Journal of Intellectual Property Rights
Vol 19, March 2014, pp 113-122

# On the Challenges Facing Patent Pooling in Biotechnology

Thomas D Jeitschko†
Michigan State University, Marshall Hall, 486 W Circle Dr, Rm 110, East Lansing, MI 48824, USA
and
Nanyun Zhang
Independent Project Analysis Inc, 44426 Atwater Dr, Ashburn, VA 20147, USA

*Received 4 October 2013, revised 14 February 2014*

The role of patent law and patent practice especially in biotech has gained considerable attention of late as there are concerns that innovative efforts are stifled rather than fostered by intellectual property in the area. In this article, the authors survey some of the difficulties encountered in biotech when it comes to innovation and discuss aspects that touch on the efficacy of patent pooling to overcome innovation barriers. In light of a review of the related research literature addressing the area, it is found that analogies to other industries and areas of R&D are not insightful. As a result, it is concluded that further empirical research and theoretical modeling of patent pooling in biotechnology are needed in order to establish sound policy recommendations.

**Keywords**: Patent pools, research and development, innovation, tacit knowledge, biotechnology, pharmaceuticals

The effect of patents and patent law on innovation has of late gained considerable attention throughout the world since public policy concerns have been raised as to whether patent systems are broken and tend to stifle, rather than foster innovation. In addition to these concerns there are supranational aspects as to how protection of intellectual property can be effectively ensured across borders, on the one hand, and how the benefits of innovation and advances, especially in medicine, can be made to benefit those in poorer countries.

While some fear that patent pooling and standard setting have become processes that run afoul of antitrust and competition concerns, the discussion in biotech is seen from the opposite vantage, namely, that lack of pooling has lead to such a patent thicket as to substantially stifle innovation and threaten advancement of medical insights and treatment possibilities.

In this article, we survey some of the difficulties encountered in biotech when it comes to innovation and discuss aspects that touch on the efficacy of pooling to overcome innovation barriers. We note that unlike the electronics industry in which patent pools are common, biotech is still an emerging area of research and precisely because of this, the formation of pools among for-profit firms is unlikely to occur. However, we also show that this need not be to the detriment of innovation as pool-formation (and other possible forms of collaboration) may dampen innovative efforts and results. We conclude that the picture to date is far from clear and analogies to other industries and areas of R&D need not be insightful. As a result, policy prescriptions are hard to come by without further empirical research and theoretical modeling of the issues specifically germane to biotechnology.

## The Patent Thicket in Biotechnology and the Debate about a Solution

In the field of biotechnology, universities have been one of the most active players in conducting basic research; and they are often the major patent holders for scientific discoveries on isolated and purified genes or DNA sequences and on methods for cloning, isolating and manipulating DNA, RNA or proteins. Since the passage of the Bayh-Dole Act in 1984, U.S. federal/publicly funded research institutions such as universities are under more and more pressure to commercialize their scientific discoveries. But universities rely on dedicated biotechnology firms[1] (DBF) to translate their discoveries into commercial

†Corresponding author: Email: jeitschk@msu.edu

products through licensing.[2] For example, based on an isolated gene discovered by a university, a biotechnology firm can develop a process for making transgenic plants that produce pharmaceutical compounds of interest and these pharmaceutical compounds can be isolated and purified from the plant and then administered to humans to treat deadly diseases. This process, however, is fraught with problems for the biotechnology firms concerning accessing patents in the license-in stage.

Biotechnology firms usually need to use multiple fragments held by different patentees in order to do the further research and ultimately innovate some foreseeable commercial products, such as therapeutic proteins or genetic diagnostic tests. Thus, they are forced to cope with 'patent thickets' in situations where multiple owners hold important underlying patents related to potential innovations. The patent thicket refers to 'a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology.'[3] In other words, researchers must bundle licenses from all patent holders to avoid being charged with infringement under multiple patents and this can be frustrating to a small biotechnology firm. For example, patents on receptors are useful for screening potential pharmaceutical products. To learn as much as possible about the therapeutic effects and side effects of potential products at the pre-clinical stage, firms want to screen products against all known members of relevant receptor families. But if these receptors are patented and controlled by different owners, gathering the necessary licenses may be difficult or impossible. Unable to procure a complete set of licenses, firms choose between diverting resources to less promising projects with fewer licensing obstacles and then proceed to animal and then clinical testing on the basis of incomplete information.[4]

The potential interdependence of research firms experiencing these difficulties is highlighted by the concept of the tragedy of the anticommons—a term that first appeared in Michael Heller's 1998 article of the same name.[5] The anticommons is used to describe the coordination breakdown that takes place when a single resource has numerous rights-holders who prevent others from using it, frustrating what would be a socially desirable outcome. As indicated above, this occurs when the development of a new invention requires the licensing of complementary patents from different patent holders. If too many owners can block each other, then it will cause stagnation in technology development. Thus, it is often the case that one firm that is stifled by others' IP-rights, is itself stifling the potential innovation of rivals.

