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PATENT POOLS AND GENOMICS: NAVIGATING A COURSE TO OPEN SCIENCE?

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"The use of patent pools in the biotechnology field could serve the interests of both the public and private industry."[1]

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[1] JEANNE CLARK ET AL., UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT

ABSTRACT

In this paper we explore the proposal that upstream[2] genomics patent pools can not only help avoid some of the potentially negative impacts of patents, but can also serve to advance open science. Our starting point is the set of issues faced by the attempt to create a patent pool based on sequencing the virus associated with severe acute respiratory syndrome ("SARS"). The paper includes a close examination of the history, goals and legal structure of patent pools, especially those intended to meet the guidelines and precedents established by United States agencies and by litigation. In reviewing efforts to form the ground-breaking SARS patent pool, we consider the challenges inherent in attempting to form patent pools in the upstream genomics arena. We postulate that use of such patent pools could support the zone of open science around upstream genomics and offer recommendations for the achievement of such aims.

I. INTRODUCTION

In 2000, a report issued by the United States Patent and Trademark Office ("USPTO") offered the provocative suggestion that patent pools could be an intellectual property ("IP") tool used for biotechnology – or genomics.[3] The fact that one of the largest patent-issuing administrative agencies in the world issued this statement represented a significant endorsement of patent pools for genomics and, in itself, has helped provide impetus for further consideration and development of such pools. For most, patent pools are known primarily for their use in emerging industrial or electronic technologies, the most

POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? 11 (2000), http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf, *reprinted in* 20 BIOTECH. L. REP. 607, 618 (2001), *available at* http://www.liebertonline.com/toc/blr/20/4.

[2] A distinction between "upstream" and "downstream" research has been employed in the literature for some time. Heller and Eisenberg, for example, initially link, without analysis or reference, "upstream" and "premarket" research; later in the article they contrast those that "pursue end-product development and those that focus primarily on upstream research." Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, SCIENCE, May 1, 1998, at 698, *available at* http://www.sciencemag.org/cgi/reprint/280/5364/698.pdf. Although the boundary between upstream and downstream is far from clear, for our purposes it is adequate to use (something like) the latter distinction: research that can directly form the basis of a product is downstream, whereas research intended to yield information or knowledge is upstream. *See also* G.M. Grossman & C. Shapiro, *Research Joint Ventures: An Antitrust Analysis*, 2 J.L. ECON. & ORG. 315 (1986).

[3] "Genomics" is commonly defined as the study of genes and their function. Medicine.Net, Definition of Genomics, http://www.medterms.com/script/main/art.asp?articlekey=23242 (last visited Dec. 1, 2009).

prominent examples including airplanes, radios, MPEG-2 audio and video compression, and DVDs.[4] It is only recently that patent pools have begun to be the subject of interest in the genomics community. In part, this is because of broader debates about the negative impact traditional patents may have on genomics in the wake of wide scale patenting in the 1990s. Critics of traditional patenting for genomics have pointed to the potential for patent thickets and the emergence of an anticommons,[5] as well as evidence that the nature and magnitude of patenting in genomics may threaten the free flow of information seen as the hallmark of science.

In this paper we explore in detail the proposal that patent pools potentially have a role to play in the genomics context. Our goal is to assess the likelihood that patent pools can achieve the aims posited for them not only as a tool for avoiding some of the negative aspects of patents, but also as a tool to advance open science.

Open science is a term loosely defined to refer to practices of transparency and sharing in science – practices which arguably advance both collegiality and the potential for research advances. To many, the concept harks back to a time idealized in the literature by Robert K. Merton,[6] but it is in reality a concept very much reflective of the present practice of science, where competition and the allure of patents and commercialization are omnipresent. The Science Commons, an organization devoted to fostering scientific sharing and openness, characterizes open science as having several interlocking pieces, including: (1) open access to literature; (2) access to research tools; (3) public access to data; and (4) a mechanism for achieving this access.[7] Ultimately, open science aims to preserve a space around and within science in which research can be freely shared, and rejects a landscape where patents shut out access to scientific knowledge.

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[4] David Serafino, *Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures*, KNOWLEDGE ECOLOGY INT'L, June 4, 2007, at 15-18, 21, 26, http://www.keionline.org/misc-docs/ds-patentpools.pdf.

[5] Gavin Clarkson & David DeKorte, *The Problem of Patent Thickets in Convergent Technologies*, 1093 ANN. N.Y. ACAD. SCI. 180 (2006); Carl Shapiro, *Navigating the Patent Thicket: Cross-Licenses, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POLICY & THE ECONOMY 118, 120 (Adam B. Jaffe, Josh Lerner & Scott Stern, eds., 2001), *available at* http://faculty.haas.berkeley.edu/shapiro/thicket.pdf; Frank Grassler & Mary Ann Capria, *Patent Pooling: Uncorking a Technology Transfer Bottleneck and Creating Value in the Biomedical Research Field*, 9 J. COM. BIOTECH. 112 (2003), *available at* http://www.cptech.org/cm/grassler092002.pdf; Heller & Eisenberg, *supra* note 2, at 699.

