries on http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=OMIM.

[90] European patent applications have been identified for example for MSH2, MLH1, PMS2 and MSH5. Patent holders include Human Genome Sciences, John Hopkins University, Oregon Health Sciences University and Dana-Farber Cancer Institute.

F. Industry Standards

Standards can be an important trigger to set up a pool, as is illustrated in the electronics and telecommunications sectors. Standards are technical specifications relating to a product or an operation which is recognized by a large number of manufacturers and users [91]. Standards may be the result of a formal consensus building procedure managed by a standardization body (*de jure* standards) or arise spontaneously due to the degree of market penetration of a particular technical solution (*de facto* standards) [92]. Although a *de jure* standard is not present in the Golden Rice and SARS cases, in contrast to what the OECD believes [93] one should not necessarily exclude the possibility that *de jure* or *de facto* standards will gradually emerge in the field of genetics.

A genetic standard should not necessarily be looked at in terms of a technical standard imposing compatibility and interoperability, but could be understood in terms of a set of mutations, recognized by the international scientific community as the calibration measure, or reflecting national or international best practice guidelines for genetic testing for a particular disease. [94] Good examples are the standards and guidelines issued by the American College of Medical Genetics (ACMG) for Cystic Fibrosis [95] and Huntington [96]. The development of such a standard and of the corresponding patent pool may well go hand in hand. One could even imagine that the same national or international bodies that discuss and issue the guidelines play a start up role in the establishment of corresponding patent pools. Such an initiator role will be an important asset in the diffusion of the awareness of the existence of patent coverage for those genetic inventions and the concomitant collection of licensing fees.

Furthermore, a genetic standard should not be approached as a static concept, but as a dynamic notion, enabling new genetic data to become part of the standard as science advances. Similar considerations apply for the patent pool. Competition law demands that patent pools are subject to continuous review. Expired patents, patents declared invalid in

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[91] See also: EUROPEAN COMMISSION COMMUNICATION OF 27 OCTOBER 1992 ON INTELLECTUAL PROPERTY RIGHTS AND STANDARDISATION, COM (92) 445 final.

[92] Johan Verbruggen and Anna Lôrinz, *Patents and Technical Standards*, 33 IIC 125, 132 (2002); Janice M. Mueller, *Patenting Industry Standards*, INT'LL PROP. L. REV. 201, 209 (2002).

[93] OECD REPORT, *supra* note 16, at 66.

[94] *See also* Geertrui Van Overwalle et al., *Models for facilitating access to patents on genetic inventions*, 7 NAT. REV. GENET. 143, at 145 (2006); Birgit Verbeure et al., *Patent pools and diagnostic testing*, 24 TRENDS BIOTECHNOL. 115, at 118 (2006); Jorge A. Goldstein et al., *Patent pools as a solution to the licensing problems of diagnostic genetics, United States and European Perspectives*, DRUG DISCOVERY WORLD 86, 86-91 (2005); EBERSOLE ET AL., *supra* note 86, at 1-8; Ted J. Ebersole et al., *Patent pools and standard setting in diagnostic genetics*, 23 NAT. BIOTECHNOL. 937, 937-938 (2005).

[95] Carolyn Sue Richards et al., *Standards and Guidelines for CFTR Mutation Testing*, 4 GENET. MED. 379, 379-391 (2002).

[96] Nicholas T. Potter et al., *Technical Standards and Guidelines for Huntington's Disease Testing*, 6 GENET. MED. 61, 61–65 (2004).

litigation or opposition procedures will have to be abandoned whereas new essential patents will have to be allowed to enter into the pool.

Contrary to standards in electronics or telecommunications, genetic standards are not concerned with compatibility or interoperability. Genetic standards are justified for quality and state of the art medical reasons. This is to say that depending on the state of the art in medical science a specific list of mutations is to be tested to diagnose a specific disease with optimal reliability of the outcome. As there is no technical necessity to comply with the genetic standard, it will generally not function as a trigger to set up a patent pool, but merely as an instrument to determine which patents are essential. [97]

G. Summary & Intermediate Conclusions

[This Section will be written after serious review at the IPSC 2006]

IV. CLEARINGHOUSES

Clearinghouse models might be another approach that facilitates access in case of overlapping, blocking multitudes of patents. The term clearinghouse is borrowed from banking institutions and refers to the mechanism by which cheques and bills are exchanged amongst member banks in order to transfer only the net balances in cash. Nowadays the concept has matured and acquired a broader meaning referring to 'any mechanism whereby providers and users of goods, services and/or information are matched'. [98]

The OECD [99], the Human Genome Organization (HUGO), [100] and the Nuffield Council of Ethics [101] support the idea of a clearinghouse in order to facilitate access to

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[97] *Contra* Van Overwalle et al., *supra* note 94, at 145; Verbeure et al., *supra* note 94, at 118 and EBERSOLE ET AL., *supra* note 86, at 1-8 (the authors argued here that standards in genetics could also trigger the establishment of a pool. After ample discussions, we have come to the conclusion that the different nature of standards in genetics will probably not permit them to serve as an incentive, but genetic standards may still be useful as a criterion in the competition law assessment.

