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# Making the Jump from Gene Pools to Patent Pools: How Patent Pools Can Facilitate the Development of Pharmacogenomics Note

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## Note

# MAKING THE JUMP FROM GENE POOLS TO PATENT POOLS: HOW PATENT POOLS CAN FACILITATE THE DEVELOPMENT OF PHARMACOGENOMICS


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*While promising great advancement in the understanding of genetic variability and drug response, the rapidly growing field of pharmacogenomics is plagued with an increasingly complex landscape of intellectual property rights. The often prohibitive transaction costs of negotiating a multitude of licensing agreements threaten to stifle innovation and limit the success that many hope pharmacogenomics will bring to personalized medicine. By aggregating intellectual property rights, patent pools offer an intriguing solution to some of the access issues confronting the pharmacogenomics industry. In the face of a proliferation of genomic patents, patent pools provide a unique opportunity to navigate the patent thicket and render proprietary technologies more accessible for use in the creation of new, potentially patentable, genomic technologies.*

*This Note examines the possibility of utilizing patent pools in order to facilitate the advancement of pharmacogenomics and, ultimately, a new era of personalized medicine. Specifically, this Note argues that patent pools minimize the threat of an anticommons, reduce transaction costs and are pro-competitive intellectual property tools that contribute to the growth of new emerging technologies in well-defined commercial settings. Finally, this Note suggests that patent pools are a particularly viable option in the field of gene-based diagnostic testing, which could serve as an illustration of how patent pools can facilitate scientific innovation.*

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# MAKING THE JUMP FROM GENE POOLS TO PATENT POOLS: HOW PATENT POOLS CAN FACILITATE THE DEVELOPMENT OF PHARMACOGENOMICS

COURTNEY C. SCALA*

## I. INTRODUCTION

In an era of rising health care costs and increased barriers to affordable and effective drugs, pharmacogenomics offers the promise of improved patient care and disease prevention in an approach to medicine that is truly "personalized."[1] By examining patterns of genetic variation across a population, pharmacogenomics attempts to identify genetic differences that influence drug metabolism and response in order to correlate those differences with drug efficacy and safety information.[2] The ability to distinguish in advance, before a prescription is written, whether a patient should take a particular drug, avoid the drug entirely, or take it in an adjusted dosage, could result in significant cost savings for the health care system.[3] In a September 2008 report entitled "Priorities for Personalized Medicine," the President's Council of Advisors on Science and Technology (PCAST) proposed a number of policy recommendations to help facilitate the progress of personalized medicine, concluding that genomics-based molecular diagnostics will be "the essential driver for the

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* Princeton University, A.B. 2004; University of Melbourne, Master of Social Policy, 2005; University of Connecticut School of Law, J.D. Candidate 2010. I would like to extend my gratitude to Professors Audrey R. Chapman and Lewis Kurlantzick for their invaluable comments and guidance throughout the writing process. I would also like to thank Christophe Renaud for his expertise and encouragement as well as the members of the *Connecticut Law Review* for their hard work. This Note is dedicated to my parents for their constant love and support; they have always taught me to be a problem-solving thinker. Any errors contained herein are mine and mine alone.

[1] *Priorities for Personalized Medicine*, PRESIDENT'S COUNCIL OF ADVISORS ON SCI. AND TECH., 1 (2008), *available at* http://www.ostp.gov/galleries/PCAST/pcast_report_v2.pdf [hereinafter PCAST REPORT]. Pharmacogenomics is the science that anchors what is commonly referred to as "personalized medicine." Teresa Kelton, *Pharmacogenomics: The Re-Discovery of the Concept of Tailored Drug Therapy and Personalized Medicine*, 19 HEALTH LAW 1, 1 (2007).

[2] Nusrat Khaleeli & Dennis Fernandez, *Patent Prosecution in Pharmacogenomics*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 83, 86 (2006). The foundational genetic units used in pharmacogenomic research are single nucleotide polymorphisms (SNPs), which are single base pair differences in an individual's DNA that can sometimes affect the way that the individual responds to drugs. Many SNPs occur in important coding regions of the human genome (i.e., DNA sequences that are used in the translation from nucleic acids to proteins). These single variations, which can sometimes cause particular genetic diseases, also influence a drug's potency and efficacy, and can even explain why some patients, but not others, suffer from adverse reactions to certain medications. *Id.* at 86–87.

[3] PCAST REPORT, *supra* note 1, at 1. "Moreover, the ability to stratify patients by disease susceptibility or likely response to treatment could also reduce the size, duration, and cost of clinical trials, thus facilitating the development of new treatments, diagnostics, and prevention strategies." *Id.*

expanding promise of personalized medicine . . . ."[4] PCAST recommended that the health care industry's top priority should be to develop the technology and tools to understand how human genetic variability affects disease susceptibility and why different individuals sometimes react differently to the same medication.[5]

While PCAST recognized the extraordinary potential for technologies to accelerate progress in personalized medicine, the report refrained from addressing the "enormously complex" intellectual property (IP) issues facing pharmaceutical and biotechnology companies involved in the various sectors of the genomics industry.[6] One of the reasons that IP rights are so complicated in the biotechnology and genomics industries is that the number of overlapping patent claims increases as new genetic inventions, research tools, and data management methods are patented. The rising transaction costs associated with negotiating a myriad of patent licenses threaten to deter competitors from investing in pharmacogenomics, thus stifling innovation and hindering further advancement.

Due to the widespread patenting of research techniques that were traditionally available in the public domain, commercial firms and research institutions are encountering significant delays in their work.[7] A great deal of concern has been voiced regarding the difficulty of accessing patented genomic technologies for basic biological research and development (R&D).[8] As the pharmacogenomics industry becomes more commercially

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[4] *Id.* at 19.

> Genomics-based molecular diagnostics offer the possibility of correlating genetic profiles with disease occurrence, disease outcome, response to therapy, adverse events, and other factors, without the need to fully understand the underlying biological mechanisms—the specific genes that are involved, the impact of the genes on physiology, and the way they function in concert. Genetic profiles will also be instrumental in identifying known genes or gene variants that correlate with various disease outcomes, as well as in identifying genetic regions correlated with outcome that can be investigated for previously unknown genes. Genetic profiles will thus facilitate the development of new single gene or protein tests as well as new therapies that target the consequences of specific genetic alterations.

*Id.*

[5] *Id.* at 19, 29.

[6] *Id.* at 21–22.

[7] Anatole Krattiger & Stanley P. Kowalski, *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 131, 140 (Anatole Krattiger et al. eds., 2007). Specific hindrances in biotechnology research and development (R&D) include uncertainty over license costs, delays in obtaining licenses, and the different definitions of "pure research" versus "product development" licensing. *Id.*

[8] *Id.* This Note does not attempt to address the ethical considerations surrounding gene patents, a debate which has received considerable attention in the scholarly literature. *See, e.g.*, *The Ethics of Patenting DNA: A Discussion Paper*, NUFFIELD COUNCIL ON BIOETHICS (2002), *available at* http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf; Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL'Y L. & ETHICS 403 (2005). Rather, this Note accepts the view that biotechnology innovation is heavily dependent on intellectual property rights, and it will focus on exploring how patents can be

focused, patent pools offer a potentially effective solution to some of these fundamental challenges.[9]

In a patent pool, IP rights are aggregated amongst multiple patent holders, the pooled patents are made available to member and non-member licensees, and the typical pool allocates a portion of the licensing fees it collects to each member according to each patent's contributory value.[10] In other words, IP rights holders combine widely dispersed property rights into "useable bundles," thus mitigating the problems associated with anticommons theory while still preserving the incentives that come with these rights.[11]

Patent pools are an effective means of cutting through the "patent thicket" that exists in the pharmacogenomics industry. A patent thicket is "a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology."[12] When patent claims are broad, various patents may overlap with each other such that patent holders may be able to lay claim to the same technologies or to aspects of the same technology.[13] These overlapping rights, or blocking patents, contribute to the density of the patent thicket and threaten innovation. This fragmentation of IP rights can increase the costs of bringing new products to market due to the high transaction costs of negotiating and obtaining multiple licenses from multiple patent holders. Subsequently, the key concern is that scientists and research entities will opt not to compete in the field, thus potentially stifling innovation.[14] Patent pools can help solve the problems created by

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used and licensed through a patent pool so that advancements in pharmacogenomics research can continue to be made in a more efficient and cost-effective manner. The impetus for embarking on this analysis can be summarized by the following statement issued by PCAST: "The ability to obtain strong intellectual property protection through patents has been, and will continue to be, essential for pharmaceutical and biotechnology companies to make the large, high-risk R&D investments required to develop novel medical products, including genomics-based molecular diagnostics." PCAST REPORT, *supra* note 1, at 21.

[9] Krattiger & Kowalski, *supra* note 7, at 140.

[10] Robert P. Merges, *Institutions for Intellectual Property Transactions: The Case of Patent Pools, in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY, INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 123, 129 (Rochelle Cooper Dreyfuss et al. eds., 2001).

[11] *Id.* For a description and discussion of the "anticommons," see *infra* Part II.B.

[12] Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam B. Jaffee et al. eds., 2001).

[13] Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1614 (2003).

[14] In 2002, the Federal Trade Commission and the Antitrust Division of the Department of Justice held a series of joint hearings entitled "Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy." The agencies heard testimony from more than 300 commentators, representing the biotechnology, computer, and pharmaceutical industries; inventors; and leading scholars and practitioners specializing in antitrust law, intellectual property law, and economics. Speakers testified on a range of topics, including "Patent Pools and Cross-Licensing: When Do They Promote or Harm Competition?" The full schedule and transcripts of the FTC/DOJ hearings is available at http://www.ftc.gov/opp/intellect/ (last visited Mar. 10, 2009). *See also* Press Release,

the patent thicket by reducing transaction costs for licensees while simultaneously preserving the financial incentives for patent holders to commercialize their existing products and undertake new, potentially patentable research.[15]

Historically known for their role in the aircraft and automobile industries in the early 1900s, patent pools have experienced a re-emergence in the latter half of the twentieth century.[16] Most notably, successful patent pools for DVD and MPEG-2 compression technology revolutionized the DVD and television industries by allowing manufacturers to concentrate their efforts on improvements and new product development rather than being delayed by license negotiations and other impediments. The pools enjoyed this success because they offered market participants something they could not find elsewhere: a way of not only cutting through the patent thicket, but also increasing efficiency by offering a one-stop licensing mechanism for new users to develop new products and encourage greater participation and innovation in the field. Patent pools allowed these emerging technologies to develop at a faster pace, with more competitors and greater efficiencies than ever before.

Patent pools offer the rapidly growing field of pharmacogenomics a solution to some of the "access issues" confronting the industry in the face of a proliferation of genomic patents.[17] When owners of "complementary patents"[18] aggregate their patents and license them as a group to third parties, the patent pool provides licensees a way to cut through the dense patent thicket and obtain licenses for patents most essential to their R&D.[19] Rather than rely on legislative, judicial, or regulatory intervention to reform proposals—all of which require much time and political gamesmanship—patent pools serve as a type of self-regulation of the

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Federal Trade Commission, Federal Trade Commission and Department of Justice Issue Report on Antitrust and Intellectual Property (Apr. 17, 2007), *available at* http://www.ftc.gov/opa/2007/04/ipreport.shtm.

[15] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION 57 (2007), *available at* http://www.usdoj.gov/atr/public/hearings/ip/222655.pdf [hereinafter ANTITRUST ENFORCEMENT REPORT].

[16] For an overview of patent pools, from the early pools of the nineteenth century to the present, see David Serafino, *Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures* (Knowledge Ecology Int'l, Research Note 2007:6, 2007), *available at* http://www.keionline.org/misc-docs/ds-patentpools.pdf.

[17] *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies*, ORG. FOR ECON. CO-OPERATION AND DEV. (OECD), 1, 11–12 (2002), *available at* http://www.oecd.org/dataoecd/42/21/2491084.pdf [hereinafter OECD REPORT].

[18] Complementary patents are those that can be used together and are not substitutes for each other. *See infra* note 57.