Both the patent thicket problem and the anticommons concerns are exacerbated by what has been termed the 'patent tsunami', namely the rapid acceleration of patent applications and issuances. In our context, this manifests itself in the situation where one particular gene has been the subject of patent applications many times over. For example, the Bone Morphogenetic Protein 7 has been the subject of a patent application twenty times. Indeed, in the context of human gene patents, there has been added controversy over the appropriateness of patents also from the political, the ethical, and the scientific perspectives. A main concern is that gene patents can delay or limit scientific research and genetic testing. In addition to this, it is claimed that patent holding companies have been controlling gene patents clinical research to an extent that hurt the interests of patients, and that gene patents based medical treatment and diagnostics are considerably over-priced due to lack of competition in the market.

All these concerns have been echoed in the recent lawsuit filed by the American Civil Liberties Union (ACLU) on behalf of multiple plaintiffs (including breast cancer patients, clinicians, and providers of genetic diagnostic testing services) against Myriad Genetics and the United State Patent and Trademark Office (USPTO). The aim of the suit was to invalidate many of Myriad Genetics' patent claims directed towards the BRCA1 and BRCA2 breast cancer genes. The major points that were raised are: (1) the patents granted to BRCA1 and BRCA2 breast cancer genes are so broad that they prevented research on substitutive diagnostic testing research; (2) Myriad made efforts to prevent clinical trials to explore just how good their test was and that patents denied patients from receiving second opinions in regards their test results; and (3) the US$ 3,200 price tag for the diagnostic testing offered by Myriad was too high. In the summer of 2013, the US Supreme Court ultimately ruled that the genes themselves could not be patented, but surrounding know-how can be.

The ruling comes in the wake of Representative Xavier Becerra's (D-CA) H.R. 977, the 'Genomic Research and Accessibility Act (GRAA)', introduced during the 110th Congress to bar the issuance of gene

patents on the human genome and naturally occurring genes as well as synthetic DNA or RNA molecules.[6] Although the bill did not pass due to lack of support, it is not entirely abandoned yet, either. Both the possible passing of GRAA and the decision in the Myriad case could prove far-reaching in the biotechnology field and beyond.

In order to better appreciate the scope of the issue, one only needs to survey the subject from reading reports and articles published in government documents, law journals and all kinds of magazines and IP blogs. In addition to GRAA, a recent call for change came from the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), at the U.S. Department of Health and Human Services.[7] Their report, Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests, published in April 2010, has found that patents on genetic discoveries do not appear to be necessary for either basic genetic research or the development of available genetic tests, and patents have been used to narrow or clear the market of existing tests, thereby limiting, rather than promoting availability of testing. As a result, among other things, the Committee recommended the 'creation of an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research.'

We find SACGHS's report informative and believe that it adds some new evidence of heretofore underappreciated problems in the current gene patenting practice. But, just as congressman Xavier Beccera (D-CA) justified his support of the Genomic Research and Accessibility Act on the grounds that '[t]he practice of gene patenting is preventing critical research from advancing because scientists are wary of trespassing patent laws,' SACGHS may have come to conclusions and the recommendation without the support of solid scientific research. Indeed, while the SACGHS' study 'consisted of a literature review, consultation with experts, the solicitation of public comments, and original case studies,' it failed to provide hard data that would indicate a widespread underlying patent thicket/anticommons phenomenon. In contrast, a large 2007 study by the American Association for the Advancement of Science found "very little evidence of an 'anticommons problem.'"[8] And a 2005 study done for the National Academy of Sciences found only 1 per cent of the scientists surveyed reported suffering a project delay of more than 1 month due to patents.[9] Without the support of solid data, one must be cautious when using the theoretically anticipated anticommons phenomena to back up any proposed legislative fix or policy amendments.

Law professor Chris Holman is one of the few researchers who have noted the absence of hard evidence that gene patents impede research. Holman studied the impact of human gene patents on innovation and access in response to arguments against gene patents.[10] Using a definition of gene patents that differed from the well cited 2005 definition of Jensen and Murry,[11] he focused his study on the small subset of human gene patents that have been asserted in court and uses litigation to serve as a measure of patent impact. Holman found that 1.1 per cent of a random sample of 1,000,000 patents issued from 1993 to 2003 have been the subject of lawsuits, very close to the previously estimated 1~2 per cent for patents in general. And he concludes that 'in these litigations, human gene patents are essentially playing a role analogous to that of drug patents in the conventional pharmaceutical context'. He noted that 'Human gene patents are clearly having an impact on the cost and availability of protein therapeutics, but, overall, the impact is likely a positive one.'