[98] Anatole F. Krattiger, *Financing the Bioindustry and Facilitating Biotechnology Transfer*, *IP STRATEGY TODAY* 1, 1-45 (2004-8).

[99] OECD Report, *supra* note 16, at 74.

[100] HUMAN GENOME ORGANISATION (HUGO), STATEMENT ON THE SCOPE OF GENE PATENTS, RESEARCH EXEMPTION AND LICENSING OF PATENTED GENE SEQUENCES FOR DIAGNOSTICS, at 3 (2003), *available at* http://www.hugo-international.org/PDFs/Statement%20on%20the%20Scope%20of%20Gene%20Patents,%20Research%20Exemption.pdf [hereinafter HUGO Statement].

[101] NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA, Discussion Paper. No. 93, at 56 (2002), *available at* http://www.nuffieldbioethics.org [hereinafter Nuffield Report].

patented genetic inventions. Present day practice shows that the general, broad clearinghouse concept can be divided into different clearinghouse models. Yet none of these organizations has precisely defined which clearinghouse model with what kind of functions and features would be best.

Five clearinghouse models are identified. [102] The first two models merely provide access to information. The first clearinghouse model includes basic data, technical information, or complex information included in patents covering these technologies (information clearinghouse). The second clearinghouse provides lists of technologies available via the clearinghouse through licensing. Thereby, it offers a platform for technology owners and users to enter into bilateral negotiations (technology exchange clearinghouse). The remaining three more advanced models aim at providing both access to and use of the (patented) inventions. Access and use can be offered by a clearinghouse on a royalty-free open-access basis (open access clearinghouse), or via standard licenses (standard licenses clearinghouse and royalty collection clearinghouse). In addition, a royalty collection clearinghouse offers royalty collection and disbursement, monitoring and enforcement of 'license-conform' behavior and an independent dispute resolution mechanism.

In contrast with the patent pool model (***one-stop*** licensing platform), the clearinghouse acts in its various appearances as a ***one-stop-shop*** (licensing) platform. The users of the information or the patented inventions enter the database, 'pick & choose' and put all the relevant 'products' in their shopping trolley. The products may come as a package or 'stand alone'. They may originate from multiple sources (data providers, patent owners) or from one single source. Users pay at the pay-desk (or not, for some information clearinghouses and the open access clearinghouse) and have fulfilled in 'one-stop' all the necessary formalities at the 'shop' for a legitimate access to (and use of) the 'products'.

A. Clearinghouse Models Facilitating Access

The information clearinghouse provides a mechanism for exchanging basic data, technical information and/or information related to the IP status of said information. Information mechanisms are relatively easy to set up but require constant maintenance and

[102] *See also* Esther van Zimmeren et al., *A Clearinghouse for diagnostic testing: the solution to ensure access to and use of patented genetic inventions?* 84 BULLETIN OF THE WORLD HEALTH ORGANIZATION 352, 352-359 (2006) and VAN OVERWALLE ET AL., *supra* note 94, at 145-147.

updating. [103] Examples vary from general search engines such as Google or PubMed, to global biodiversity information networks, such as the Global Biodiversity Information Facility (GBIF) [104] and the Convention on Biological Diversity Clearinghouse [105]. Well-known examples of information clearinghouses in the field of patents are Espacenet from the European Patent Office (EPO), [106] which is freely accessible, and fee-based databases, like Delphion, [107] STN International, [108] Dialog [109] or Micropatent [110]. There are specific patent biotech search platforms as well, such as Patent Lens. [111] Patent Lens is established in the framework of the BiOS initiative launched by Cambia [112] and offers a free, fully text-searchable database of US, European and Australian agricultural and life science patents, complemented with advisory and educational services.

With regard to genetic diagnostics especially the information clearinghouses in the field of patents are relevant. These information clearinghouses facilitate searches by patent experts a freedom-to-operate analysis with regard to a specific product or process. Researchers may use them as a source of detailed, technical information for further innovation. Despite the facilitation of access to information on the patented invention, these clearinghouses do not contribute directly to the solution of the above-mentioned obstacles except for the search costs for locating the licensing partners. The name of the inventor, applicant or proprietor, mentioned on the patent is helpful though in the light of the current trend of mergers, strategic IP management and complicated ownership arrangements within universities this will not necessarily be the competent licensing partner.

The technology exchange clearing house is inspired by the basic Internet business-to-business (B2B) model. This model provides an information service that lists the available technologies to allow technology owners and/or buyers to initiate negotiations for a license. Additionally, it may provide more comprehensive partnering, mediating and managing

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[103] GRAFF & ZILBERMAN, *supra* note 64, at 4-6; KRATTIGER, *supra* note 98, at 20.
[104] GBIF offers free digital access to primary scientific data on biodiversity to everyone in the global community. *See* http://www.gbif.org/.
[105] The Convention on Biological Diversity Clearinghouse aims at promoting technical and scientific cooperation, and facilitating the exchange of scientific, technical, and legal information related to biodiversity. *See* http://www.biodiv.org/chm/.
[106] *See* http://www.ep.espacenet.com.
[107] *See* http://www.dephion.com.
[108] *See* http://www.stn-international.de.
[109] *See* http://dialog.com.
[110] *See* http://www.micropatent.com/static/index.htm.
[111] *See* http://www.bios.net/daisy/bios/patentlens.html.
[112] *See* http://www.bios.net.