[6] ROBERT K. MERTON, ON THE SHOULDERS OF GIANTS: A SHANDEAN POSTSCRIPT (University of Chicago Press, 1993) (1965).

[7] Science Commons, Principles of Open Science, http://sciencecommons.org/resources/readingroom/principles-for-open-science (last visited Apr. 1, 2009).

It should be noted that the concept of a "patent pool" is broad and there are many disparate collective arrangements that are called patent pools in the literature.[8] The basic notion is straightforward: "A 'patent pool' is an agreement between two or more patent owners to license one or more of their patents to one another or third parties."[9] However, "patent pool" is not a term of art and there are no specific laws on these arrangements in the U.S., although there have been pools for over 150 years and there are guidelines and litigation relating to them.[10] At present, a pool-like arrangement can request that the Department of Justice ("DOJ") assess its structure and terms and issue a Business Review Letter to see whether it will be the subject of a DOJ anti-competition action. However, there is no requirement that the request be made and there are no notification requirements for pool-like arrangements (or for most other licensing arrangements).[11] In fact, since the mid-1990s there have only been four Business Review Letters issued with respect to patent pools,[12] and yet many more pools are identified in surveys.[13]

Our examination of patent pools was prompted initially by our interest in the recent effort to create a patent pool based on discoveries around the severe acute respiratory syndrome ("SARS") virus.[14] Those proposing the SARS patent pool indicated their intention to form a pool in accordance with U.S. law. Because of that, and because the U.S. policies around pool requirements are so detailed and elaborate, we have taken the U.S. guidelines for pools as the base notion. As we explored the SARS case, it became clear that the use of

[8] Serafino, *supra* note 4, at 2.

[9] CLARK ET AL., *supra* note 1, at 4.

[10] Joel I. Klein, Acting Assistant Att'y Gen., Antitrust Div., U.S. Dep't of Justice, Address to the American Intellectual Property Law Association: Cross-Licensing and Antitrust Law 2-3 (May 2, 1997) (transcript available at http://www.usdoj.gov/atr/public/speeches/1118.pdf) [hereinafter Joel Klein Address]; *see also* Serafino, *supra* note 4, at 2.

[11] Joel Klein Address, *supra* note 10, at 12-14.

[12] Letter from Thomas Barnett, Assistant Att'y Gen., Antitrust Div., Dep't of Justice, to William Dolan, Esq., and Geoffrey Oliver, Esq., Jones Day (Oct. 21, 2008), http://www.justice.gov/atr/public/busreview/238429.pdf; Letter from Joel I. Klein, Assistant Att'y Gen., Antitrust Div., Dep't of Justice, to Carey Ramos, Esq., Paul, Weiss, Rifkind, Wharton & Garrison (June 10, 1999), http://www.usdoj.gov/atr/public/busreview/2485.pdf; Letter from Joel I. Klein, Assistant Att'y Gen., Antitrust Div., Dep't of Justice, to Garrard Beeney, Esq., Sullivan & Cromwell (Dec. 16, 1998) [hereinafter 1998 Letter from Joel Klein to Garrard Beeney], http://www.justice.gov/atr/public/busreview/2121.pdf; Letter from Joel I. Klein, Acting Assistant Att'y Gen., Antitrust Div., Dep't of Justice, to Garrard Beeney, Esq., Sullivan & Cromwell (June 26, 1997) [hereinafter 1997 Letter from Joel Klein to Garrard Beeney], http://www.justice.gov/atr/public/busreview/215742.pdf.

[13] *E.g.*, Serafino, *supra* note 4, at 2.

[14] *Id.* at 34.

patent pools in genomics could have broad implications for science and could play a role in efforts to ensure, particularly in the upstream arena, that innovations in science are freely and openly available to other researchers.[15] Our goal in this paper is to explore the role of patent pools in this larger context.

We begin in Section II with an examination of the goals that have been posited for patent pools. In Section III, we discuss some of the key legal considerations and recent precedents that define patent pools. Although in this paper our focus is squarely on arrangements that qualify as patent pools under U.S. guidelines, we include a brief account of various other forms of collective arrangements. Some of these have been termed "patent pools," yet do not aspire to qualify as such under U.S. law. In Section IV, the case of the proposed SARS pool is examined in detail. Even though some of its patents have not yet issued and the impetus for forming a pool has diminished in tandem with the perceived threat of a SARS pandemic, the proposed SARS pool is important as a tool for examining the possibilities and potential hurdles faced by genomics patent pools. In Section V, we examine some of the main challenges that patent pools have to face and offer considerations that may help counter those challenges. Section VI outlines goals for genomics patent pools in expanding open science and offers some recommendations for achievement of these aims.