Although his use of litigation as a measure of the impact of gene patents is limited, the importance of Holman's concepts is undisputed. However, we do acknowledge the existence of 'a tragedy of the anti-commons' conceived by Heller and Eisenberg and agree that there is enough anecdotal evidence to suggest that fragmentation of rights is a serious concern in biotech. Indeed, the absence of a reported curtailment may simply be an equilibrium response to the problem at hand: researchers simply do not report their research being stifled by patents, because they make their choice of research areas on the grounds of where there are fewer problems with blocking patents to be anticipated. This, then, is also the reason for comparably low rates of litigation. In other words, research that would become cumbersome in light of the patent thicket and anticommons is simply not pursued, even though it is in areas that are generally viewed as being of critical importance.

Our research does not challenge the logic behind the advocacy of abandoning the whole gene patenting system based on the concerns surrounding the patent thicket, the patent tsunami, and the anticommons; nor

do we directly cast doubt on the utility of compiling theories to prove the effectiveness of the patenting system as such either. The questions that we want to have posed and addressed are: without radical reform of the current system, how does one best organize patents to facilitate access to genetic patents and how can different institutional arrangements enhance innovation and competition in biotech? Two types of possible remedies to handle the patent thicket or tsunami problem are the focus our attention: one is a patent pool and the other is contractually constructed liability (CCL). In this paper, we focus on the former extensively, but CCL is also briefly discussed.

**The Current Practice of Patent Pooling in Biotech**

A patent pool is an arrangement in which distinct patent holders bundle their patents and jointly market and license them. The first pool in the United States formed in 1856 and covered patents related to sewing machines. It has since been successfully applied in many areas, prominently so for MPEG and DVD technologies in recent years, which has helped lower the transaction cost and set the standard for those industries. After initially being considered as part of the doctrine of freedom of contract,[12] the U.S. Supreme Court in 1912 found that patent pools are subject to antitrust scrutiny.[13] Since then a nuanced view has emerged that distinguishes 'blocking' (complementary) patents from 'competitive' (substitutable) patents.

Shapiro[3] analogizes Cournot's analysis of independent monopolies providing perfectly complementary inputs to a downstream producer, in which neither of the upstream suppliers incorporate the negative externality that their pricing decision has on the other.[14] He finds that when patents in the pool are perfect complements, the pool is actually beneficial because it overcomes the implied double-marginalization (royalty-stacking) problem that otherwise results in lower producer and consumer surplus. The finding is substantiated by Lerner and Tirole who show that the more complementary the patents in the pool are, the greater are the welfare benefits associated with the pool formation.[15] Contemporary antitrust recommendations and practice in Europe and the U.S. are in line with these insights and hold that pooling complementary patents is generally not anti-competitive.[16]

The implication of these studies to the application of patent pools in biotech is that as long as the patents in the pool are essential and complementary, patent pools could be used to lower the transaction cost in the licensing process and eliminate negative externalities of royalty setting and thus solve anticommons problems. In line with this, the US Patent and Trademark Office (USPTO) issued a white paper in 2000 on the use of patent pools in the biotechnology industry as a means of reconciling the interests of both the public and private sector and solving the patent thicket problem.[17] But how has patent pooling in biotechnology actually been practiced since then?

In 2000, Ingo Potrykus and his team succeeded in genetically enriching rice grains with β-carotene after seven years of research. In order to transfer the resulting 'Golden Rice' materials to developing countries for further breeding—in the hopes of ultimately reducing malnutrition problems—Potrykus approached six key patent holders and gained the right to grant licenses as a package, free of charge, to developing countries, with the right to sub-license. The Golden Rice pool is the first instructive genetic patent pool, operated as a non-profit humanitarian organization.