services. [113] An example of a global technology exchange model is BirchBob, [114] an internet platform that brings together offers and demands for innovations with services dedicated to find and facilitate contacts between technology holders and technology seekers. Over 25,000 innovations from 1900 organizations worldwide are currently searchable by investors, entrepreneurs and scientists looking for new business or scientific opportunities. Specific healthcare technology platforms include Pharmalicensing [115] or TechEx [116] which provide online support for partnering and licensing in the biopharmaceutical and biomedical industry. Specific biotechnology technology platforms include PIPRA (Public Intellectual Property Resource) [117], a collaboration among universities, foundations and non-profit research institutions to make agricultural technologies more easily available.

The technology exchange clearinghouse model is in general cheap to maintain and requires only relatively low operating costs. However, the clearinghouse is dependent on the cooperation of patent holders in providing the necessary information. It is difficult to bring together a critical mass of genetic patents in order to turn the clearinghouse into an effective tool which ensures access to patented inventions. At present, most of the clearinghouses only offer a small (pro)portion of the market and a low density of patents, and one has to search various websites (sometimes paying considerable registration fees). Small and medium-sized companies in general have a rather large interest in transferring information on their inventions, provided they pursue an active out-licensing strategy, to foster their 'visibility' as a patent holder. On the other hand, the big pharma and biotech multinationals with their own IP and licensing departments will most likely appreciate technology exchange clearinghouses more from the in-licensing perspective, than for out-licensing purposes. This might lead to a rather one-sided technology portfolio of the clearinghouse.

Moreover, this model seems to be especially suitable for technologies that can be easily defined and valued. Therefore, it might be a useful model for general purpose research methods, such as PCR, and for patents protecting very specific and well defined improvements to familiar upstream products or processes. [118]

It is essential to note that effective access to the patented inventions is not granted by the clearinghouse but by the individual patent holder after one-to-one licensing negotiations have taken place with the licensee. These negotiations are, nevertheless, based on the

[113] GRAFF & ZILBERMAN, *supra* note 64, at 6-8; KRATTIGER, *supra* note 98, at 21-22.
[114] See also: http://www.birchbob.com.
[115] See also http://www.pharmalicensing.com.
[116] See also: http://www.techex.com.
[117] See also: http://www.pipra.org.
[118] KRATTIGER, , *supra* note 98, at 22 and GRAFF ET AL., *supra* note 64, at 6-7.

information provided by the clearinghouse. The clearinghouse provides access to the technical information described in the patent and contact information on the patent holder involved, but does not provide a one-stop-shop for the license thereby authorizing the use of the patented invention. The transaction costs may be lower then without the intervention of the clearinghouse as the information on available technologies is nicely organized and at hand. Hence, the search costs will be lower than without the technology exchange clearinghouse. The user should, however, still enter into negotiations with the patent holder, which, on the one hand, gives opportunities to bargain a well-tailored license fitting the desires of both parties. But, on the other hand, generally, such an optimal result will only be achieved when a legal counsel is involved and after a period of intense discussions. Some of the technology exchange clearinghouses offer more comprehensive packages of match-making and negotiating services to their clients (licensors/licensees). If the licensee would expect a stacking of royalties in view of the 'thicket' of licenses that has to be negotiated, he will need good negotiation skills to persuade the patent holders to insert a 'royalty stacking clause' in the license. Therefore, bargaining costs will still be high. An eventual remedy for the royalty stacking will not result from the intervention by the clearinghouse but rather from the negotiation skill of the licensee's representative. Nor would there be any safeguard to drag a non-cooperative patent holder into negotiations.

B. Clearinghouse Models Facilitating Access and Use

A rather unique type of clearinghouse is the open access clearinghouse that fosters the free exchange of information and inventions. This type of clearinghouse does not only foster free access to information about inventions as its name may suggest, but also to standardized free use of inventions. Frankly, this model does not completely fit into the layered system presented here, where every model builds on the previous model. The technology exchange model includes all the elements of information clearinghouse and some more. Whereas the open access clearinghouse comprises the main building blocks of the information and technology exchange clearinghouse, the standard licenses clearinghouse and the royalty collection clearinghouse do not follow from the open access clearinghouse.