[19] When entering a patent pool, patent holders should be able to retain ownership of their respective patents and license them non-exclusively to others. Each patent holder should also retain the right to license their patents individually and independent of the patent pool. *See* ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 85.

market that will not distort incentives to innovate.[20] The private and public sectors are already experimenting with contractual means of obtaining access to genetic inventions (e.g., through various forms of cross-licensing arrangements); patent pools take this collaborative spirit one step further.

Widespread adoption of pharmacogenomics is still several years away.[21] Nevertheless, the biomedical community has demonstrated the collaborative spirit that is necessary through initiatives such as the Personalized Medicine Coalition,[22] the SNP Consortium,[23] and the proposed SARS patent pool.[24] One area where patent pools could be exceptionally advantageous today is in the field of disease-specific diagnostics.[25] As pharmacogenomics knowledge increases, such as understanding how specific polymorphisms in a patient's genome correlate with drug metabolism, gene-based diagnostic testing (diagnostic testing) will become instrumental in early detection, prognosis, and tailored treatments of disease. New diagnostic tests will be particularly important for the identification of candidate populations for drug development, clinical testing, and marketing.[26] At the same time, much of this knowledge—particularly the genetic sequences and disease-causing mutations that must be known in order to develop the tests—will be patented. Unsurprisingly, developing diagnostic tests for pharmacogenomics research will become more complex once firms have to negotiate multiple patents and cross-licensing agreements.[27] These transaction costs could eventually make the R&D process too burdensome

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[20] OECD REPORT, *supra* note 17, at 31–32 (describing the advantages and disadvantages of various reform suggestions).

[21] Kelton, *supra* note 1, at 7 ("[T]he full promise of [pharmacogenomics] will not likely be realized for about 15 years . . . .").

[22] The Personalized Medicine Coalition is an independent, non-profit group working to advance the understanding and adoption of personalized medicine. *See* Personalized Medicine Coalition, http://www.personalizedmedicinecoalition.org (last visited Mar. 11, 2009).

[23] *See infra* Part V.A.

[24] *See infra* Part V.B.

[25] As Krattiger and Kowalski note:

> Unlike the general area of genomics, which is broadly diverse, diagnostic genetics is commercially focused on identified diseases with clear industry standards (mutations for analysis), and the players in the field share common goals. Hence, patent pools . . . could have great utility in overcoming IP thickets that inhibit access to advances in genetic diagnostics.

Krattiger & Kowalski, *supra* note 7, at 141.

[26] *See* COMM. ON INTELLECTUAL PROP. RIGHTS IN GENOMIC AND PROTEIN RESEARCH AND INNOVATION, NAT'L RESEARCH COUNCIL OF THE NAT'L ACAD., REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 14 (2005) (assessing the current and future impact of IP rights on genetic diagnostics and recommending, inter alia, that the NIH undertake a study of potential university, government, and industry arrangements for the pooling of genomic patents).

[27] Leslie Tucker, *Pharmacogenomics: A Primer for Policymakers* 21 (Nat'l Health Pol'y F., Background Paper, 2008), *available at* http://www.nhpf.org/library/background-papers/BP_Pharmacogenomics_01-28-08.pdf.

and prohibitively expensive for any but the largest laboratories.[28] Patent pools present an alternative to these high transaction costs and an opportunity to keep diagnostic tests affordable and accessible.

This Note explores the possibility of creating patent pools in the emerging field of pharmacogenomics in order to cut through the patent thicket and ultimately advance the goal of bringing effective personalized medicine to market. Specifically, this Note analyzes the significance of applying patent pools to genomic IP, arriving at the conclusion that patent pools are pro-competitive IP tools that can help facilitate the growth of new emerging technologies in well-defined commercial settings such as diagnostic testing. Part II provides background on the pharmacogenomics industry and its related IP challenges. Part II also considers how a multi-tiered royalty schedule can offer a solution to the research exemption debate. Part III explores the concept of patent pools and how they can resolve patent bottlenecks in order to allow new emerging technologies to advance. Part IV examines some of the antitrust issues involved in patent pools and evaluates their pro- and anti-competitive effects. Part V provides two anecdotal examples of collaborative strategies in genomic IP that have set a precedent for patent pools to work in pharmacogenomics. Part VI proposes how successful, pro-competitive patent pools could be used in the field of diagnostic testing. This Note concludes by encouraging industry participants and policy makers to strongly consider the advantageous role patent pools can play in developing more appropriate, effective, and personalized medicine to health care providers and their patients.

## II. PHARMACOGENOMICS AND IP CHALLENGES

### A. *Introduction to Pharmacogenomics*

Pharmacogenomics holds the promise that drugs might one day be tailor-made for individual patients, offering truly personalized medicine. This rapidly growing field examines the complicated patterns of genetic variation across a population and attempts to identify genetic differences that influence drug metabolism and response in order to correlate those differences with drug efficacy and safety information.[29] Building off the Human Genome Project and the SNP Consortium, pharmacogenomics uses diagnostic testing to classify patients and diseases according to their genetic variations in order to determine which individual patients are predisposed to disease and how they will respond to therapeutic

[28] *Id.*

[29] Khaleeli & Fernandez, *supra* note 2, at 86–87.

intervention.[30] In other words, through diagnostic testing, health care providers can determine, before a prescription is written, whether a patient should take the drug, avoid the drug, or take it in an adjusted dosage.[31] As opposed to the current "one size fits all" approach of modern pharmaceutical medicine, pharmacogenomics is based on the idea that human genetic variability accounts for some of the differences in how people interact with drugs and explains why not all patients who take the same drug respond similarly.[32] In an era of rising health care costs, pharmacogenomics offers an opportunity to harness biotechnological and genomic knowledge in order to streamline health care delivery.[33] But understanding the genetic variability in drug response is only part of the process of improving drug efficacy and safety and bringing personalized medicine to market.

While there is great potential for pharmacogenomics to make significant contributions to the health care industry,[34] there are numerous challenges and policy decisions that must be addressed before the science can progress. Simply stated, the key limitation to the widespread use of pharmacogenomics is cost. A major contributor is the transaction costs associated with licensing and securing IP rights for the development of new diagnostic tests, research tools, methods, and standards for drug dosage and treatment schedules.[35] For pharmacogenomics to become

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[30] Tucker, *supra* note 27, at 3.

[31] Diagnostics will also be useful in identifying those patients who are likely to suffer an adverse reaction from a particular medication. PCAST REPORT, *supra* note 1, at 1; *see also* PERSONALIZED MEDICINE COALITION, THE CASE FOR PERSONALIZED MEDICINE 4 (2006) (citation omitted), *available at* http://www.ageofpersonalizedmedicine.org/objects/pdfs/TheCaseforPersonalizedMedicine_11_13.pdf ("Studies estimate that over 2 million serious adverse drug reactions (ADRs) occur annually in the United States, causing as many as 137,000 deaths . . . . Some of these deaths could be prevented by testing individuals for genetic variations indicating their susceptibility to toxic reactions.").

[32] Gary E. Marchant, *Personalized Medicine and the Law*, AZ ATT'Y, October 2007, at 12, 13–14.

[33] Scientists also hope that pharmacogenomics will reduce the time and cost of drug development by requiring smaller and fewer clinical trials, generating more consistent trial results, and making it easier to gain FDA approval. Khaleeli & Fernandez, *supra* note 2, at 87–88.

[34] *See, e.g.*, PERSONALIZED MEDICINE COALITION, *supra* note 31, at 3–7 (listing several benefits of personalized medicine); PRICEWATERHOUSECOOPERS, PERSONALIZED MEDICINE, THE EMERGING PHARMACOGENOMICS REVOLUTION 12–19 (2005), *available at* http://www.pwc.com/techforecast/pdfs/pharmaco-wb-x.pdf (discussing the "promise of pharmacogenomics").

[35] Khaleeli & Fernandez, *supra* note 2, at 87. Other challenges to the progress of pharmacogenomics include narrowing down and categorizing single nucleotide polymorphisms (SNPs) in order to identify closely associated polymorphisms that tend to occur in clusters and thus serve as accurate genetic markers for disease. *Id.* This process, known as haplotyping, is currently being coordinated through the International HapMap Project. International HapMap Project, http://www.hapmap.org (last visited Mar. 11, 2009). The process of deciphering which combinations of SNPs account for what biological effects is a long and arduous task, considering that amidst the combination of three billion DNA bases (coding for roughly 22,000 genes) that make up the human genome, there are an estimated ten million SNPs. Tucker, *supra* note 27, at 8. Additionally, various other tools are needed for collecting, standardizing, and interpreting the massive amount of data generated by pharmacogenomics studies, many of which are made publicly available through databases such as the Pharmacogenetics and Pharmacogenomics Knowledge Base and the SNP Consortium. Pharmacogenomics Knowledge Base, http://www.pharmgkb.org (last visited Mar. 11, 2009).

practicable, the transaction costs involved need to be reduced so that companies have a reasonable chance of a return on their investment. Without this incentive to compete in the marketplace, prohibitive transaction costs threaten to stifle innovation and limit the success that many people hope pharmacogenomics will bring.

Diagnostic testing is one area where pharmacogenomic knowledge is especially advantageous and where patent pools can offer an efficient alternative to an increasingly complex IP environment. Genetic diseases can be caused by a variety of mutations in one gene, or by one or more mutations in several genes.[36] In developing diagnostic tests, not only is it critical to determine which mutations should be used as markers for diagnosing the disease, but it is also important to determine how many different parties hold the patents on those genetic sequences and causative mutations that would necessarily be infringed in the development of a new diagnostic product.[37] Determining which patents are most relevant and obtaining licenses for each can be a very time-consuming and expensive process. This is particularly true considering the fact that scientific research is more complicated than a mere linear progression, since "one firm's research tool may be another firm's end product."[38] Discovery and innovation have become "progressively more dependent on access to a common pool of accumulated scientific knowledge" that, if inaccessible, could thwart future advancements in the field.[39] In these situations, a patent pool, consisting of the essential genomic patents for a particular genetic disease, could help surmount the patent thicket and render the proprietary technologies more accessible for use in developing a diagnostic test that ultimately advances therapeutic options.[40]

### B. *Are IP Rights Stifling Innovation? The Theory of the Anticommons and the Patent Thicket*

Thousands of patents have been granted for specific genes, gene fragments, mutations, genetic testing methods, and other research tools.[41] In fact, one study revealed that approximately twenty percent of the genes in the human genome, particularly those with medical relevance, are

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[36] Birgit Verbeure et al., *Patent Pools and Diagnostic Testing*, 24 TRENDS IN BIOTECH. 115, 118 (2006).

[37] Ted J. Ebersole et al., *Patent Pools as a Solution to the Licensing Problems of Diagnostic Genetics*, 17 INTELL. PROP. & TECH. L.J. 6, 6 (2005).

[38] Rebecca S. Eisenberg, *A Technology Policy Perspective on the NIH Gene Patenting Controversy*, 55 U. PITT. L. REV. 633, 647 n.51 (1994); *see also* Clarisa Long, *Patents and Cumulative Innovation*, 2 WASH. U. J.L. & POL'Y 229, 230 (2000).

[39] Long, *supra* note 38, at 234–35.

[40] Verbeure et al., *supra* note 36, at 118.