Another example is the effort surrounding the formation of a SARS-related patent pool in 2004. After the SARS (severe acute respiratory syndrome) outbreak in February 2003, several research teams around the world were competing to bring SARS vaccines to the market based on their own findings of sequences of the genome of the SARS coronavirus. To prevent the delay of the development of SARS vaccines due to the complex and uncertain intellectual property situation, the WHO SARS consultation group recommended that 'a strategy be developed, in consultation with stakeholders, to address potential SARS CoV-related IP issues and thus enhance development of intervention approaches.' As a result, the four parties known to own key patent applications had expressed their willingness to form a patent pool with the goal to enable wide access to the SARS genome.[18]

These examples of patent pools in biotech have something in common: they are organized and operated by not-for-profit organizations. Does patent pooling always conflict with for-profit organizations? The recently formed patent pool in biotech called Librassay® implies the answer is 'no' when it comes to genetic diagnostic testing. Launched by one-stop patent licensing leader MPEG LA in September 2012

and starting with some 400 patents, Librassay makes diagnostic patent rights from the world's leading research institutions available to everyone through a single license. The patent pool plays the role of a patent licensing 'supermarket' that makes essential patent rights available on a nonexclusive, nondiscriminatory basis. Its goal is to accelerate adoption and availability of genetic diagnostic tests leading to personalized medical solutions in service to the entire market.

It is not totally incidental that the first patent pool in biotech that is not limited to non-profit organizations was formed for diagnostic testing. As a matter of fact, the diagnostic genetics industry is not as diverse as the overall genomics industry. The genomics industry works with and patents at least three kinds of genes: those encoding (i) therapeutic proteins, (ii) sequences with diagnostic information, or (iii) receptors useful in high-throughput screening for drug discovery. In contrast, the field of diagnostic genetics is more commercially focused and, when further limited to individual diseases such as breast cancer or cystic fibrosis, and to diseases that have a consensus statement on standard mutations, is ideal for a patent pool to be instituted. Unlike the varied genomics industry, the players in the market for disease-specific diagnostic genetics—regardless of whether or not they are a commercial enterprise or a not-for-profit entity—have a clear common goal: to provide accurate tests and analytic devices so as to minimize false negative or false positive results for a given disease.[19]

Similar to diagnostic testing, any 'component' based or 'assembly' based technology in biotech is theoretically susceptible to patent pooling. For example, antiretroviral drugs are medications for the treatment of infection by retroviruses, primarily HIV. As different classes of antiretroviral drugs act at different stages of the HIV life cycle, an effective antiretroviral therapy must consist of the combination of at least three antiretroviral (ARV) drugs to maximally suppress the HIV virus. If different companies own different ARV drugs for an antiretroviral therapy, then forming a patent pool can potentially benefit each patent owner and eventually help the patients as well. UNITAID is an international facility for the purchase of drugs against HIV/AIDS, malaria and tuberculosis. It was founded in September 2006 on the initiative of Brazil and France, and is facilitated by the World Health Organization (WHO) in Geneva. UNITAID formed an HIV-related medicine patent pool in the middle of 2010 to facilitate the development of fixed-dose-combinations (FECs). In October 2011, the Medicines Patent Pool signed a license agreement with the pharmaceutical company, Gilead Sciences to increase access to antiretroviral therapy in developing countries. This is the first time a pharmaceutical company has joined the Medicines Patent Pool and marks a turning point for future private sector collaboration in sharing innovation to advance the response to HIV. Under the agreement, Gilead will share intellectual property on a range of medicines to treat HIV. The agreement will allow for the production of the HIV medicines tenofovir, emtricitabine, cobicistat, and elvitegravir as well as a combination of these products in a single pill known as the 'Quad'. Cobicistat, elvitegravir and the Quad are products still in clinical development. Companies interested in producing generic versions of the medicines for developing countries will be able to approach the patent pool to negotiate licensing terms.[20]

Potential pooling opportunities also exist in the vaccine industry. In 2000, an alliance called Global Alliance for Vaccines and Immunization (GAVI) was formed bringing together developing country governments, the vaccine industry, research agencies and philanthropists, to enable the delivery of vaccines to children in the poorest parts of the world by Medecines sans Frontiers (Doctors without Borders). GAVI showed the powerful positive impact a public-private partnership could generate on global health, but it differs from a patent pool in that the primary focus is dissemination, rather than the furtherance of drug development.

As there is no patent pool formed for non-diagnostic testing products among for-profit organizations, it is important to further explore the issue to better appreciate the challenges facing the application of patent pools in biotech in more general settings.

## Obstacles to Innovation for Non-Diagnostic Products

Although many economists and biotech professionals advocate patent pools as a solution to the patent thicket problem, patent holders in general are much less enthusiastic about this, especially when compared to the electronics industries. Empirical studies on patent pooling in general actually develop a

mixed picture. For example, Baron and Delcamp explore the impact of contemporary patent pools on firm patenting strategies.[21] They show that firms that are already members of a pool are able to include narrower, more incremental and less significant patents than outsiders. Lampe and Moser report on how patent pools encouraged innovation using data from the first patent pool in U.S. history, the Sewing Machine Combination (1856-1877).[22] Their data confirm that member firms patent more in the years leading up to the pool; but, they patent less as soon as the pool is established. Because the sewing machine pool discouraged innovation by increasing the threat of litigation for outside firms, innovation slowed for the duration of the pool and only increased again after the pool had expired. Their data also indicate that outside firms shifted towards inferior technologies. Joshi and Nerkar empirically showed that patent pools reduce the innovation quantity and quality by both the licensors and the licensees, using data from the optical disc industry.[23]