Not many examples of this model exist in the life sciences, except for the SNP Consortium [119]. The goal of the SNP Consortium, a non-profit entity, [120] was providing public

[119] *See* http://snp.cshl.org.

genomic data. Genetic markers called single nucleotide polymorphisms ("SNPs", pronounced "snips") are common DNA sequence variations among individuals and have great significance for biomedical research. Scientists believe that these SNPs can help signal the subtle genetic differences that predispose some but not others to diseases and that underlie variability in individual responses to a given drug. Such knowledge can be used to spur the development of new therapies (based on an understanding of genetic variations that predict response to therapy) and of novel diagnostic tests, ultimately resulting in more adequate treatment or even prevention of the disease. The consortium's mission was to identify and collect up to 300,000 SNPs distributed evenly throughout the human genome and create and make publicly available the SNP Map of the human genome without any proprietary rights retained by the members of the Consortium in order to enable further drug discovery. In order to obtain this objective, a careful IP policy was developed. After identification of the SNPs public release was withheld and provisional patent applications were filed to establish priority dating to prevent facilitating the patenting of the same SNPs by third parties. These provisional applications have been converted to utility applications and after public release of the SNPs, the utility applications have been converted to invention records. [121]

An exponential increase in the amount of human genetic sequence data that became available from the Human Genome Project enabled the consortium to proceed at a much faster pace than originally envisioned. In the end, the SNP Consortium identified and mapped 1.5 million SNPs, which have been placed in the public domain. Through the collaboration, a high-density, high-quality map could be created very quickly, and with shared financial risk and less duplication of effort than if each company had pursued development of a SNP map on its own. The activity was perceived as "pre-competitive" under US antitrust and European competition law, so that there could not arise competition problems for the enterprises participating in the consortium. [122]

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[120] The SNP Consortium was established as a collaboration between major (pharmaceutical) companies (Bayer Group AG, Bristol-Myers Squibb Company, Glaxo Wellcome PLC, Aventis, Monsanto Company, Novartis AG, Pfizer Inc, Roche Holding Ltd., SmithKline Beecham PLC, and Zeneca Group PLC. In addition, Motorola, Amersham Pharmacia Biotech, and IBM became members of the SNP Consortium), the Welcome Trust (medical research charity) and five leading academic centres (Whitehead Institute/MIT Center for Genome Research, Washington, University, the Sanger Center, Stanford University, and the Cold Spring Harbor Laboratory).

[121] Arthur L. Holden, *The SNP Consortium: Summary of a Private Consortium Effort to Develop an Applied Map of the Human Genome*, 32 BIOTECHNIQUES 22, 22-26 (2002).

[122] JOHN G. STEWART, PRE-COMPETITIVE COLLABORATIONS IN GENOMICS: SNP CONSORTIUM AND HAPMAP PROJECT, WORKSHOP ON COLLABORATIVE MECHANISMS: ENSURING ACCESS ORGANIZED BY THE BIOTECHNOLOGY DIVISION OF ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (Washington D.C – 8th-9th December 2005).

An open access clearinghouses may be a readily available model for sharing and exchanging unpatented technology. It will significantly decrease search and bargaining costs and prevent royalty stacking. The model can be effectively used to ensure freedom to operate/freedom to do research, as is shown by the SNP Consortium. This may function as an important non-monetary incentive. However, most of the genetic inventions are the outcome of long-lasting, expensive research projects. Both private and public entities wish to recover those investments and apply for patent protection. For this reason, apart from situations where the patent rights are extremely fragmented, as illustrated by the SNP Consortium, or cases where one may seriously doubt whether the patentability requirements can be met, holders of patents related to genetics will not have a strong incentive to *voluntarily* cooperate in a scheme where the patented inventions will end up in the public domain without any monetary compensation. Moreover, the establishment costs of an open access clearinghouse may be considerable. Therefore, the scope of application for this type of clearinghouse in genetic diagnostics is expected to be rather limited, at least in the near future.

An upcoming and celebrated model is the standard licenses clearinghouse providing access to and standard licenses for the use of protected inventions. An example of this scheme is the Science Commons Licensing Project. [123] This effort is still exploratory. It examines, in cooperation with the stakeholders concerned, standard licensing models to facilitate wider access to scientific subject matter. [124] Science Commons works in three project areas: publishing, licensing and data. It aims at broadening access to scholarly communications in a range of disciplines [125] and at encouraging intellectual property licensing, technology transfer and data sharing. Its 'mother-organization' Creative Commons, [126] has already been in operation for a couple of years facilitating the use of copyrighted material by way of

[123] *See* http://sciencecommons.org/.

[124] For instance the Biological Material Transfer Project. Although a standard material transfer agreement exists in this field, the Uniform Biological Transfer Agreement (UMBTA, 1995), this single standard is very complex and does not cover enough types of biological transfers, so in practice institutions substitute their own MTAs. Science Commons envisages a solution using the UMBTA as the basic agreement with a standard set of options that can be mixed and matched to create a customized agreement, tailored to fit the large variety of circumstances in material transfers. For more information, *see* http://sciencommons.org/licensing/scmta/.

[125] Institutions that adopted this approach are the Public Library of Science (PLoS http://www.plos.org/) and MIT with regard to its Open Course Ware (free searchable access to MIT's course materials). *See* http://ocw.mit.edu/OcwWeb.

[126] *See* http://creativecommons.org/.

standardized, simplified licenses. [127] The criteria decisive for the applicable copyright license are whether the work would be used commercially, whether it could be modified, what would be the appropriate jurisdiction, and the format (text, image, video, audio, etc.) of the work. In addition to these 'general' copyright licenses, some more specific copyright licenses have been developed, amongst which the so-called "developing nations license", the "music sharing license" and the Creative Commons GNU GPL [128]. The most far-going license is the "public domain dedication" by which the right holder promises not to enforce his copyright. The latter approach aligns with the goals of the open access clearinghouse. The Science Commons Licensing Project aims at extending such practices beyond copyright into the realms of patents, technology transfer and intellectual property licensing. The existing Creative Commons licenses do not stipulate license fees to be paid. Besides the development of the standard licenses Creative Commons and Science Commons do not provide other legal services. Monitoring and enforcement of the licenses is in principle the responsibility of the right owner.