[41] Burk & Lemley, *supra* note 13, at 1625–26.

patented.[42] Patents are important to ensure investors a limited monopoly on their work, during which they can hope to recoup their investment in R&D. By allowing a licensee to use the patented invention, patent holders can promote the dissemination of technology within an industry.[43] At the same time, high transaction costs required to negotiate complex licensing agreements, as well as difficulties in determining which patents are essential to a technology (and thus must be licensed), can present disincentives to investing in biomedical research. Some commentators, therefore, argue that the proliferation of patents in biomedical research raises concerns about an "anticommons" problem as well as an increasingly treacherous "patent thicket."[44]

According to the anticommons theory, when numerous property owners hold exclusionary rights over a scarce resource, the result is an underutilization of the resource.[45] Applied to biomedical research, the anticommons theory warns that granting too many competing patent rights could deter innovation by preventing useful products from entering the market when making those products requires permission to use many different inventions.[46] Response to the anticommons theory has been varied, however, with some commentators—the "optimists"—focusing on the integration of disparate property rights where patent holders establish "formal and informal mechanisms" to lower costs.[47] Moreover, the threat of an anticommons in biomedical research seems largely anecdotal, as empirical research has shown that the protection of IP rights has not led to breakdowns in negotiations, significantly delayed biomedical research, or

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[42] Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239, 239 (2005). While large segments of the human genome are unpatented, "some genes have up to 20 patents asserting rights to various gene uses . . . including diagnostic uses." *Id.*

[43] The technical information that is disclosed when a patent is issued can be instrumental in furthering innovation by others. Cynthia M. Ho, *Who Deserves the Patent Pot of Gold?: An Inquiry into the Proper Inventorship of Patent-Based Discoveries*, 7 DEPAUL J. HEALTH CARE L. 185, 190 (2004). A patent holder's decision to grant licenses to third parties makes the invention even more accessible.

[44] Shapiro, *supra* note 12, at 124.

[45] Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 624 (1998).

[46] Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 699 (1998) ("Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation."); *see also* Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173, 192–94 (2001) (arguing that upstream patents in biotechnology could lead to bargaining breakdown and impede innovation).

[47] Merges, *supra* note 10, at 128–29. As an example of one of these formal "institutions," Merges looks at the American Society of Composers, Authors, and Publishers (ASCAP), a collective rights organization which reduces transaction costs by gathering together a large number of musical composition copyrights, issuing a "blanket license" for all songs in its repertoire, and distributing a share of the licensing fees as royalty payments to individual copyright holders. *Id.*

otherwise harmed innovation.[48] Indeed, experience has shown that firms and research entities often seek out "'working solutions' which allow them to continue to innovate relatively unimpeded."[49] Therefore, while researchers may find it costly and time-consuming to negotiate licensing agreements, recent research suggests that innovation has not suffered despite the threat of an anticommons.[50] Notwithstanding these findings, another study has indicated that the threat of an anticommons persists when clinicians and research laboratories stop developing and performing diagnostic tests due to patents, licensing restrictions, and related transaction costs.[51]

### C. *The "Research Use" Exemption Dilemma and a Multi-Tiered Royalty Schedule Solution*

Closely related to anticommons and patent thicket concerns is the issue of a "research use" exemption for the purpose of non-commercial research.[52] The research use exemption provides an affirmative defense against patent infringement liability where the alleged infringer is using the patented invention for non-commercial research purposes.[53] Recent case law, however, has dramatically limited the scope of the research use exemption.[54] Concerned that without this common law protection, patents

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[48] *Stifling or Stimulating—The Role of Gene Patents in Research and Genetic Testing: Hearing Before the Subcomm. on Courts, the Internet, and Intell. Prop. of the H. Comm. on the Judiciary*, 110th Cong. 3 (2007) (statement of E. Jonathan Soderstrom, Managing Director, Office of Cooperative Research, Yale University) (citing John P. Walsh et al., *View From the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002–03 (2005)), *available at* http://judiciary.house.gov/hearings/pdf/Soderstrom071030.pdf. Other empirical evidence has demonstrated that the technology transfer and licensing behavior of academic institutions often allow for collaboration and sharing of DNA-based inventions. *Id.* (citing Lori Pressman et al., *The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECH. 31, 31 (2006)).

[49] OECD REPORT, *supra* note 17, at 50.

[50] John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 331–36 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (concluding innovation has not been impeded but cautioning "ongoing scrutiny is warranted").

[51] Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 5 (2003) (finding that twenty-five percent of U.S. clinical laboratory directors surveyed stopped performing diagnostic tests due to patents and licenses, and fifty-three percent decided not to develop or perform a diagnostic test because of a patent).

[52] A research use exemption for patented inventions generally allows non-commercial researchers to use an invention without infringing the rights of the patent holder. Without an exemption, universities and non-profit research organizations may be sued for patent infringement if they use the patented invention without first obtaining a license. The term "experimental" is often used interchangeably with "research" for these types of exemptions.

[53] This common law doctrine was originally articulated by Justice Story in *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) ("[I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.").

[54] *See*, *e.g.*, Merck KGAA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 205–08 (2005) (holding that the use of patented compounds in preclinical studies is protected under 35 U.S.C § 271(e)(1) as

on research tools will have adverse effects on innovation, a number of commentators have called for a statutory experimental use exemption from patent infringement liability so that research can proceed unimpeded.[55] Despite these proposals from the legal community, there has been little movement in terms of actual legislation. That said, there are alternatives—aside from legislative action—that could serve the same purpose by allowing research institutions to access patented technology without the same financial burdens as those firms utilizing the technology for purely commercial purposes. A patent pool with a multi-tiered royalty schedule could serve this purpose. For instance, a patent pool for diagnostic testing would not require legislation to extend research and clinical use incentives to licensees. Through a multi-tiered royalty schedule, the patent pool could allow clinicians and non-commercial research entities to purchase patent portfolio licenses at a reduced rate, while maintaining normal license rates for commercial users.

## III. SOLUTION: PATENT POOLS

### A. *Introduction to Patent Pools*

A patent pool is a voluntary arrangement among multiple patent holders to aggregate their patents.[56] While there are different forms of patent pools, these arrangements fundamentally consist of the interchange of rights to essential patents by a number of patent holders (i.e., the pooled patents are available to each member of the pool), as well as pre-

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long as the research is done for the purposes of submitting the pharmaceutical for FDA regulatory approval); Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) (indicating that the "very narrow and strictly limited" research exemption applies only to acts that are "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry").

[55] *See generally* Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457 (2004); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001); Katherine J. Strandburg, *What Does the Public Get?: Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81 (2004). It is worth noting, however, that these concerns only become problematic if patent holders refuse to license their inventions. If patent pools containing research tools are widely adopted, there is no issue since patent holders are clearly willing to commercialize and license their inventions. Mueller, *supra*, at 15.

[56] Merges, *supra* note 10, at 129. In other words, a patent pool is "the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by [a] patentee to [a] licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool." Joel I. Klein, Acting Assistant Att'y Gen., Antitrust Div., U.S. Dep't of Justice, Address to the Am. Intell. Prop. Law Ass'n: Cross-Licensing and Antitrust Law, 3 n.3 (May 2, 1997), *available at* http://www.usdoj.gov/atr/public/speeches/1118.pdf [hereinafter Klein Address] (noting that in *United States v. Line Material Co.*, 333 U.S. 287, 313 n.24 (1948), the Supreme Court stated that the term "patent pool" is not a term of art).

determined standard licensing terms to third parties.[57] The pool may have a licensing entity that administers the patent pool and issues licenses to third parties on a nondiscriminatory basis; however, individual pool members are typically free to negotiate licenses directly with licensees, independent of the pool.

Firms typically organize patent pools within established, technology-intensive industries in order to regularize the frequent interactions between different IP rights owners where rights are scattered amongst several owners and bundling is most efficient.[58] As an example of what Robert P. Merges refers to as a "collective rights organization," patent pools accommodate consistent innovative growth in an IP-dominated field.[59] Potential members are attracted to join a patent pool for what it offers: decreased transaction costs, the freedom to operate in a technology field for commercial and research purposes, and a reliable royalty income stream generated from member and nonmember licensees.[60] Interested parties are then able "to gather all the necessary tools to practice a certain technology in one place, e.g., 'one-stop shopping,' rather than obtaining licenses from each patent holder individually."[61] By combining "far-flung

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[57] Krattiger & Kowlaski, *supra* note 7, at 137. A key difference between a patent pool and a cross-licensing agreement between two patent holders is that a patent pool "explicitly allows for (package) licensing to third parties." Patrick Gaulé, *Towards Patent Pools in Biotechnology?*, 2 INNOVATION STRATEGY TODAY 123, 124 (2006), *available at* http://www.biodevelopments.org/innovation/ist5.pdf. Ebersole et al. provide clear definitions of these different types of patents:

> Critical to the structuring and implementing of patent pools are the definitions of *complementary*, *competing*, *blocking*, and *essential* patents. *Complementary* patents are for "technologies that may be used together, and not substitutes for each other." Two different patents each on a different SNP for the same disease would be complementary. *Competing* patents cover technologies that substitute for each other. A patent on a SNP and another one on an antibody might be competing technologies to diagnose the same disease. A *blocking* patent "block[s] another if [the latter] can not be practiced without infringing on the basic patent." A patent on an isolated gene and all its fragments might be blocking to all genetic testing for a disease. *Essential* patents have been defined as ones having "no technical alternative" and useful "only in conjunction with other pooled patents." An example would be a patent on the critical SNP or the gene correlated to the disease.

Ebersole et al., *supra* note 37, at 8 (internal citations omitted).

[58] Merges, *supra* note 10, at 130. "Pools can comprise as few as two patents, or as many as hundreds." Steven C. Carlson, Note, *Patent Pools and the Antitrust Dilemma*, 16 YALE J. ON REG. 359, 367–68 (1999). The Hartford-Empire pool, for example, comprised over 600 patents. Hartford-Empire Co. v. United States, 323 U.S. 386, 400 (1945).

[59] *See* Robert P. Merges, *Contracting Into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1340–42 (1996) (characterizing a patent pool as a private transactional mechanism that requires a voluntary assumption of liability rules so as to regularize technology transactions).

[60] *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy: Hearing on Patent Pools and Cross-Licensing Before the Fed. Trade Commission and Dep't of Justice*, 108th Cong. 4 (2002), *available at* http://www.ftc.gov/opp/intellect/020417lawrencemsung1.pdf (statement of Lawrence M. Sung, Assistant Prof. of L., Univ. Md.) [hereinafter Sung Testimony].

[61] Press Release, U.S. Pat & Trademark Off., USPTO Issues White Paper on Patent Pooling (Jan. 19, 2001), *available at* http://www.uspto.gov/web/offices/com/speeches/01-06.htm.

property rights into useable bundles," patent pools overcome the threat of an anticommons and preserve the incentives that accompany IP rights.[62] For emerging technologies such as pharmacogenomics, with genetic information representing an "industry standard" analogous to those in the electronics and telecommunications areas, "the landscape of increasing patent protection to this genetic material favors the voluntary entry of biotechnology industry members into patent pooling arrangements."[63] Moreover, introducing a multi-tiered royalty schedule to these patent pools, in which different types of IP rights users (i.e., commercial versus purely research-focused) pay different fees to access the pooled technologies, can further enhance the attractiveness of patent pools for pharmacogenomics.

### B. *Patent Pools in Biotechnology*

Since the mid-1980s, technological advances have both created tremendous excitement about the potential for genomic innovation as well as elicited concern on the part of public and private research entities about how to protect and profit from their inventions.[64] The completion of the Human Genome Project embodied these competing interests and sparked a public debate: What is the patentability of genetic inventions and how can society benefit from such technology?[65] A number of scientists, ethicists, and policy makers voiced concern that when genetic information is patented, "researchers will no longer have free access to the information and materials necessary to perform biological research."[66] The sheer size of the biotechnology and genomics industries and the substantial resources needed to develop any significant finding demand collaboration. If pharmacogenomics is to advance efficiently, patent holders and researchers

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[62] Merges, *supra* note 10, at 129. Applying conventional economic principles, Merges explains that "[w]ith 'gains from trade' to be had, the parties figure out a deal that makes everyone better off. . . . [A patent pool] creates a mechanism that lowers the average cost of transaction enough to make ongoing exchange worthwhile." *Id.* at 129–30.

[63] Sung Testimony, *supra* note 60, at 5.

[64] Jeanne Clark et al., *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* 2 (U.S. Pat. & Trademark Off., 2000), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf.

[65] As Clark et al. explained:

> Part of the public concern lies in the corporate utilization of information from several genome projects that have been placed in the public domain. Companies have used this information in their own proprietary research, thereby, capitalizing on publicly funded efforts and removing further developments of such efforts from the public domain. There is great consternation that some private concerns are attempting to reap benefits from patented technologies that would not have been possible without publicly funded research, such as the Human Genome Project.

*Id.* at 2–3.