Recent related work also looks at other forms of collaboration. Siebert for instance, notes that most results tied to the empirical study of research joint ventures (RJVs) may not be generalizable to collaboration more broadly, since RJVs are self-reported institutions and therefore there is a selection bias in only engaging in socially beneficial activities.[24] Moreover, he notes that most collaboration may take other forms, which may be less conducive to fostering innovation. On the basis of a study of the semi-conductor industry he estimates that pre-discovery licensing actually leads to reduced subsequent patenting and innovation.

Turning specifically to the difference between biotech and existing pools in other areas, Krattiger and Kowalski[25] suggest that the reason for deficient pool-formation in for-profit biotech non-diagnostic ventures lies in the lack of alignment in industry interests: 'when considered from the perspective of the overall biotechnology industry, while patent pools may be very useful for assembling IP related to platform technologies that need to establish industry-wide standards (for example, DVD, MP3), the value of patent pooling is much less when industry interests are not aligned (still maturing industries), which, indeed, is the general case with biotechnology. Hence, in the context of R&D in many biotechnological applications, for example, with respect to vaccines—an evolving field with no platform and with no technology clearly in the lead—industry interests can hardly be considered aligned. Indeed, if a technology has not matured to the stage where industry standards can even be contemplated, then a patent pool would likely not be the favored option. At these earlier stages in the R&D of innovative technologies, few companies will have an interest in giving their rivals preferential access to their technologies. Companies also typically become cautious about antitrust issues when a patent pool is suggested, which might also hinder participation.'[25]

Krattiger and Kowalski give a good explanation for how maturity and standardization affect pool formation—thus offering the rationale for the formation of Librassay, but the insights do not shed direct light on why the lacking of aligned interests or non-standardized product innovation prevents the formation of patent pools when these are not salient aspects of the subsequent commercial viability. To better understand this, we researched gene related discoveries and found that compared to patents in the existing patent pools, biotechnology patents have two distinct characteristics that differentiate them to the detriment of pool formation: one is the *incompleteness* of patents, i.e. pioneer inventions owned by the patent holders are not complete and need further innovations to be embodied in a final product that is to be marketed; the other is that *tacit knowledge* plays a crucial role in the process of licensing. Scientific discoveries are characterized by tacit knowledge that would not be disclosed in a patent and cannot be fully revealed and transferred in the licensing process. Thus, discovering scientists are often closely involved in the subsequent innovation and patent holders have the right and option to decide on the depth of the technology transfer by choosing the research cooperation effort or how much retained intellectual human capital they will release.[26]

Formal modeling in Jeitschko and Zhang[27,28] illustrates the incentives for patent holders to form a pool and how this impacts consumer welfare and social welfare in general. In the model two patents are perfect complements and their holders ($k$ and $l$) can license them to two downstream firms ($i$ and $j$) either individually or as a pool (see Fig. 1). The pooling decision affects spillovers in subsequent development ($\beta$) in the firms' innovation stage and the differentiation level of products ($\gamma$) in the downstream final demand market. The structure is captured in the figure.