Standard licenses for *patented inventions* could be differentiated as to the nature of the user, the objective of the use and the profile of the eventual product to be developed by the licensee. Whereas the existing Creative Commons licenses without license fees may do in the area of copyright, it will most likely be more difficult to persuade patent holders into such a licensing scheme. Setting the royalty rate is probably the most sensitive and controversial issue in negotiating a license. Fixing a certain percentage and/or upfront payment in a standard license will meet with strong opposition. In practice, drafting the clauses of licenses necessitates a careful balancing of all the licensing conditions. In order to function as an effective alternative, the standard licenses should at least offer enough variety. Each standard license has to grant a standard set of options that can be mixed and matched to create a customized agreement.

Replacing the tailored license by a standard license agreement diminishes – once the standard licenses have been developed in consultation with the stakeholders – the bargaining costs for individual licenses. Optimally, the standard license contains well-balanced conditions from the perspective of both the right holders and the licensees. Licensees have but

[127] Creative Commons offers its standardized licenses in three versions: the official license including all the legally correct terms and detailed licensing conditions, the versions readable for the general public and the machine readable version.

[128] GNU is a recursive acronym for "GNU's Not UNIX". The GNU Project was launched in 1984 by the Free Software Foundation to develop a complete UNIX like operating system which is free software. The General Public License (GPL) is GNU's free software license. The Creative Commons GNU GPL is a license which adds the Creative Commons metadata and the Commons deed (human readable version of the license) to GNU General Public License.

one choice; 'take it or leave it'. It is desirable that only in exceptional circumstances licensees are allowed to notify the clearinghouse of a reasoned request to enter into negotiations for an adapted version of the standard license. Otherwise, the decrease of transaction costs would yet be undone. In order to prevent the accumulation of royalties in the interest of the licensees, licenses contain a royalty stacking clause. With respect to the third obstacle, I note that as long as the licenses are not embedded in a scheme where the patent holder can no longer decide whether a license is granted to a specific user, the owner administers the access to his inventions. Therefore, access to and use of the patented inventions can not be guaranteed. A non-cooperative patent holder cannot, unless competition law would provide ground for action, be prevented from refusing the grant of a license.

Finally, the royalty collection clearinghouse comprises all the major elements of the information clearinghouse, the technology exchange clearinghouse and the standard licenses scheme. In addition, the royalty collection clearinghouse sets up a royalty management administration which cashes license fees from users on behalf of patent holders in return for use of certain technologies or services. [129] Patent holders are reimbursed by the clearinghouse pursuant a set allocation formula or on the basis of the use of the patented inventions reported by the licensees.

It has been suggested to set up a royalty collection clearinghouse in the field of patents and genetics to overcome the anticommons effect; in particular rule out the high transaction costs by acting as a one-stop-shop. [130]. The patent royalty collection clearinghouse serves as a one-stop-shop for information, licensing and royalty management. It facilitates access to the information on the patented and 'licensable' inventions and enables the use of the patented inventions by the licensee by clearing the bargaining process: the clearinghouse matches the licensee with the patent holder and offers the appropriate standard license. Search and bargaining costs will therefore – to a large extent – be borne by the clearinghouse. The clearinghouse monitors the compliance with the licensing conditions by licensees. It notifies the licensee in case of breach of contract. If the breach continues the patent holder is notified. The dispute is preferably settled via the internal dispute resolution mechanism. With respect to infringements by non-licensees which are more complicated to track, patent owners may

[129] MERGES, *supra* note 9, at 1327-1337.
[130] GRAFF & ZILBERMAN, *supra* note 64; KRATTIGER, *supra* note 98, at 3; OECD REPORT, *supra* note 16, at 73-74; ALRC FINAL REPORT, *supra* note 55, at para. 22.76; GOLD, *supra* note 39, at 359; NUFFIELD REPORT, *supra* note 101, at 56; OECD GUIDELINES, *supra* note 20, at points 39 and 46; HUGO STATEMENT, *supra* note 100, at 3.

procure additional services outside the standard set of services offered by the clearinghouse such as monitoring and enforcement.

The intervention by the royalty collection clearinghouse in the licensing process bridges the gap between patent holders/licensors and licensees and thus leads to a decrease in search and bargaining costs for both licensors and licensees. Patent holders transfer the available technology to the clearinghouse for licensing and determine the conditions in consultation with the clearinghouse administrator without further need to interact with any users of their inventions. Licensees who seek freedom to operate address the clearinghouse which will provide information on the relevant patents and the available licenses. Negotiations between licensees and licensors will be exceptional, unless both the licensor and the licensee prefer an alternative non-standard license. Even monitoring and enforcement may be tasks assumed by the clearinghouse, provided the patent holder pays an appropriate additional administration fee. It remains to be seen to what extent this is feasible and whether the clearinghouse would be able to more cost-efficiently monitor breach of contract by licensees and patent infringements than the patent holder.