[66] *Id.* at 3. A significant concern related to biotechnology patents is the removal of valuable research resources from the public domain. *Id.*

will need to pool their collective resources and knowledge.

Recognizing the importance of the biotechnology industry to the American economy, as well as the industry's dependence on patent protection in order to maintain its viability, the United States Patent and Trademark Office (USPTO) released a White Paper in 2000 examining the potential implications of patent pools in biotechnology.[67] In particular, the USPTO was interested in addressing the challenges many firms face in licensing multiple patents in order to access specific biotechnology products and processes.[68] What resulted, both in the White Paper and in subsequent research, was a growing awareness of the significant benefits that genomic patent pools offer to scientific understanding and technological advancement.

### C. *Benefits of Patent Pools*

Patent pools provide pro-competitive benefits by reducing transaction costs, avoiding infringement litigation, clearing blocking patents, eliminating problems associated with royalty stacking, distributing risks, and promoting the dissemination of technological information.[69] When deciding to join a patent pool, a patent holder will consider whether the economic, legal, and practical benefits of such collective rights arrangements will outweigh the costs of membership.[70] For an emerging field such as pharmacogenomics, the opportunity to affordably and efficiently access information and technology through a reasonably priced patent pool license will enhance the commercial potential for innovation.[71] This Section describes the various benefits of patent pools.

#### 1. *Patent Pools Reduce Transaction Costs*

When a firm requires licenses to a number of patents, held by a number of different firms, patent pooling arrangements create substantial efficiencies by reducing the transaction costs of multiple licensing negotiations.[72] Rather than negotiating separate licenses with each patent

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[67] Press Release, U.S. Pat & Trademark Off., *supra* note 61.

[68] *Id.*

[69] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 5.5 (1995), *available at* http://www.usdoj.gov/atr/public/guidelines/0558.pdf [hereinafter ANTITRUST–IP GUIDELINES]. The dissemination of technological information relates to trade secrets, which often get bundled with patents when patent holders contribute their intellectual property rights to a pool.

[70] Often, this cost-benefit analysis will evaluate the potential long-term implications of joining the patent pool, since many of the economic benefits would likely occur in the future (e.g., royalty rates, dissemination of technical information, etc.). Clark et al. assert that the re-emergence of patent pools in the late 1990s, suggest that the social and economic benefits of patent pools outweigh their costs. Clark et al., *supra* note 64, at 8.

[71] Clark et al., *supra* note 64, at 9.

[72] ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 57.

owner, a firm seeking to access a collection of technologies can do so through the less costly alternative of obtaining a patent pool license.[73] As with other forms of collective rights organizations, the basic economic rationale is that patent pools resolve transactional bottlenecks. That is, they offer licenses at independently-determined rates so as to minimize the length of time and the hassle of exchanging rights through a series of individual licensing deals.[74] A patent pool's simplified approach to licensing, from the licensee's perspective, can facilitate more rapid development and adoption of new technologies than could be achieved through individual cross-licensing alone.[75] These transaction cost savings are particularly attractive for small biotechnology firms lacking significant resources for negotiating and acquiring licenses from a vast arrangement of patent holders.

2. *Patent Pools Reduce Enforcement Costs*

Patent pools are also a highly efficient way of reducing enforcement costs and resolving legal conflicts involving potential patent infringement cases.[76] Patent infringement litigation requires considerable time and money. In addition, the inherent uncertainty of patent litigation compounds the problem, as litigants can sometimes face judges and juries ill-equipped to handle complex technical disputes.[77] Just as lower transaction costs are attractive to both patent holders and licensees, lowered enforcement costs can provide such a strong incentive that it makes sense for patent holders to join the pool.[78]

In some instances, firms with limited resources may opt for an alternative strategy and try to determine which infringed patents are the most likely to be litigated, obtain only those licenses, and accept the risk of potential infringement litigation from the others. Or, they may simply decide not to obtain any licenses.[79] These risky alternatives increase the chances of costly and uncertain patent infringement litigation as well as harm for patent holders who would not only lose royalty revenue, but would also have to constantly monitor the field for potential infringers. Patent pools limit these enforcement costs and related uncertainties, thus

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[73] *Id*. at 65.
[74] Merges, *supra* note 10, at 131–33.
[75] ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 65.
[76] *Id.*
[77] Carlson, *supra* note 58, at 380.
[78] Merges, *supra* note 10, at 132.
[79] *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy: J. Hearing on Patent Pools and Cross-Licensing Before the Fed. Trade Commission and Dep't of Justice*, 108th Cong. 7 (2002), *available at* http://www.ftc.gov/opp/intellect/020417jamesjkulbaski.pdf (statement of James J. Kulbaski, Oblon, Spivak, McClelland, Maier & Neustadt, P.C.) [hereinafter Kulbaski Testimony].

making these pools very attractive to potential members and licensees alike.

### 3. *Patent Pools Overcome Problems Associated with Blocking and Stacking Patents*

The problem of "blocking patents" can significantly disrupt the commercialization of new technology.[80] This phenomenon occurs when numerous patents have claims that overlap each other such that the invention claimed on one patent cannot be practiced without necessarily infringing the claims of another patent.[81] While the allowance of improvement patents provides incentives to innovate, inevitable legal entanglements can result when rival patentees are given "the right to exclude each other from making, using, or selling the patented technology."[82] In biotechnology, firms often encounter blocking patents as they develop new products that require access to a multitude of patents on nucleic acids, genes, and DNA fragments.[83]

Pioneer technologies, as exemplified by airplanes in the early 1900s and pharmacogenomics today, frequently face problems associated with blocking patents, which threaten the development of new commercial products.[84] While blocking patents are proof of technological advancement, without some form of cooperative agreement between the patentees, blocking patents can frustrate the patent system and complicate

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[80] Clark et al., *supra* note 64, at 8.

[81] Merges provides the following explanation of how blocking patents arise:

> Two patents are said to block each other when one patentee has a broad patent on an invention and another has a narrower patent on some improved feature of that invention. The broad patent is said to "dominate" the narrower one. In such a situation, the holder of the narrower (subservient) patent cannot practice her invention without a license from the holder of the dominant patent. At the same time, the holder of the dominant patent cannot practice the particular improved feature claimed in the narrower patent without a license.

Robert P. Merges, *A Brief Note on Blocking Patents and Reverse Equivalents: Biotechnology as an Example*, 73 J. PAT. & TRADEMARK OFF. SOC'Y 878, 878–79 (1991).

[82] Carlson, *supra* note 58, at 379.

[83] To illustrate this point, suppose Firm A invents Method X for detecting a particular mutation on a particular gene that is highly correlated with Alzheimer's disease. Firm A patents Method X and holds a limited monopoly on that invention. Firm B then invents a way to do Method X for 1/100th the cost and is granted an improvement patent (as compared to Firm A's basic patent). A license to use Firm B's improvement patent, however, will not be useful without a license to use Firm A's basic patent. Likewise, a license to use Firm A's basic patent on Method X will not be useful without a license to use Firm B's improvement patent. Therefore, if Firm C wants to use Method X's technology, it must receive licenses from both Firm A and Firm B. Without those licenses, Firm C is "blocked" from practicing the technology. *See, e.g.*, Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 809–10 (Fed. Cir. 2002) (providing a hypothetical illustration of the use of a blocking patent).

[84] For a review of the Wright-Curtiss blocking patents dispute in the airplane industry, and the resulting patent pool, see George Bittlingmayer, *Property Rights, Progress, and the Aircraft Patent Agreement*, 31 J.L. & ECON. 227, 230–35 (1988). *See generally* Harry T. Dykman, *Patent Licensing Within the Manufacturer's Aircraft Association (MAA)*, 46 J. PAT. OFF. SOC'Y 646 (1964).

licensing arrangements. Courts have recognized this dilemma and have identified the blocking patents problem as a justification for patent pools.[85]

Another important feature of patent pools is that they can eliminate royalty stacking and mitigate further problems that often occur when multiple patent holders individually negotiate licenses.[86] Royalty stacking occurs in the absence of pooled licensing arrangements, where multiple patents overlap a technology, forcing licensees to "bear multiple patent burdens."[87] Depending upon the demands of the individual patent holders, this buildup of licensing fees can increase costs and decrease commercial profitability of the end product.[88] As a result, royalty stacking can result in an inefficiently low use of a technology, magnify the monopoly burden of the patent system, and even cause certain products not to be produced at all.[89] Similarly, additional problems can arise when licensees need multiple complementary patent licenses and patent holders strategically delay license negotiations so as to advantageously position themselves as the last bidding seller.[90] This "hold-out" scenario results in a higher royalty payment burden than if all the blocking patents are licensed as a package and a single royalty is required to access all the pooled patents.[91] But when patent holders form patent pools, licensees can access all the essential patents required for the production of a certain technology at a lower, more reasonable royalty rate than if each license fee were independently negotiated.[92] Therefore, patent pools can be invaluable to firms trying to avoid the cost-prohibitiveness of entering into a new emerging field, particularly one involving pioneer patents.

4. *Patent Pools Distribute Risks Among Members*

Another efficiency gained in the formation of a patent pool is the distribution of risks.[93] The sharing of royalties among the various pool members increases the likelihood that each patent holder will be able to recover some, if not all, of its R&D costs.[94] By creating a mechanism for a

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[85] Carlson, *supra* note 58, at 379 (citing Standard Oil Co., v. United States, 283 U.S. 163, 171 (1931); Int'l Mfg. Co. v. Landon, Inc., 336 F.2d 723, 730 (9th Cir. 1964)).

[86] ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 57.

[87] *Id.* at 61; Shapiro, *supra* note 12, at 124.

[88] Shapiro, *supra* note 12, at 124.

[89] *Id.*

[90] ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 64–65 n.40 (citing Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1298 n.9 (1996)).

[91] *Id.* at 65; Shapiro, *supra* note 12, at 123–24 (describing Cournot's theory of complements and hold-out scenario as providing strong support for the adoption of patent pools).

[92] ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 61.

[93] Clark et al., *supra* note 64, at 9.

[94] *Id.* Royalty rate setting is often negotiated upfront when the patent pool is first formed, and there are several options regarding how to spread the royalty payments amongst the pool members. *Id.* For example, all essential patents in a patent pool can be deemed equal in value, with royalties shared

patent holder to share the risks associated with technology ventures, patent pools provide incentives to collaborate and innovate. The ability to recoup investments and distribute the risks of developing new technologies is particularly attractive in the biotechnology industry, where risks of failure are high, as are the potential payoffs.[95]

### 5. *Patent Pools Facilitate Exchange of Non-Patented Technical Information*

In addition to the above-mentioned legal and economic efficiencies, patent pools can also institutionalize the exchange of non-patented technical information.[96] Without the mechanism of a patent pool, much of this technical information related to the patented technology would be kept a trade secret.[97] This benefit is particularly advantageous for smaller companies—such as those populating the biotechnology industry—because the information and insight exchanged through participation in a patent pool can accelerate the spread of technical knowledge "to the far corners of the industry."[98] Patent pools can also facilitate the crucial task of creating a framework for developing an industry standard.[99] Thus, the advantages of patent pools extend "far beyond a cessation of patent hostilities,"[100] becoming "critically important mechanisms for enabling widespread use of new technologies . . . ."[101]

## IV. PROTECTING COMPETITION AND PROMOTING INNOVATION: ARE PATENT POOLS ANTICOMPETITIVE?

Commentators have noted a tension between the seemingly divergent policy goals of IP and antitrust law, with the courts' deference to each of

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equally. *Id.* Alternatively, a pool could engage in more complex calculations of the valuation of each participating patent and structure its royalty payment scheme accordingly.

[95] Carlson, *supra* note 58, at 381–82.

[96] ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 65.

[97] Verbeure et al., *supra* note 36, at 116.

[98] Merges, *supra* note 10, at 139 n.66 and accompanying text (citing WILLIAM GREENLEAF, MONOPOLY ON WHEELS 246 (1961)); *see* OECD REPORT, *supra* note 17, at 51–52 (explaining that the biotechnology industry often relies on small to medium-sized specialist companies to perform the early exploratory stages of drug development).