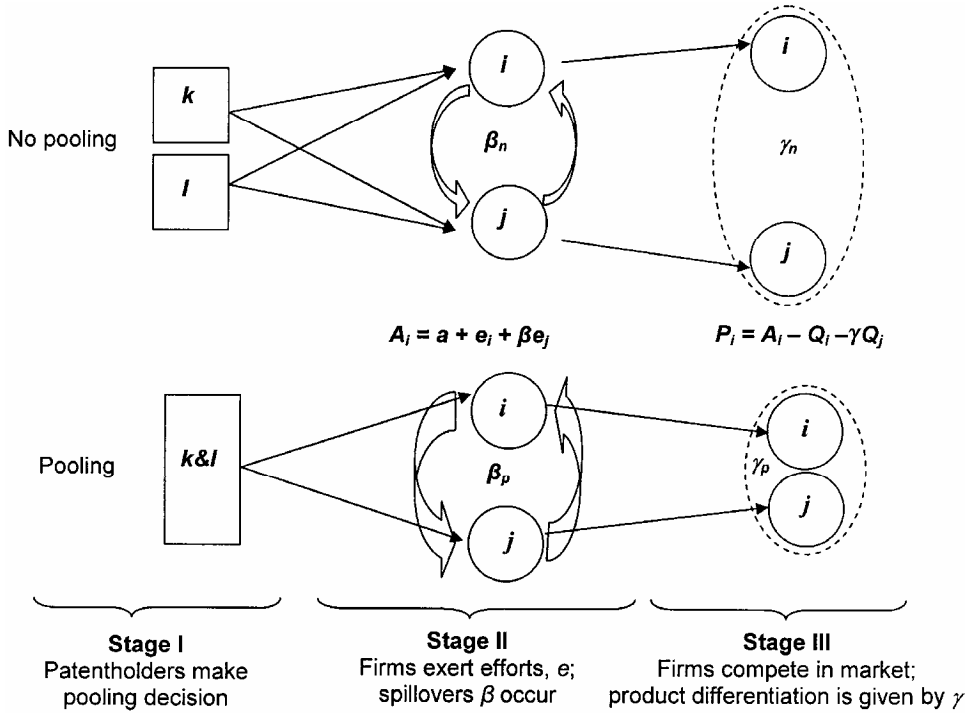


Fig. 1 – Incentives for pool formation: Impact on research spillovers and product homogeneity

The focus is on gaining a better understanding of the potential welfare implications of patent pooling under perfect complements, given heretofore disregarded effects that pooling may have on both subsequent development efforts and on downstream product characteristics. A result of the analysis is a substantiation of the conventional wisdom that patent pools of perfectly complementary patents are beneficial for a general setting in the following sense: When patent holders contract with licensors on the basis of per-unit royalties, whenever patent holders prefer the pool structure over the no-pool structure, patent pools also increase consumer surplus.

An even stronger result emerges for the case that consumer surplus is viewed as the relevant criterion for antitrust sanctioning of pools and royalties are paid on a per-unit-of-output basis. In this case, the pooling structure is always preferred over the non-pooling structure; regardless of the degree of spillovers and product differentiation and how pooling affects these. This also suggests why patent pools are often initiated by not-for-profit entities in biotech and medicines. However, if the antecedent does not hold, two important results emerge from the general analysis that go against some of the public discussion and advocacy concerning patent pooling of perfectly complementary patents. First, if total welfare is considered to be the relevant benchmark, rather than consumer surplus, then patent pools may reduce industry profits to a degree that is sufficient to not be overcome by increases in consumer surplus, despite patents being perfect complements. Secondly, as discussed in Jeitschko and Zhang[28], even if consumer surplus is considered decisive, patent pools for perfectly complementary goods may be undesirable in cases of upfront fees in place of per unit royalties, especially if pooling does not lead to large increases in spillovers yet diminishes the degree of horizontal product differentiation.

The findings substantiate that the maturity of the industry may be key in understanding the benefits of pooling. But, more than that, they also show that the profit motive may be insufficient to establish pools, and—critically—that even absent a profit motive, reduced innovative activity and greater degrees of homogeneity due to the pool, may make pooling

undesirable even from a total welfare standpoint or from a consumer welfare perspective.

Models of patent pools generally assume contractible and low risk innovations. However, as noted above, a salient feature of much of the research in biotechnology is tied to incompleteness and tacit knowledge. As a result, innovation has aspects that are non-contractible, highly uncertain and inherently risky. When facing a non-contractible, uncertain and dynamic nature of innovation, the CCL regime can play an important role. Aoki categorized various clearing mechanisms and contractually constructed liabilities according to economic functions.[29] Three categories are defined: (1) Exchanges, which simply reduce transaction costs; (2) Collective Rights Organizations (CRO), which include copyright and patent pools and set prices to intellectual property so that they will be used optimally for production; and (3) Incomplete Contract Structures (ICS). Although the author gives important formal analyses to both Exchanges and CRO, the description about the newly introduced concept of ICS is still abstract and could be further developed. Rai *et al.* describe this new concept as "Participating firms agree on a supplementary system of royalties that would govern compensation to any firm that had provided structural information about its molecules to a researcher deciding among promising 'hits.' In other words, firms would be contracting into a subsidiary set of 'take and pay rules', or liability rules, rather than relying entirely on exclusive property rights."[30] Their brief introduction of this new institution is based on intuition and logical analysis. It is important to supplement this with a rigorous model that will help to substantiate how CCL would increase access to gene patents and help downstream firms lower the risk and cost in highly uncertain and risky circumstances.