In order to prevent the accumulation of royalties in the interest of the licensees, the clearinghouse applies anti-royalty stacking rules requiring reduced royalties or a cap on royalties in the event of stacking. Even licensors may benefit from a royalty stacking clause to the extent that otherwise the licensee might not be able to develop and commercialize a certain product at all. The clearinghouse should underline this common benefit.

One may doubt whether Section I.D's third obstacle concerning the non-cooperative patent holder might be overcome by a voluntary royalty collection clearinghouse. A patent holder who does not wish to grant licenses at all or on conditions not conform the clearinghouse's objectives cannot be compelled to join the clearinghouse. As a back-door mechanism to lure the unwilling patent holder in the clearinghouse scheme, a reciprocal positive comity or a grant-back clause might be imposed via the standard licenses. A positive comity clause obliges the patent holder to cooperate with the clearinghouse and take social responsibility in the light of access to medicines. From this perspective, it is fair to expect users of the patented inventions included in the clearinghouse (licensees) to (voluntarily) transfer their patent exploitation rights to the clearinghouse (and thus become licensors in this respect), or adopt a more sensible unilateral licensing strategy outside the clearinghouse. A broad grant-back clause requires the patent holder to grant back his (essential) patents to the clearinghouse if he applies for licenses from the clearinghouse. However, competition law dictates cautiousness with regard to such invading measures.

C. Royalty Collection Clearinghouses

At present, no examples of a royalty collection clearinghouse exist in the field of patents. However, Drahos' proposal concerning a Global Bio-Collecting Society (GBS) [131] was a praiseworthy attempt to design an exchange model in life sciences for traditional knowledge. Moreover, in most countries copyright collection societies exist. I admit that the simple analogy with copyright does not justify the establishment of a royalty collection clearinghouse for patents. The historical, legal and philosophical context of patent law and copyright differ considerably. Nevertheless, it provides a legal and economic framework for the present analysis and the experience of the copyright collection societies, for instance regarding the compatibility with competition law, may serve as a source of inspiration for framing the patent royalty collection clearinghouse.

1. GBS-clearinghouse

The GBS model was designed by Peter Drahos to function as an efficient, fair and equitable exchange model of indigenous knowledge between knowledge holders (indigenous groups) and knowledge users (life science industry). The GBS model was never realized, probably because traditional knowledge is a highly sensitive issue, and no consensus could be reached among the stakeholders, nor was there the necessary political support. Despite the fact that the GBS model was construed to encourage arrangements between merely non-IP holders (indigenous groups) and IP holders, the clearinghouse concept could also be applied onto the more classic IP licensing relationship between IP holders (patent owners, licensors) and IP users (licensees).

2. Copyright Collection Societies

In the area of copyright, collective royalty management is a common practice since the 18th century. ASCAP (the American Society of Composers, Authors and Publishers) [132], PRS and MCPS (the Performing Rights Society and Mechanical Copyrights Protection Society), [133] GEMA (the German Gesellschaft für musikalische Aufführungs – und mechanische Vervielfältigungsrechte), [134] JASRAC (the Japanese Society for Rights of

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[131] Peter Drahos, *Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-Collecting Society the Answer?*, 20 EUR. INT'LLL PROP. REV. 245, 245-250 (2000).
[132] *See* http://www.ascap.com/.
[133] *See* http://www.prs.co.uk/ and http://www.mcps.co.uk/. In 1998 MCPS and PRS formed a joint venture, the MCPS-PRS Alliance, which manages common activities and services with a view to sharing the costs of administration. See: http://www.mcps-prs-alliance.co.uk/.
[134] *See* http://www.gema.de/.

Authors, Composers and Publishers) [135] and numerous other national societies operate as copyright societies for mechanical reproduction rights, public performances, playing music on air, etc. Considerable differences exist between these organizations with respect to e.g. their legal basis, legal structure, decision-making procedures, price-setting procedures, licensing conditions.

[This Section will be completed with a description of the main features of collective copyright collection].

D. Strengths and Weaknesses Royalty Collection Clearinghouse

Royalty collection clearinghouses show a number of strengths and weaknesses in their role as a one-stop-shop.

For users of patented inventions such an organization would simplify licensing negotiations in genetic diagnostics and, therefore, facilitate access to and use of the patented inventions. The Human Genome Organization (HUGO) already suggested that the clearinghouse model could also lead to increased levels of licensing and to make licenses to sequences and genes accessible for researchers at a reasonable cost, which may encourage the pursuit of research in areas from which they might have been deterred in the past. [136] Hence, the clearinghouse advances innovation by facilitating the exploitation of patents by a broader 'audience'. For the patent holder, increased visibility of the patent rights and the streamlining of royalty collection and monitoring, may lead to a rise in licensing and, thus, licensing revenue. At the same time, awareness and respect for intellectual property rights may grow among researchers and their public and private institutions, leading to decreased enforcement costs through fewer infringements. Hence, a reasonable price for licensees (royalties, transaction costs) and licensors (royalties, transaction costs, and enforcement costs) may be achieved. Especially SMEs could benefit a lot from a royalty collection clearinghouse. The clearinghouse could guide them through the process of both in- and out-licensing and provide them with the necessary specialized knowledge of IP licensing. This way, SMEs no longer would feel overwhelmed by all the necessary negotiations related to bilateral licensing and the