[99] *See Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy: J. Hearing on Patent Pools and Cross-Licensing Before the Fed. Trade Commission and Dep't of Justice*, 108th Cong. (2002), *available at* http://www.ftc.gov/opp/intellect/020417barynfuta.pdf (statement of Baryn Futa, Manager & CEO, MPEG LA, LLC) [hereinafter Futa Testimony] (describing the MPEG-2 Patent Portfolio for digital compression technology and its success in playing a large role in the worldwide utility of the MPEG-2 technology standard).

[100] Merges, *supra* note 10, at 139.

[101] *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy: J. Hearing on Economic and Other Perspectives on Patent Standards and Procedures Before the Fed. Trade Comm'n and Dep't of Justice*, 108th Cong. 700 (2003) (transcript for Feb. 28, 2002), *available at* http://www.ftc.gov/opp/intellect/020228ftc.pdf [hereinafter Competition and Intellectual Property Law Transcript].

these bodies of law vacillating throughout the twentieth century.[102] Intellectual property laws establish exclusive property rights—in the form of limited monopolies—for the creators of new and useful products while, conversely, the antitrust laws prohibit certain actions that may restrict or harm competition.[103] Notwithstanding this apparent contradiction, IP law and federal antitrust regulation are actually complementary, as both are "aimed at encouraging innovation, industry and competition."[104]

One area where the tension between IP and antitrust laws has been particularly acute is in the formation of patent pools. In the early 1900s, the Supreme Court gave great deference to the policy goals of IP laws, finding much of patent law immune from antitrust scrutiny.[105] With the 1912 decision in *Standard Sanitary Manufacturing Co. v. United States*,[106] however, the Court began to limit the absolute freedom of patentees to form collusive patent pools, a trend which dominated until the mid-1900s. In *Standard Sanitary*, manufacturers of enameled ironware (e.g., bath tubs, sinks, and drinking fountains), controlling eighty-five percent of the relevant market, "entered into and engaged in a combination and conspiracy to restrain such trade and commerce" by forming a combination of patents with heavy restrictions on participants.[107] According to the Court, collusive agreements such as these "clearly . . . transcended what was necessary to protect the use of the patent or the monopoly which the [patent] law conferred upon it," and, thus, violated Section 1 of the Sherman Act[108] as an unreasonable restraint on trade.[109] Likewise, in 1945, the Supreme Court disbanded a collusive glass manufacturing patent pool which, in the words of Justice Black, represented a "completely successful economic tyranny."[110] In *Hartford-Empire Co. v. United States*, a cartel of major glass manufacturers entered into a scheme to monopolize glass-making in the United States by pooling together over 800 patents and

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[102] *See, e.g.*, Carlson, *supra* note 58, at 360.

[103] ANTITRUST–IP GUIDELINES, *supra* note 69 at § 1.0.

[104] Clark et al., *supra* note 64, at 5 (citing Atari Games Corp. v. Nintendo of Am., Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990)); *see also* Sheila F. Anthony, *Antitrust and Intellectual Property Law: From Adversaries to Partners*, 28 AIPLA Q.J. 1, 3 (2000) (stating that since joining the FTC in 1997, Commissioner Anthony found that "the goals of intellectual property and antitrust law are not mutually exclusive and, in fact, are quite similar").

[105] In *E. Bement & Sons v. National Harrow Co.*, for example, the Court found that a patent pool engaging in outright price fixing with no apparent transfer of technology merited immunity from antitrust scrutiny. 186 U.S. 70, 91 (1902) ("[T]he general rule is absolute freedom in the use or sale of rights under the patent laws of the United States."); *see also* Anthony, *supra* note 104, at 5.

[106] Standard Sanitary Manufacturing Co. v. United States, 226 U.S. 20 (1912).

[107] *Id.* at 35.

[108] 15 U.S.C. § 1 (2006) ("Every contract . . . or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.").

[109] *Standard Sanitary*, 226 U.S. at 48.

[110] Hartford-Empire Co. v. United States, 323 U.S. 386, 436 (1945) (Black, J., dissenting in part).

effectively controlling the entire glass-making industry.[111] The Court held that the parties had violated Sections 1 and 2 of the Sherman Act[112] and Section 3 of the Clayton Act[113] by regulating and suppressing competition.[114]

Such hostility toward the potentially collusive effects of patent pools continued through the middle of the twentieth century, but began to lessen when the Court recognized that IP and antitrust laws could co-exist.[115] In the 1960s and 1970s, the Department of Justice (DOJ) devised a policy for the evaluation of patent licensing practices, enumerating nine specific licensing practices that it viewed as *per se* violations of antitrust law, and implicitly approving practices that did not violate these "Nine No No's."[116] Since then, the Federal Trade Commission (FTC) and the DOJ have begun to recognize the interconnected relationship between antitrust law and IP rights.[117] Moreover, these agencies have acknowledged that patent pools can have significant pro-competitive effects that enable businesses to survive in our current era of rapid technological innovation.[118]

### A. *Antitrust Guidelines for the Licensing of Intellectual Property*

In 1995, the FTC and the DOJ jointly issued *Antitrust Guidelines for the Licensing of Intellectual Property* (Antitrust-IP Guidelines), a

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[111] *Id.* at 400. Specifically, the members of the pool were found to have discouraged new inventions of glass making machinery, suppressed competition in the manufacture and sale or licensing of glass-making machinery, and employed a system of restricted licensing in order to further suppress competition and fix prices. *Id.* "The result was that 94% of the glass containers manufactured in this country on feeders and formers were made on machinery licensed under the pooled patents." *Id.*

[112] 15 U.S.C. §§ 1–2 (2006) (forbidding monopolies and contracts that operate "in restraint of trade or commerce").

[113] 15 U.S.C. § 14 (2006) (outlawing exclusive dealings and tying contracts that "substantially lessen competition or tend to create a monopoly").

[114] *Hartford-Empire*, 323 U.S. at 406–07.

[115] Anthony, *supra* note 104, at 5.

[116] *Id.* The "Nine No-No's" include the following licensing practices: tying arrangements; grantback provisions; vertical distribution restraints; restricting a licensee's freedom to deal in products or services outside the scope of the patent; a licensor's agreement not to grant further licenses; mandatory package licensing; requiring a licensee to pay royalties in an amount not reasonably related to the licensee's sales of products covered by the patent; restrictions on a licensee's use of a product made by the use of a patented process; and requiring a licensee to adhere to any specified or minimum price with respect to the resale of the licensed products. *See* Bruce B. Wilson, Special Assistant to the Assistant Attorney Gen., Antitrust Division, U.S. Dep't of Justice, Remarks before the Fourth New England Antitrust Conference: Patent and Know-How License Agreements: Field of Use, Territorial, Price and Quantity Restrictions (Nov. 6, 1970), *reprinted in* ANTITRUST PRIMER: PATENTS, FRANCHISING, TREBLE DAMAGE SUITS 11, 12–14 (Sara-Ann Sanders ed., 1970) (describing these policies).

[117] Anthony, *supra* note 104, at 7 ("[T]he aims and objectives of patent and antitrust laws may seem, at first glance, wholly at odds. However, the two bodies of law are complementary . . . .") (quoting Atari Games Corp. v. Nintendo of Am., Inc., 897 F. 2d 1572, 1576 (Fed. Cir. 1990); ANTITRUST–IP GUIDELINES, *supra* note 69, § 1.0.

[118] Clark et al., *supra* note 64, at 5–6.

comprehensive set of federal guidelines that specifically addressed cross-licensing and patent pooling arrangements.[119] The Antitrust-IP Guidelines expressly state that pooling arrangements are *pro-competitive* when they integrate complementary technologies, reduce transaction costs, clear blocking patents, avoid costly patent infringement litigation, and promote the dissemination of technology.[120] Such pooling arrangements, however, risk heightened antitrust scrutiny if they significantly diminish competition in the relevant market.[121] Anticompetitive effects may also occur if the pooling arrangement "deters or discourages participants from engaging in research and development, thus retarding innovation."[122] The Antitrust-IP Guidelines also recognize that patent pools can have pro-competitive benefits "by exploiting economies of scale and integrating complementary capabilities of the pool members."[123]

By outlining the standards with which the FTC and the DOJ would evaluate the legality of patent pools, the two agencies articulated a policy that recognized a balancing of the pro-competitive and anti-competitive effects of pooling IP rights. Shortly after the release of the Antitrust–IP Guidelines, both the FTC and the DOJ applied this analysis to proposals for new patent pools, specifically in the computer and digital technology industries.[124] In their reviews, the DOJ examined the proposed license pooling arrangements by asking two principal questions: (1) whether the patent pool "is likely to integrate complementary patent rights" and (2) "whether the resulting competitive benefits are likely to be outweighed by

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[119] *See generally* ANTITRUST–IP GUIDELINES, *supra* note 69.

[120] *Id.* at 28.

[121] *Id.* at 28.

[122] *Id.* at 29. The Antitrust–IP Guidelines provide the example of a pooling arrangement that involves compulsory licensing for future technologies. A compulsory licensing requirement may reduce the incentives of the pool's members to engage in R&D due to the fear of other members free riding on their accomplishments. *Id.* Such an arrangement, however, is likely to be anticompetitive "only when [it] includes a large fraction of the potential research and development in an innovation market." *Id.*

[123] *Id.*

[124] *See, e.g.*, Letter from Joel I. Klein, Acting Assistant Att'y Gen., Antitrust Division, U.S. Dep't of Justice, to Gerrard R. Beeney, Partner, Sullivan & Cromwell (June 26, 1997), *available at* http://www.usdoj.gov/atr/public/busreview/215742.pdf [hereinafter MPEG-2 Review Letter] (approving a patent pool for the MPEG-2 standard for the compression of audio and visual digital signals); Letter from Joel Klein, Assistant Att'y Gen., Antitrust Division, U.S. Dep't of Justice, to Garrard R. Beeney, Partner, Sullivan & Cromwell (Dec. 16, 1998), *available at* http://www.usdoj.gov/atr/public/busreview/2121.pdf [hereinafter Sony Review Letter] (approving a patent pool for DVD-ROM and DVD-Video formats for Sony et al.); Letter from Joel I. Klein, Assistant Att'y Gen., Antitrust Division, U.S. Dep't of Justice, to Carey R. Ramos, Attorney, Paul, Weiss, Rifkind, Wharton & Garrison (June 10, 1999), *available at* http://www.usdoj.gov/atr/public/busreview/2485.pdf [hereinafter Toshiba Review Letter] (approving a patent pool for DVD-ROM and DVD-Video formats for Toshiba et al.). *But see In re* Summit Tech., Inc., 127 F.T.C. 208, 219–22 (1999) (dismantling a patent pool because the patent holders were the only firms authorized in the United States to use the patented technology and because the pooling arrangement was entered into for the purpose of restraining competition and fixing prices).

competitive harm posed by other aspects of the program."[125] Successful patent pool proposals called for an independent expert in the relevant technology to determine the essentiality of each patent in the pool; included a joint licensing arrangement which preserved each patent holder's right to independently license its patents and enforce its patent rights against infringement; ensured no foreclosure of competition in relevant markets; and produced positive effects on innovation in which pool participants agree to license to each other "essential" patents they obtain in the future.[126]

### B. *The FTC and the DOJ's Reaffirmation of the Antitrust–IP Guidelines in 2007*

In the spring of 2007, the FTC and the DOJ issued a joint report, *Antitrust Enforcement and Intellectual Property Rights* (Antitrust Enforcement Report), reaffirming the agencies' policies set forth in the 1995 Antitrust-IP Guidelines.[127] In it, the agencies espoused their earlier analysis, adding further reinforcement to the notion that IP and antitrust laws "work in tandem" and "share the same fundamental goals" of promoting innovation and enhancing consumer welfare by bringing new and better technologies, products, and services to consumers at lower prices.[128] Reaffirming the agencies' policies that IP rights do not automatically violate the antitrust laws,[129] the Antitrust Enforcement Report stated that the antitrust enforcement agencies would continue to analyze IP licensing arrangements using a "rule of reason" approach that considers both their efficiencies and potential anticompetitive effects.[130]

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[125] *See, e.g.*, Sony Review Letter, *supra* note 124, at 9.