In principle, there are also other arrangements that are found in many instances of R&D affecting potential rivals. Research joint ventures or research sharing joint ventures (RSJVs) (see, e.g., Greenlee[31]) can form such bases. Related to this are pre-discovery licensing agreements, in which research is independent, but results are agreed upon to be shared in advance. However, these arrangements require a large degree of upfront coordination and will therefore suffer from some of the same shortcomings already identified and discussed. Moreover, as noted by Van Overwalle, who cites two surveys in the medical biotechnology sector, the fear of loss of secrecy and control are pervasive in biotech and therefore influence decisions against sharing and collaboration.[32]

**Outlook**

For a deeper understanding of the biotech industry and the future of patent pooling in this area, it is critical to obtain more empirical work on gene related patenting. More specifically, how the introduction of gene patents based products will affect the competition and welfare in biomedical markets. A good start is the study by Chaudhuri *et al.*[33] which empirically investigates the welfare effects of enforcing product patents for pharmaceuticals on developing countries using data for the fluoroquinolones sub-segment of the systemic anti-bacterials segment of the Indian pharmaceuticals market.[33] Although their study is related to patents, its results do not have direct implications on the study of gene patents. Basically they study the substitution between patented foreign products and the domestically produced generic products. The enforcement of patents will lead to the withdrawal of domestic products. If we assume gene patents are as effectively enforced as in the USA, the competition is between gene patents based products and the non-gene patents based products, rather than imitation products. Because product withdrawal from the market is not a consequence of gene patenting unless infringement occurs, the welfare impact of gene patenting on the medical market is not necessarily negative. A promising empirical study can address the specific scenarios and generate important results that offer implication on policy making and shed insights on patent pooling study in biotech.

Moreover, despite the extensive discussions about the impact of patent pooling on efficiency and social welfare, two important questions are yet to be addressed. First, how patent pooling affects patent holders' innovation incentives in the initial stage of the research; and second, how patent pooling affects the access to gene patents for downstream firms. To answer the first question, a patent race stage needs to be considered and modeled. And to answer the second question, licensees' technology choice decisions need to be modeled. Based on such extended research, simulations can be conducted on questions such as how compulsory licensing influences innovators' incentives to invest in the initial stage and how the

payment contracts between the licensor and licensees affect the access to gene patents.

More broadly speaking, it is still critical to develop models of patent pooling in biotech that realistically account for and incorporate the initial research and development efforts, as well as integrate the downstream development and commercialization process; where it needs to be recognized that welfare measures may diverge between firms and consumers within a country, but also between countries.

## References


1 Many DBFs are founded just to exploit a particular biotechnology discovery. Although some DBFs are direct spin-offs of the university system, and some biotech subunits of the existing large firms also participate in the transformation of the up-stream university technology, in this paper, we treat them all as an 'intermediate' link in the innovation chain in biotechnology.

2 Murray Edwards M F & Yu R, Value creation and sharing among universities, biotechnology and pharma, *Nature Biotechnology*, 21 (6) (2003) 618-624.

3 Shapiro C, Navigating the patent thicket: Cross licenses, patent pools, and standard setting, in *Innovation Policy and the Economy*, edited by A Jaffe, J Lerner and S Stern (MIT and NBER Press, Cambridge, MA), 2001.

4 Heller M & Eisenberg R, The anticommons in biomedical research, *Science*, 280 (5364) (1998) 698-701.

5 Heller M, The tragedy of the anticommons, *Harvard Law Review*, 111 (3) (1998) 621.

6 Genomic Research and Accessibility Act, H.R. 977, 110th US Congress, 2007.

7 SACGHS: Direct-to-Consumer Genetic Testing: Report of the Secretary's Advisory Committee on Genetics, Health, and Society, April 2010.

8 Hanson S, Kisielewski M & Asher J, *Intellectual Property Experiences in the United States Scientific Community* (American Association for the Advancement of Science, Washington DC) 2007.

9 Walsh J, Cho C & Cohen W, Patents, material transfers and access to research inputs in biomedical research, Final Report to the National Academy of Sciences' Committee Intellectual Property Rights in Genomic and Protein-Related Inventions, 2005.

10 Holman C M, The impact of human gene patents on innovation and access: A survey of human gene patent litigation, *UMKC Law Review*, 76 (2007) 295-307.

11 Jensen K & Murray F, Intellectual property enhanced: Intellectual property landscape of the human genome, *Science*, 310 (5746) (2005) 239-240.

12 *E. Bement & Sons* v *National Harrow Co.*, 186 U.S. 70 (1902)

13 *Standard Sanitary Manufacturing Co.* v *U.S.*, 226 U.S. 20. For a brief synopsis of the historical development see Miller M & Almeling D, DOJ, FTC redefine antitrust rules on patent pools, *Special to the National Law Journal*, 2007, http://www.omm.com/files/upload/MillerAlmelingNational LawJournal.pdf (1 February 2014) or Gilbert R, Antitrust for patent pools: A century of policy evolution, *Stanford Technology Law Review*, 3 (2004), http://stlr.stanford.edu/pdf/gilbert-patent-pools.pdf (1 February 2014).