[135] *See* http://www.jasrac.or.jp/ejhp/index.htm.
[136] HUGO STATEMENT, *supra* note 100, at 3.

complicated licensing clauses. One may even imagine developing a simplified version of the standard licensing agreements comparable to the Creative Commons for use by SMEs. [137]

Compared to patent pools the royalty collection clearinghouse may more effectively deal with the plethora of patent access problems. Patent pools aim at settling the stacking of *multiple* patents *and multiple* patent holders and hence do not offer an appropriate solution for cases where either *one* paramount patent, belonging to a *single* patent holder, or where *several* patents, belonging to *one*, single patent holder are hindering downstream research and commercialization. The royalty collection clearinghouse, on the other hand, is perfectly capable of settling the three sets of circumstances. Irrespective of the origin of the licensed patented inventions being one single patent holder or multiple patent holders, the clearinghouse deals with patent holders and licensees on an individual basis and grants (sub-)licensees to the licensee regarding all the selected patented inventions. This might be one invention or a package of inventions originating from one single patent holder or multiple patent proprietors.

Moreover, there is no reason to restrict the catalogue of the royalty collection clearinghouse to diagnosis specific patents. Technology specific patents could be listed as well. For some patented inventions this will not be of much use as the patent holder sells the product together with the license, e.g. PCR. However, in many other cases only a license and not a tangible product is required which may be part of the sets offered by the clearinghouse.

However, a royalty collection clearinghouse also has some drawbacks en weaknesses. Standard licenses and licensing practices of the clearinghouse may have potential anti-competitive effects, even more so if the clearinghouse operates on a global scale and thus has a ‘supermonopoly’.

Patent holders may be reluctant to voluntarily participate in a royalty collection clearinghouse. Patent holders have to grant a license to the clearinghouse which then issues (sub-)licenses to all applicants without discrimination and on a non-exclusive basis for a fixed royalty fee. As a consequence, patent holders would lose control over their business licensing strategy. Hence, the patent right is no longer a right to exclude others from exploiting your invention, but renounced to a ‘remuneration right’. Still it is only worthwhile to establish a royalty collection clearinghouse if many patent holders or an entire branch of industry

[137] Creative Commons offers its standardized licenses in three versions: the official license including all the legally correct terms and detailed licensing conditions, the machine readable version and the version readable for the general public. The latter is very compact and includes simple images to indicate the permitted use of the work concerned.

participate(s). [138] Patent holders might be relieved by the idea that they may select certain patents to be included in the clearinghouse, and could leave others outside the framework of the clearinghouse for strategic IP management. Unavoidably, this flexibility creates the risk that patent holders add but their least valuable, unexploited patents to the clearinghouse. It remains to be seen, whether despite this drawback the benefits of the royalty collection clearinghouse could persuade patent proprietors with a strong portfolio and an in-house IP & licensing department to voluntarily participate in the clearinghouse responsive to public health interests.

Unless the clearinghouse represents a critical mass of all relevant patented inventions, it might not be a viable and effective alternative nor could it prevent the emergence of an anticommons effect. Moreover, an important prerequisite for the royalty collection clearinghouse to be effective is that there should be a recurring need to transact in the patents included in the clearinghouse. [139] As diagnostic tests are carried out on a regular basis on a worldwide level (although there might be differences between states regarding the diseases for which patients are regularly tested), and both public and private entities are performing research on existing tests and developing complementary and alternative tests, in genetic diagnostics this requirement will most probably be fulfilled. This is further strengthened by the developments in chip technology.

Royalty clearinghouses might be more complicated and costly to set up in comparison with the other clearinghouse models. Highly educated scientists and experienced lawyers will have to be hired to evaluate the often very complex patents, to match licensees with the patented inventions, to develop standard license agreements, and for monitoring and dispute resolution.

Standard licenses might not allow for measures highly appreciated in commercial licensing practices, such as the setting of milestones, due diligence and the maintenance of long-term business relationships, and the exchange of know-how. The exchange of relevant technical know-how is often fundamental for the smooth application and further development of the patented invention. Know-how is generally protected as a business secret, but the clearinghouse will probably not be able to guarantee the exchange of know-how and maintain secrecy. Thus, with respect to complex technologies, direct negotiations between the licensor and the licensee on the issue of know-how may still be required, which might cancel out some of the advantages of the royalty collection clearinghouse. This drawback might be a reason to

[138] KRATTIGER, *supra* note 98, at 19.
[139] *See also* MERGES, *supra* note 40, at 1293-1386.

advocate the establishment of a royalty collection clearinghouse that is limited to inventions that do not require the exchange of technical know-how, such as patented DNA sequences and mutations, and a handful of commonly used diagnostic tools.