[126] *See, e.g.*, Toshiba Review Letter, *supra* note 124, at 3–10, 14–15; *see also* Sony Review Letter, *supra* note 124, at 4–8, 13. A patent is "'essential,'" the DOJ concluded, if there is no alternative to it in implementing the pooled technology. Toshiba Review Letter, *supra* note 124, at 3.

[127] ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 3. The Antitrust Enforcement Report represented the culmination of ten months' worth of hearings, entitled "Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy" jointly conducted by the DOJ and the FTC in 2002. *See supra* note 14 and accompanying text.

[128] ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 1.

[129] *Id*. at 2; *see also* ANTITRUST–IP GUIDELINES, *supra* note 69, at § 2.2 ("The Agencies will not presume that a patent, copyright, or trade secret necessarily confers market power upon its owner.").

[130] ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 85. A dominant approach to antitrust cases in the early part of the twentieth century, the modern rule of reason analysis is not wholly unrecognizable from that espoused by Justice Brandeis. *See* Board of Trade of City of Chicago v. United States, 246 U.S. 231, 238 (1918) ("Every agreement concerning trade, every regulation of trade, restrains."). In the context of patent pools, the DOJ's modern version of the rule of reason is somewhat updated and tailored to address the particular circumstances that may question an antitrust violation. In these situations, the DOJ will generally analyze the relationship of the intellectual property rights being pooled; the nature of the markets in which those rights compete; the extent to which the pool controls access to those rights; the openness of the pool to outsiders; and the extent to which the arrangement controls the terms on which future innovations in the field will reach the market. Klein Address, *supra* note 56, at 4.

During the FTC and DOJ's 2002 joint hearings,[131] many panelists highlighted the efficiencies and pro-competitive benefits of patent pools.[132] One panelist proclaimed that "[p]atent pools have become critically important mechanisms for enabling widespread use of new technologies that require access to a multitude of patents dispersed among a multitude of parties."[133] After reviewing these submissions and perspectives on the interplay between patent pools and antitrust law, the Antitrust Enforcement Report concluded that the agencies' patent pool analysis—as outlined in the 1995 Antitrust-IP Guidelines and as supplemented in several business review letters issued by the DOJ and enforcement actions by the FTC—provided adequate guidance for the formation and implementation of future patent pools.[134]

### C. *Recommendations for Avoiding Antitrust Violations for a Genomic Patent Pool*

When assembling a genomic patent pool, it is essential to bear in mind the history of the relationship between antitrust law and IP rights and to consider how best to maintain the pro-competitive effects of a robust marketplace while also providing appropriate patent protection to promote future innovation. It is worth noting that the Antitrust-IP Guidelines, the DOJ's business review letters and subsequent patent pool approvals, and the Antitrust Enforcement Report, taken together, are a remarkable endorsement of the potential for patent pools to preserve competition and advance the development of new technologies. While future patent pools will certainly not go unchecked by the antitrust enforcement agencies, if structured properly, they should be able to withstand FTC and DOJ scrutiny. Therefore, before requesting a proposed business practice review from the Antitrust Division of the DOJ[135] or an advisory opinion from the FTC,[136] it will be important for a genomic patent pool to ensure that they steer clear of potential antitrust violations.

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[131] *See supra* note 14 and accompanying text.

[132] ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 64–66.

[133] *See* Competition and Intellectual Property Law Transcript, *supra* note 101, at 700 (Steve Fox); *see also* Futa Testimony, *supra* note 99 (explaining that the MPEG-2 patent pool includes more than 425 essential patents in 39 countries owned by 20 companies and a leading university and that widespread adoption of MPEG-2 technology "has made video communication interoperable, global, competitive, innovative and efficient").

[134] ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 66–67.

[135] 28 C.F.R. § 50.6 (2008) provides the procedure under which the Antitrust Division of the DOJ will state its enforcement intentions for proposed business conduct.

[136] The FTC considers and responds to requests for advisory opinions pursuant to 16 C.F.R. §§ 1.1–1.4 (2008).

## V. EXAMINING THE PRECEDENTS: EXAMPLES OF COLLABORATIVE IP MANAGEMENT

Although successful patent pools are frequently found in consumer electronics industries such as radio, semiconductors, DVD, and MPEG-2 compression technology, there is evidence that patent pools can be successful in the health and biomedical industries as well. The SNP Consortium and the patent pool for the Severe Acute Respiratory Syndrome (SARS) vaccine are both evidence of the collaborative spirit necessary for successful patent pools in the life sciences and that public and private actors can work together to achieve biotechnological progress. These collaborative strategies have set a precedent for creating patent pools in the biomedical sciences.

While the science of pharmacogenomics is still developing, one area that is well-suited for patent pool arrangements today is diagnostics. Developing diagnostic tests will help to identify which genomic sub-group patients belong to in order to accurately diagnose and tailor their treatment regimens to their genotypes. As genomic knowledge increases, so too will the number of patents involved in diagnostics. Patent pools, if structured properly, will be able to effectively navigate the patent thicket so that scientists can focus on developing diagnostic tests and advancing pharmacogenomics.

### A. *The SNP Consortium*

In the late 1990s, scientists began to appreciate the value of single nucleotide polymorphisms, commonly referred to as SNPs, for their use as "disease markers" and their inestimable value as diagnostic tools in genomic research.[137] When the French biotechnology firm Genset began applying for patents on an undisclosed number of SNPs, several "big pharma" companies began to fear that an inevitable flurry of SNP patents would threaten the development of genetic diagnostics and, relatedly, personalized medicine.[138] In response, in April 1999, a group of ten major pharmaceutical companies and the U.K.'s Wellcome Trust announced the creation of the SNP Consortium, a non-profit enterprise with the goal of placing a human genome-wide SNP map in the public domain.[139] By

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[137] Robert P. Merges, *A New Dynamism in the Public Domain*, 71 U. CHI. L. REV. 183, 189 (2004). An SNP is a one base pair variation in a DNA sequence that can sometimes affect a person's disease susceptibility or influence their response to certain drug regimens. As a result of SNP detection and research, diagnostics for many diseases can be improved. *See* Human Genome Project Information: SNP Fact Sheet, http://www.ornl.gov/sci/techresources/Human_Genome/faq/snps.shtml#whoare (last visited Mar. 15, 2009).

[138] *See* Merges, *supra* note 137, at 189; Ken Garber, *Homestead 2000: The Genome*, SIGNALS, Mar. 3, 2000, http://www.signalsmag.com/signalsmag.nsf/657b06742b5748e888256570005cba01/fd168fb6c42acf6e882568950015e2d0?OpenDocument.

[139] *See* Allen C. Nunnally et al., *Intellectual Property and Commercial Aspects of*

enabling a "better understanding of the relative positioning of genes along the human genome . . . [a] standardized SNP map was predicted to be of great value in drug discovery."[140]

While the initial goal was to identify and map 300,000 SNPs, evenly spaced throughout the human genome, the Consortium surpassed that target by placing a database containing approximately 1.8 million SNPs in the public domain.[141] In doing so, the Consortium offered the international medical research community free access to a high-quality genetic map of common DNA sequences that could be useful in accelerating the development of personalized medicine.[142] These collaborative efforts were spurred by the idea that placing SNPs in the public domain would facilitate whole-genome disease gene association studies, considered the "key" to unlocking the genetic origins of complex diseases such as Alzheimer's disease, diabetes, cancer, heart disease, and schizophrenia.[143] Thus, the ultimate goal of the SNP Consortium's mapping initiative was to help scientists more quickly identify the specific genes associated with disease and to develop novel diagnostic tests and custom-tailored medicines.[144]

In theory, several SNPs might be present in an important gene (e.g., a common mutated gene that causes Alzheimer's disease) such that any firm involved in studying, testing for, or even developing a therapy to treat a particular disease, would have to obtain a license from each of several patentees.[145] Problems associated with royalty stacking, holdups, and an increasingly dense patent thicket would appear to be inevitable. Moreover, the transaction costs of negotiating multiple licenses to multiple mutations,

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*Pharmacogenomics*, *in* PHARMACOGENOMICS, SOCIAL, ETHICAL, AND CLINICAL DIMENSIONS 126 (Mark A. Rothstein ed., 2003). Contributing pharmaceutical companies, which together committed at least $30 million to the Consortium's efforts included APBiotech, AstraZeneca Group PLC, Aventis, Bayer Group AG, Bristol-Myers Squibb Co., F. Hoffmann-La Roche, Glaxo Wellcome PLC, IBM, Motorola, Novartis AG, Pfizer Inc., Searle, and SmithKline Beecham PLC. The U.K.'s Wellcome Trust contributed at least $14 million. *See* Human Genome Project Information: SNP Fact Sheet, *supra* note 137.

[140] Frank Grassler & Mary Ann Capria, *Patent Pooling: Uncorking a Technology Transfer Bottleneck and Creating Value in the Biomedical Research Field*, 9 J. COM. BIOTECH. 111, 113 (2003).

[141] *See* Human Genome Project Information: SNP Fact Sheet, *supra* note 137. Now that the discovery phase has been completed, emphasis has shifted to studying SNPs in populations. Many members of the SNP Consortium have now moved on to a more ambitious project: mapping associated groups of SNPs in "haplotype blocks" to form a "haplotype map" (or "HapMap"). *See* International HapMap Project Home Page, *supra* note 35. As of 2007, an updated haplotype map revealed over 3.1 millions SNPs. *See* The International HapMap Consortium, *A Second Generation Human Haplotype Map of Over 3.1 Million SNPs*, 449 NATURE 851 (2007).

[142] Kristen Philipkoski, *Making Medicine to Fit*, WIRED, Apr. 16, 1999, http://www.wired.com/science/discoveries/news/1999/04/19159.

[143] Garber, *supra* note 138.

[144] Philipkoski, *supra* note 142 (quoting Arthur Holden, the SNP Consortium's director: "It's in those nucleotides that we hope to begin to identify the genetics associated with diseases or susceptibility or different responses to medical therapies . . . .").

[145] Merges, *supra* note 137, at 189–90.

SNPs, and diagnostic tests would quickly become prohibitive.[146] Instead of succumbing to the anticommons, the SNP Consortium ensured public access to the most fundamental and valuable diagnostic research tools. And by working with public research institutions such as the National Human Genome Research Institute,[147] as well as with private entities, the SNP database helped to accelerate the research process so that scientists could begin to develop better therapies for serious diseases more quickly and efficiently.[148]

Although not a formal patent pool,[149] the SNP Consortium demonstrates that pooled IP and collaborative efforts by several different entities can achieve both a cost-efficient and pro-competitive outcome.[150] As such, the SNP Consortium is an excellent example of private parties taking measures into their own hands in order to counteract the threat of an anticommons.[151] The private companies involved in the Consortium understood that they would all eventually need access to a multitude of SNPs for their collective commercial success, and, recognizing the long-term benefits of a cooperative venture, decided to pool their resources and work together.[152] The SNP Consortium can therefore serve as a precedent for patent pools in pharmacogenomics since a spirit of collaboration and shared vision of mutually advantageous IP arrangements are two of the essential features necessary to form a successful patent pool.

### B. *The SARS Patent Pool*

When SARS broke out in late 2002, many research institutes and private firms rushed to sequence the SARS genome and apply for patents.[153] The World Health Organization (WHO) set up a network of

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[146] Ebersole et al., *supra* note 37, at 7.

[147] National Human Genome Research Institute, http://www.genome.gov/ (last visited Mar. 15, 2009) (one of twenty-seven research institutes that make up the National Institute of Health, with the specific task of understanding the structure and function of the human genome and its role in health and disease).

[148] Philipkoski, *supra* note 142.

[149] The primary difference between the SNP Consortium and a traditional patent pool is that the goal of the former is to place SNPs into the public domain rather than, in the case of a patent pool, requiring users to obtain a license from the pool in order to gain access to the information. OECD REPORT, *supra* note 17, at 68.