14 Cournot illustrates his point by considering the pricing decisions of a monopolist for copper and a monopolist for zinc, providing the necessary inputs to a downstream producer of brass. Cournot A, *Recherches sur les Principes Mathématiques de la Théorie des Richesses*, 1838; Shapiro C, Navigating the patent thicket: Cross licenses, patent pools, and standard setting, in *Innovation Policy and the Economy*, edited by A Jaffe, J Lerner and S Stern (MIT and NBER Press, Cambridge, MA) 2001.

15 Lerner J & Tirole J, Efficient patent pools, *American Economic Review*, 94 (3) (2004) 691-711. It should be noted that they recognize that, in the context discussed, the notions of complementarity and substitutability are not actually as clear-cut as it might seem, but a meaningful distinction is nonetheless possible on the basis of changes in patentees' willingness to pay for additional patents.

16 Compare to the Guideline on the Application of Article 81 of the European Commission Treaty to Technology Transfer Agreements (2004/C 101/02), and Chapter 3 of USDOJ/FTC (2007).

17 Clark J *et al.*, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?*, (United States Patent and Trademark Office, Washington DC), 2000.

18 Simon J *et al.*, Managing severe acute respiratory syndrome (SARS) intellectual property rights: The possible role of patent pooling. *Bulletin of the World Health Organization*, 83 (2005) 707-710.

19 Ebersole T, Guthrie M & Goldstein J, Patent pools and standard setting in diagnostic genetics, *Nature Biotechnology*, 23 (2005) 937-938.

20 Medical News Today, 15 October 2011.

21 Baron J & Delcamp H, Strategic inputs into patent pools, 2010, http://hal-ensmp.archives-ouvertes.fr/docs/00/48/82/72/PDF/BARON_DELCAMP_Strategic_Inputs_into_Patent_Pools_CWP_2010-05.pdf, 2010 (1 February 2014).

22 Lampe R & Moser P, Do patent pools encourage innovation? Evidence from the 19th-Century sewing machine industry, *Journal of Economic History*, 70 (4) (2010) 898-920.

23 Joshi A & Nerkar A, When do strategic alliances inhibit innovation by firms? Evidence from patent pools in the global optical disc industry, *Strategic Management Journal*, 32 (11) (2011) 1139-1160.

24 Siebert R, A dynamic model of the impact of pre-discovery licensing on innovation and product market efficiency: Evidence from the semiconductor industry, mimeo, 2013, Purdue University, http://www.law.northwestern.edu/research-faculty/searlecenter/events/entrepreneur/documents/Siebert_EAL_130216.pdf (1 February 2014).

25 Krattiger A & Kowalski S, Facilitating assembly of and access to intellectual property: focus on patent pools and a review of other mechanisms, in *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, Vol 1 (MIHR, Oxford, UK), 2007, pp. 131-144.

26 Zucker L, Darby M & Armstrong J, Commercializing knowledge: University science, knowledge capture and firm performance in biotechnology, *Management Science*, 48 (1) (2002) 138-153.

27 Jeitschko T & Zhang N, Adverse effects of patent pooling on product development and commercialization, *The B.E. Journal of Theoretical Economics*, 14 (1) (2014) 1-31.

28 Jeitschko T & Zhang N, Patent pools and product development: Perfect complements revisited, Working Papers 2011-02, Department of Economics, Towson University.

29 Aoki R, Access to genetic patents and clearinghouse model - Economic perspective, in *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Model and Liability Regimes*, edited by G Van Overwalle (Cambridge University Press, Cambridge, MA), 2009, pp. 350-364.

30 Rai A *et al.*, Pathways across the valley of death: Novel intellectual property strategies for accelerating drug discovery, *Yale Journal of Health Policy, Law & Ethics*, 8 (1) (2008) 53.

31 Greenlee P, Endogenous formation of competitive research sharing joint ventures, *Journal of Industrial Economics*, 53 (3) (2005) 355-391.

32 Van Overwalle, G, Uncorking trade secrets: Sparking the interaction between trade secrecy and open biotechnology, in *The Law and Theory of Trade Secrecy: A Handbook of Contemporary Research*, edited by R Dreyfuss and K Strandberg (Edward Elgar, Cheltenham, UK), 2012.

33 Chaudhuri S, Goldberg P & Jia P, Estimating the effects of global patent protection in pharmaceuticals: A case study of quinolones in India. *The American Economic Review*, 96 (5) (2006) 1477-1514.