E. Competition Law & Clearinghouses

1. Lessons Learnt from Copyright Collection Societies

2. Health Care Concerns

F. Case Study Royalty Collection Clearinghouse

In a royalty collection clearinghouse for genetic diagnostics, patent holders license their patents to the clearinghouse in order to enable the clearinghouse to issue sub-licenses to the sub-licensees (hereinafter simply 'license' and 'licensees'). The clearinghouse verifies whether the patent has not expired and whether the maintenance fees have been paid. Before the clearinghouse will fully operate, it develops standard licensing agreements in consultation with the appropriate stakeholders. Such standard licenses could be differentiated in accordance with the nature of the user, the intended use and the profile of the eventual product to be developed by the licensee. Individual patent holders will be free to choose which standard licenses will be made available for his patented inventions concerned. These are the boundaries within which the licensees will move when they 'pick & choose' the relevant inventions.

Forms are drafted with tick-boxes related to the nature of the user, the specific goal of the intended use (such as research, product development (an improvement or a new product), or diagnostic testing), followed by a list of the different patented genetic inventions (such as DNA sequences, mutations, proteins, or technical applications) included in the clearinghouse. The clearinghouse provides information to the potential licensees on patents and claims relevant to a specific application in genetic diagnostics and indicates to what extent licenses would be available, much like an information clearinghouse. It would then "match" licensees and the patented inventions (like a technology exchange clearing house) while at the same time offering the previously mentioned standardized licensing agreements, which could provide flexible yet standardized, reasonable royalties (like the standard licenses

clearinghouse). Within the boundaries set by the individual patent holder in consultation with the clearinghouse, any potential licensee ticks boxes according to his or her needs, and royalties are calculated accordingly. Payment of the royalty fees entitles the licensee to access all the essential patents in accordance with the standardized license drafted for the objective pre-specified by the licensee.

Although the clearinghouse facilitates access to and use of multiple patents, the simple "ticking of boxes" related to the relevant genetic inventions by the licensee entails a risk of accumulation of royalties. Such an accumulation may make the intended use prohibitively expensive for licensees. To solve this problem, the clearinghouse insists on reduced or capped royalties through so-called royalty stacking clauses stipulated in the standardized license.

Additionally, a royalty disbursement accounting system is established. The clearinghouse collects the royalties from the licensees and compensates patent holders in accordance with a set allocation formula after deduction of administration costs or on the basis of reported use of the patented inventions. Furthermore, the clearinghouse might also monitor infringements of patents by both licensees and non-licensees (and notify the patent holder) and provide dispute resolution services by way of mediation or arbitration by a neutral board.

A royalty collection clearinghouse in genetic diagnostics could be set up as a neutral, independent agency by a public entity or as a private initiative by the stakeholders involved accountable to and supervised by an external authority. In principle, it might be implemented by a not-for-profit or profit (private) organization as a voluntary scheme or as a statutory framework on a mandatory basis. However, implementation of a statutory regime with an obligation to participate should be a last resort.

Various national or regional clearinghouses (European, North American, Asian, etc.) could be set up to identify, match, negotiate, collect royalties, monitor infringements and assist in dispute resolution. All these services could be coordinated by a worldwide, "umbrella" organization. Such a global approach would not only be cost effective but could also encourage patent holders to participate in the model by limiting the points of registration yet increasing their visibility for technology users. However, one should beware of any misconduct of a clearinghouse with such an immensely strong position. Certainly, the global character of the genetics market place means that potential licensees acting on a global scale themselves would be better served with a global checkpoint for existing patent rights. This suggestion is thorny because patents operate on a national level. Therefore, standard licenses should be drafted in such a way that the territorial scope of application of the patents is taken

into consideration. For instance, licensees will only apply for a license for the territories where a patent has been granted and where they wish to exploit the invention.

G. Industry Standards

Industry standards serve as an important incentive for the establishment of patent pools in electronics and telecommunications. They would probably not function as an incentive to address a royalty collection clearinghouse but could be useful as a tool for managing the royalty collection clearinghouse. As has been argued above within the framework of patent pools, a genetic standard should not necessarily be looked at in terms of a specification to ensure compatibility and interoperability between specific technologies, but could present itself as national or international best practice guidelines for genetic testing for a particular disorder.

The rights collected in the clearinghouse for genetic diagnostics can be identified and grouped on the basis of such best practice guidelines to increase transparency and effectiveness. All the patented products and methods that such guidelines deem to be essential for genetic testing for a particular disease could be made available by the royalty collection clearinghouse as a bundled set, with a standardized license at a reasonable royalty fee. In addition to these sets of patented inventions, the royalty collection clearinghouse should continue to allow scientists, clinical geneticists, laboratories or clinics the option to 'pick and choose' individual licenses relevant to their practice. To limit licensees to buying sets of patents might have anti-competitive effects: users would no longer be free to determine their (competitive) business strategy. Moreover, the sets of patented inventions and the related standardized licenses should be dynamic, as the best practice guidelines are subject to continuous review.

H. Summary & Intermediate Conclusions

[This Section will be written after serious review at the IPSC 2006]

V. CONCLUDING REMARKS

[This Section will be written after serious review at the IPSC 2006]