[150] Grassler & Capria, *supra* note 140, at 113.

[151] Merges refers to this type of collaboration as "property-preempting investments" (PPIs), which exist for the explicit purpose of preempting the potentially stifling intellectual property rights claims of economic competitors. Merges, *supra* note 137, at 185–86.

[152] Moreover, the fact that the Consortium comprises both public and private funding and advances commercial and noncommercial interests suggests that alternative contractual solutions to the access problem in IP do exist and may function well under certain circumstances. OECD REPORT, *supra* note 17, at 68.

[153] Knowledge Ecology International, *IGWG Submission on Collective Management of Intellectual Property—The Use of Patent Pools to Expand Access to Essential Medical Technologies* 3

laboratories to research and contain the disease, subsequently leading to the isolation of the causative virus and the sequencing of its genome.[154] These findings led to several of the participating researchers filing a multitude of patent applications incorporating various parts of the SARS genome.[155] The rapid containment and sequencing of SARS is an example of the effectiveness of scientific collaboration, as well as an apt illustration of how the recent explosion in genomics-related patents has led to a thicket of fragmented IP rights that create an obstacle to the R&D of products that could benefit public health.[156]

As public health officials struggled to effectively navigate the SARS patent thicket, the WHO SARS Consultation Group and the key SARS IP owners created the "SARS IP Working Group" in order to work together to address the need to develop a vaccine in the face of an IP rights and public health nightmare.[157] Concerned that R&D would be "delayed and constricted by the multiplicity of patents," the SARS IP Working Group proposed forming a patent pool in order to package all relevant information and patents in an efficient manner.[158] The proposed patent pool would comprise patents incorporating genomic sequences of SARS so that R&D could take place downstream, thus stimulating greater investment in a SARS vaccine.[159] Not only might the patent pool lead to the development of vaccines against SARS, but it would also "set the precedent that may help the formation of analogous pools in other areas of the life sciences that face similar issues, such as malaria, tuberculosis and avian influenza, and lead to increased dissemination of key technologies that might help combat disease."[160] If created, the SARS patent pool could produce a mutually advantageous situation for all parties involved; the pool would enable patent holders to commercialize their inventions and licensees could gain access to important patented technology in order to more quickly

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(KEI Research Note Sept. 30, 2007), *available at* http://www.who.int/phi/public_hearings/second/contributions_section2/Section2_ManonRess-PatentPool.pdf [hereinafter KEI Research Note].

[154] James H.M. Simon et al., *Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling*, 83 BULL. WORLD HEALTH ORG. 707, 707 (2005), *available at* http://www.who.int/bulletin/volumes/83/9/707.pdf.

[155] *Id.*

[156] *Id.* at 709.

[157] KEI Research Note, *supra* note 153, at 3.

[158] *Id.*

[159] Simon et al., *supra* note 154, at 709 (explaining that the SARS patent pool would enable widespread access to the genomic sequence of SARS, thus driving competition away from patenting sequences and toward focusing on developing innovative products using those sequences).

[160] *Id.* Simon et al. further concluded that the SARS situation was ideal for setting a precedent for patent pools in the life sciences because of its relative simplicity, namely, that all the patent applications were at a similar, early stage of patent prosecution; the potential pool members were limited in number; there was not yet a significant market for SARS-related products covered by the patents; the parties were either public health organizations or closely linked with such organizations; and the public health implications of SARS provided a strong incentive to move forward. *Id.*

develop a vaccine, thus leading to an overall public health benefit.

While the SARS patent pool has not yet come to fruition,[161] its support by public health organizations, such as WHO and the National Institutes of Health (NIH), demonstrates the potential for patent pool success in biotechnology and medicine. Similarly, a number of other industry sectors have received proposals for the creation of patent pools, especially in the area of access to essential medical technologies in developing countries.[162] In response to an increasing recognition of the disproportionate access to medical technology in developing countries, WHO's Secretariat on Public Health, Innovation and Intellectual Property commissioned an intergovernmental working group to examine these proposals.[163] The result was not only an acknowledgment by WHO that patent pools may be a feasible option to improving access to medical technologies, but also a recognition that they may promote innovation.[164] And in July 2008, UNITAID agreed in principle to establish a patent pool to expand access to more appropriate and affordable medicines in low and middle income countries.[165] With every additional proposal for patent pools in areas such

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[161] As of the fall of 2005, the SARS patent pool proposal had gained support from WHO and the NIH's Office of Technology Transfer. The relevant parties had been identified, a principle agreement between the parties had been reached, a letter of intent to form the patent pool had been signed, and legal experts had been retained to provide their antitrust and intellectual property expertise to the project on a pro bono basis. *See id.* at 709. To date, however, the full agreement has not yet been completed, highlighting the potentially lengthy timeframe and difficulty in setting up patent pools.

[162] Examples include an Essential Patent Pool for AIDS (EPPA) and an Essential Medical Inventions Licensing Agency (EMILA), both of which were motivated by the crises in access to essential treatments for AIDS and access to medical products and vaccines in developing countries. *See* Letter from Essential Inventions, Inc. to WHO, UNAIDS, and The Global Fund (Jan. 17, 2005), *available at* http://www.essentialinventions.org/docs/eppa/cover17jan05.pdf; *see also* Knowledge Ecology International, EMILA Working Plan (June 1, 2007), *available at* http://www.keionline.dforg/index.php?option=com_content&task=view&id=64&Itemid=44.

[163] In May 2006, at the Fifty-Ninth World Health Assembly, Member States established an Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG). The Working Group's mandate was to prepare a global strategy and plan of action on public health, innovation and intellectual property to discuss ways to foster innovation, build capacity and improve access to health products in order to achieve better health outcomes in developing countries. *See* World Health Assembly Resolution on Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action, WHA Res. 59.24, 59th World Health Assembly, 9th plen. mtg. (May 27, 2006), *available at* http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_R24-en.pdf.

[164] In May 2008, the Sixty-First World Health Assembly adopted Resolution WHA 61.21. *See* World Health Assembly Resolution on Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHA Res. 61.21, 61st World Health Assembly, 8th plen. mtg, WHO Doc. WHA61/2008/REC.21 (May 24, 2008), *available at* http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf (instructing the WHA to "examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices").

[165] Press Release, UNITAID, UNITAID Moves Towards a Patent Pool for Medicines (July 9, 2008), *available at* http://www.unitaid.eu/en/NEWS/UNITAID-moves-towards-a-patent-pool-for-medicines.html. Established in 2006 through the initiative of the governments of France, Brazil, Chile, Norway and the United Kingdom, UNITAID is a drug purchasing facility aiming to improve access to treatments against HIV/AIDS, malaria, and tuberculosis in developing countries. The international

as genomic research, vaccines, and medical technologies, the IP, commercial, and scientific research communities take another step closer toward realizing the benefits of patent pools in pharmacogenomics.

## VI. AN OPPORTUNITY FOR PATENT POOLS IN DIAGNOSTIC GENETIC TESTING

The field of diagnostic genetics is more commercially focused than the broad field of genomics, or even biotechnology, and when further limited to individual diseases with standard mutations, it is ideal for patent pooling.[166] In order to assess the risks of a particular polymutational disease, diagnostic tests are used to identify the genetic mutations that are correlated with the disease.[167] Before performing any tests, however, scientists must first determine which mutations are significant for diagnosis, that is, which mutations should be considered "standard" when performing the tests.[168] One of the largest challenges facing diagnostic genetics, however, is the patent thicket problem that arises when several patents are required in order to develop a diagnostic test for a particular polymutational disease.[169] With genetic testing available for more than 1500 diseases or conditions in more than 1250 clinical laboratories, it is easy to see how problems associated with patent exclusivity and royalty stacking can complicate the landscape of patent licensing.[170] For those looking to offer diagnostic products to health care providers and their patients, patent pools offer an efficient alternative by making patents related to the diagnosis of polymutational diseases available at reasonable,

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agency is funded primarily through a tax on airline tickets. Donald G. McNeil, Jr., *Effort for Lower Drug Prices Would Focus on Gaining Patents*, N.Y. TIMES, July 8, 2008, at F6, *available at* LEXIS, News Library, NYT File.

[166] Ebersole et al., *supra* note 37, at 10.

[167] *Id.* at 6. A polymutational disease is a disease correlated with multiple genetic mutations on either a single gene or multiple genes. Examples of polymutational diseases include Alzheimer's disease, cystic fibrosis, hereditary breast and ovarian cancers, and hereditary hemochromatosis. Certain diseases such as Huntington's or Canavan, both of which are caused by a single nucleotide mutation, might not be suitable for a patent pool because there will only be one patent owner for the genetic variation. *Id.* at 6, 10.

[168] *Id.* at 6.

[169] For a practical example, see Turna Ray, *Whole-Genome Sequencing Poses 'Serious Challenge' to US Patent System, HHS Finds*, PHARMACOGENOMICS REP., Dec. 10, 2008, http://www.genomeweb.com (search "Whole-Genome Sequencing Poses 'Serious Challenge' to US Patent System, HHS Finds"; then follow hyperlink) (quoting the Navigenics website: "[I]f we obtain licenses from third parties to 10 patents, each covering the use of one SNP included in our service, and each subject to a royalty of between 1 percent and 5 percent of our net sales of the service, we would be required to pay between 10 percent and 50 percent of our net sales revenue—just for gene patent licenses!").

[170] SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY, U.S. SYSTEM OF OVERSIGHT OF GENETIC TESTING: A RESPONSE TO THE CHARGE OF THE SECRETARY OF HEALTH AND HUMAN SERVICES 39 (2008), *available at* http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf.

nondiscriminatory royalties.[171]

### A. *The Need for Efficiency in Diagnostics*

As licenses are necessary to develop new diagnostic tests, it is critical to facilitate such licensing through a system that is as efficient as possible.[172] The availability of a patent pool as a mechanism for securing licenses, in reasonably practical and financially efficient terms, will encourage scientists to pursue research in different areas and will help persuade users (e.g., manufacturers and diagnostic laboratories) to seek those licenses and pay royalties.[173]

A patent owner has exclusive control over his or her invention and therefore has the power to determine who may, or may not, use the invention. In the case of a patented genetic sequence that is necessary in order to develop a new diagnostic test, the patent holder has the power to prevent others from testing for that particular genetic sequence.[174] This exclusive control can serve as a hindrance for medical researchers trying to understand how a single mutation or mutated gene sequence affects the manifestation of a particular disease or the metabolism of a particular drug, especially if the patent holder is unwilling to grant a license.[175] In such a case, a medical research facility seeking access to a multitude of licenses can easily get lost in the patent thicket, with license negotiations and other transaction costs delaying the process.[176] Sometimes, a patent holder can have such restrictive licensing practices that they prevent other researchers and testing facilities from accessing the patented products.[177] Thus,

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[171] Ebersole et al., *supra* note 37, at 7.

[172] S. Aymé et al., *Patenting and Licensing in Genetic Testing, Recommendations of the European Society of Human Genetics*, 16 EUR. J. HUM. GENETICS S3, S7 (2008).

[173] *Id.*

[174] Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65, 89 (2002).

[175] John H. Barton, *Patents, Genomics, Research, and Diagnostics*, 77 ACAD. MED. 1339, 1340 (Dec. 2002). Additional burdens can be imposed on licensees, for instance, if the patent holder demands that samples taken for diagnostic testing be sent to the patent holder's laboratory for analysis rather than using the licensee's own facilities. *See* Rebecca S. Eisenberg, *Why the Gene Patent Controversy Persists*, 77 ACAD. MED. 1381, 1382 (2002) (noting that professional associations of doctors and medical geneticists have been particularly outspoken critics of disease gene patents and exclusive licenses for DNA diagnostics).

[176] These delays have significantly affected clinicians seeking to provide diagnostic testing services and perform research using the patented material. For example, a 2001 survey of clinical laboratory directors in the U.S. indicated that twenty-five percent stopped performing diagnostic tests due to patents and licenses, and fifty-three percent decided not to develop or perform a diagnostic test because of a patent. Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 5 (2003).

[177] This is the case of Myriad Genetics' monopolization of diagnostic testing for breast cancer. *See* NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA: A DISCUSSION PAPER 39–40 (2002), *available at* http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf (describing the patents granted to the U.S. company Myriad Genetics, giving it a monopoly on the

restrictive licensing practices and high transaction costs threaten to block the clinical use of diagnostic tests and inhibit follow-on research.[178] Patent pools control these transaction costs and offer an efficient solution to the licensing challenges in diagnostics.

### B. *Patent Pools Are a Viable Option for the Field of Diagnostic Testing*

Unlike the broad area of biotechnology, diagnostics is a commercially focused industry in which all the players share common goals centered around accepted standards.[179] Whereas the interests and goals of the players in the biotechnology or genomics markets are quite diverse and sometimes even contradictory, all market participants in the field of disease-specific diagnostic genetics share the same common goal: to provide accurate tests and analytic devices to health care professionals and their patients.[180] To achieve this goal, the scientific community relies on a standard panel of genetic mutations that have been found to have significant predictive value for a given disease.[181] Those in favor of patent pools for diagnostic genetics suggest that the American College of Medical Genetics (ACMG)[182] could serve as the standard-setting body.[183] Other possibilities include the NIH, WHO, OECD, and the Wellcome Trust, all of which have played important roles in collaboratives and are well-positioned to broker these arrangements and evaluate the feasibility,

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diagnosis of susceptibility to breast cancer linked to mutations in the BRCA1 and BRCA2 gene sequences); *see also* Thomas M. Burton, *Test for Breast-Cancer Risk Could Miss Mark*, WALL ST. J., Mar. 22, 2006, at D4, *available at* LEXIS, News Library, WSJNL File (explaining that Myriad Genetics is the sole provider for the diagnostic tests for the BRCA gene mutations and charges up to $3000 for the test). For a case study describing Myriad's controversial IP strategies and hardball tactics, see generally E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm* (Int'l Expert Group on Biotech., Innovation and IP, Sept. 2008), *available at* http://www.theinnovationpartnership.org/data/ieg/documents/cases/TIP_Myriad_Report.pdf.

[178] COMM. ON INTELLECTUAL PROP. RIGHTS IN GENOMIC & PROTEIN RESEARCH & INNOVATION, NAT'L RESEARCH COUNCIL OF THE NAT'L ACAD., REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 111 (2005) ("Because clinical research often is more efficiently done with an entire battery of tests, both blocking and an anti-commons might be in effect.").

[179] Krattiger & Kowalski, *supra* note 7, at 141; *see also* Ebersole et al., *supra* note 37, at 10. Some commentators point to potential problems with forming patent pools in genomics, suggesting that the industry is too broad, industry players do not share common goals, and the technology advances too quickly to establish industry standards and identify essential patents for a patent pool. Ebersole et al., *supra* note 37; *see also* Rochelle K. Seide & Michelle LeCointe, *TRENDSPOTTER: Just Say No to Patent Pooling for Genomics*, GENOMEWEB DAILY NEWS, July 13, 2001, http://www.genomeweb.com/issues/news/117309-1.html.

[180] Ebersole et al., *supra* note 37, at 10. Regardless of whether or not the market participant is a commercial enterprise or a non-profit entity, both strive toward developing tests that minimize false negative or false positive results. *Id.*

[181] *Id.*

[182] *See* ACMG Home Page, http://www.acmg.net (last visited Mar. 15, 2009).

[183] Ebersole et al., *supra* note 37, at 10. There is already a precedent of the ACMG as a potential standard-setting body, as it has developed standards and guidelines for clinical genetics laboratories for Cystic Fibrosis and Huntington's disease. Verbeure et al., *supra* note 36, at 118.

benefits, and costs of patent pools in diagnostics.[184] Furthermore, the criticism that a broad industry-wide patent pool would be too large and pose an anticompetitive threat would be absent in patent pools for diagnostic tests since each pool would focus only on one disease and only the essential and complementary patents would be included.[185]

### C. *How to Structure a Successful Patent Pool*

The structure of a patent pool in diagnostics should not be significantly different from the patent pools in other emerging technology fields. In fact, much of the hard work involved in designing a framework for patent pools—eliminating the threat of an anticommons, demonstrating the long-term efficiencies, determining the antitrust boundaries of anticompetitive behavior, and setting a precedent for the collaborative spirit required within an industry—has already been done. In order to ensure that a patent pool is attractive to potential members and there is no threat of antitrust violation or high transaction costs, the following guidelines should be adopted.

First, all licenses in the pool should be non-exclusive; that is, participating patent holders should retain the right to license their patents individually and independent of the pool.[186] The non-exclusive nature of the pooled patents is important to ward off various antitrust concerns as well as to entice both private and public patent holders (i.e., research firms and university laboratories alike) to voluntarily join the pool. Moreover, this criterion is particularly important for those firms holding patents whose full utility is unascertainable at the time of the formation of the pool.

Second, an independent expert in the relevant technology should evaluate the current state of the art in order to determine which patents are "essential" to the technology and thus ought to be included in the pool.[187]

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[184] *See id.* at 119.

[185] Ebersole et al., *supra* note 37, at 10. For instance, a diagnostic patent pool for Cystic Fibrosis would first require the standard-setting body to define the panel of standard mutations that, if present in an individual, would result in a greater likelihood of accurately diagnosing the disease. Based on that panel, the patent pool's independent expert would identify those essential and complementary patents covering those SNPs or genetic mutation sequences, including any blocking "isolated gene" patents. The pool would not include competing or substitute patents, nor would it include patents on non-DNA technology, such as chips, software, detection devices, or reagents. In doing so, the pool would avoid multiple platforms in the same pool as well as any threats of collusion or otherwise anticompetitive behavior. *See generally id.*

[186] *See, e.g.,* ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 79–80; *see also* MPEG-2 Review Letter, *supra* note 124, at 12; Sony Review Letter, *supra* note 124, at 13–14; Toshiba Review Letter, *supra* note 124, at 15.

[187] A patent is "essential" if it is "necessarily infringed" or "there is no realistic alternative" to it in implementing the pooled technology. Toshiba Review Letter, *supra* note 124, at 3. A standard-setting body such as the ACMG would be the likely source for providing guidance as to what "essential" means and for whom and for what purpose.

These essential patents must be complements of, not substitutes for, each other.[188] Throughout the duration of the patent pool, this expert should continue to monitor developments in the field so as to ensure that each patent's essentiality is maintained, as well as to incorporate additional patents if necessary. Providing a mechanism for future review is essential to ensuring the validity of each participating patent.[189]

Third, access to the pool's patent portfolio should be provided in a non-discriminatory manner.[190] Any entity, whether a private firm or a public research facility, should have access to the pool's patent portfolio. Non-discriminatory licensing will enhance the pro-competitive nature of the patent pool and ward off potential antitrust concerns of anticompetitive behavior.[191]

Fourth, royalty rates should be reasonable and distributed in accordance with a pre-established formula.[192] Determining the reasonability of a pool's royalty rate scheme can, however, be challenging. While the Antitrust Enforcement Report states that the FTC and the DOJ will not interfere with royalty rate schemes, unreasonably high rates could raise concerns of collusion.[193] The role of the independent patent expert discussed above could include the responsibility of providing a mechanism for determining the market value of each participating patent for the purpose of setting appropriate royalty rates within the patent pool. There are a number of different possible royalty rate schemes, and the decision of the most appropriate scheme may be particular to each individual pool.[194]

Fifth, the patent pool should not be run by the government or by any

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[188] MPEG-2 Review Letter, *supra* note 124, at 10. Pooling substitute patents (i.e., patents that can be used in competition with each other) raises "serious competitive concerns" such as eliminating competition between the patents and price fixing. If, on the other hand, the patent pool comprises complementary patent rights, it will be deemed "an efficient and pro-competitive method of disseminating those rights to would-be users." Limiting the pool to "technically essential patents, as opposed to merely advantageous ones," ensures that the patents "are not competitive with each other." *Id.* at 9–10.

[189] This feature will also help to eliminate the risk of free-riders, invalid or expired patents, and pool fragmentation. *See* MPEG-2 Review Letter, *supra* note 124, at 9 (explaining that the starting point for an antitrust analysis of a patent pool is "an inquiry into the validity of the patents and their relationship to each other.").

[190] *See, e.g.*, Sony Review Letter, *supra* note 124, at 13; Toshiba Review Letter, *supra* note 124, at 14.

[191] *See* Ebersole et al., *supra* note 37, at 8–9.

[192] *See, e.g.*, MPEG-2 Review Letter, *supra* note 124, at 12; Sony Review Letter, *supra* note 124, at 13; Toshiba Review Letter, *supra* note 124, at 14.

[193] *See* ANTITRUST ENFORCEMENT REPORT, *supra* note 15, at 82–83.

[194] *See* Daniel G. Swanson & William J. Baumol, *Reasonable and Nondiscriminatory (RAND) Royalties, Standards Selection, and Control of Market Power*, 73 ANTITRUST L.J. 1, 25–45 (2005) (proposing the use of the "efficient component pricing rule" to determine a competitively neutral and nondiscriminatory licensing fee and to serve as a "safe harbor" in order to avoid allegations of anticompetitive price discrimination). *See generally* Glenn S. Newman et al., *How Reasonable Is Your Royalty?*, J. ACCOUNTANCY, Sept. 2008, at 57–58 (discussing different valuation approaches to royalty rate setting).

member firm, but by an independent organization.[195] While not absolutely necessary, maintaining the appearance of independence can be beneficial in persuading different types of potential participants to join the pool. As discussed above, it is essential that both the public and private sectors work in concert to help move the pharmacogenomics industry forward.[196]

Finally, patent pools in pharmacogenomics should consider employing a multi-tiered royalty schedule, with different patent portfolio license prices depending upon the nature of the use and the role of the licensee. This system could be an effective way to help address the research use exemption, a heated debate in modern IP, while simultaneously enhancing the attractiveness of patent pools.[197]

Patent pools that conform to these criteria provide a "win-win" situation for pool participants, licensees, the industry, and the public at large.[198]

## VII. CONCLUSION

As knowledge about the complex interactions between pharmaceuticals, genomics, and disease increases, there will be a concurrent proliferation of patents for pharmacogenomic-based inventions. Navigating the patent thicket will require a significant investment in negotiating licenses, monitoring the market for blocking patents, and litigating possible infringement suits. These transaction costs—prohibitively expensive for some and uncertain for all—threaten to stifle innovation and hinder further R&D. Patent pools offer an alternative by minimizing the threat of an anticommons and allowing IP rights holders the chance to facilitate the advancement of new emerging technologies.

Patent pools provide pro-competitive benefits by reducing transaction costs, distributing risks, and promoting the dissemination of technical information. For an industry that is heavily dependent upon innovation and investment in IP, pharmacogenomics will be able to benefit significantly from these cost-saving and efficiency-enhancing features of patent pool arrangements. While patent pools find their boundaries in antitrust law, both the FTC and the DOJ have provided guidance on how to structure patent pools while promoting competition and innovation. Collaborative efforts such as the SNP Consortium and the SARS patent pool proposal provide a precedent for the collaborative spirit necessary for patent pools as a mechanism to accelerate and focus research. One

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[195] The patent pool's administrator would presumably handle administrative tasks such as signing up licensees, collecting royalties from the licensees, and distributing the royalties to the essential patent holders. *See* Kulbaski Testimony, *supra* note 79, at 1–2.

[196] *See supra* Part V.

[197] For a discussion of the research use exemption, see *supra* Part II.C.

[198] Kulbaski Testimony, *supra* note 79, at 2.

particular area where patent pools could make significant strides is in developing accurate and reliable diagnostic testing. Much of the success of pharmacogenomics will rely on the methods developed and data accumulated through these new diagnostics. Thus, encouraging R&D of diagnostic testing is critical. Patent pools with multi-tiered royalty schedules will provide affordable access to patented diagnostic technologies such that important research as well as immediate consumer use can take place. Facilitating scientific innovation and improving access to pharmacogenomics will greatly enhance the future of personalized medicine. Creative working solutions such as patent pools provide the opportunity to make this happen.