II. GOALS OF PATENT POOLS

The goals for establishing patent pools in the United States have changed dramatically between the mid-nineteenth century and the present. The pools of the 19th century were largely mechanisms for creating cartels and fixing prices.[16] In the early 20th century, pools were created as a response to government policy. From 1995 onwards, patent pools have been created as a way to resolve the transaction costs and inefficiencies resulting from "patent thickets" and avoid the problem of an anticommons.[17] Patent thickets occur when multiple organizations each own at least one patent that is collectively necessary for a particular technology. A patent thicket occurs when a company wishing to develop a technology is confronted by "a dense web of overlapping intellectual property rights . . . [it must get] through in order to actually

[15] Although we are focusing on patent pools in genomics, much of what we say could apply more widely to other aspects of biotechnology and perhaps beyond.

[16] However, as Mossoff clearly demonstrates, avoidance of patent thickets was a major goal of the sewing machine patent pool of the mid-nineteenth century, the very first U.S. patent pool. *See* Adam Mossoff, *A Stitch in Time: The Rise and Fall of the Sewing Machine Patent Thicket* 1 (George Mason L. & Econ. Research Paper No. 09-19, 2009), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1354849.

[17] Shapiro, *supra* note 5, at 134.

commercialize new technology."[18] The more patents that are required to develop a product, the more licensing agreements a developer needs to negotiate, and each license negotiation may require a considerable outlay of time and resources.[19] Further, the existence of a patent thicket increases the possibility that at least one of the seminal patent holders may block access to the technology by refusing to license broadly. Such behavior would hinder the development process and increase the potential that upstream patents will be infringed during the commercialization process. In contemporary discussions of patent pools, the aim of forming a pool is specifically to overcome such obstacles and to save patentees and licensees time and money.[20]

"Anticommons" is a term that was used in the genomics context by M. A. Heller and R. A. Eisenberg to describe a situation "in which people underuse scarce resources because too many owners can block each other" and non-owners.[21] In this sense, an anticommons can result from the existence of too many patents in a particular area and from the existence of patent thickets. Both the concepts of "patent thickets" and "anticommons" reflect genuine concerns about the relationship between genomics and IP and have resonated within and outside the research community. More recently, some have raised questions about the significance of an anticommons in genomics. As articulated in Heller and Eisenberg's seminal article, an anticommons was hypothesized to arise from the numerous patents issued in the genomics arena.[22] The net impact postulated would be a potential decline in scientific research and innovation.[23] Empirical studies carried out in recent years have questioned the extent or impact of such an anticommons.[24]

Whether or not an anticommons can be said to exist in genomics, the

[18] Shapiro, *supra* note 5, at 120; Clarkson & DeKorte, *supra* note 5, at 180.

[19] Patent thickets can occur both in upstream research and development and in downstream product development. The concept in each case is the same: a proliferation of patents in a particular area makes it difficult for subsequent researchers/developers to access necessary IP rights.

[20] CLARK ET AL., *supra* note 1, at 8.

[21] Heller & Eisenberg, *supra* note 2, at 698. Heller used the term "anticommons" in a previous article and traces its origins to the early 1980s. Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 667 (1998). However, we believe the Heller and Eisenberg article is the first to apply the concept to IP and biotechnology.

[22] Heller & Eisenberg, *supra* note 2, at 698.

[23] *Id.*

[24] Ronald Bailey, *The Tragedy of the Anticommons: Do Patents Actually Impede Innovation?*, REASON, Oct. 2, 2007, http://reason.com/archives/2007/10/02/the-tragedy-of-the-anticommons; Timothy Caulfield et al., *Evidence and anecdotes: an analysis of human gene patenting controversies*, 24 NATURE BIOTECH 1091 (2006).

potential for patent thickets is very real as a large number of genomics patents have been filed and issued.[25] Patent thickets can not only make it difficult for firms to capitalize on their patents, but may also make it difficult for innovators to conduct research and development, and for third parties to effectively access necessary patents. However, patent holders may be motivated to form a pool in the face of government threats of compulsory licensing (to help developers access necessary patent rights). This is, in large part, what occurred with respect to airplanes when the U.S. government determined that a group of patent holders was blocking its efforts to "[scale up] aircraft manufacturing" for the conduct of WWI.[26] Patent holders may alternatively be motivated to break through thickets based on the belief that significantly broadening the base of practitioners is the best way to maximize the value of their patents or products. This scenario has been in effect for the four most recently established patent pools, all of which relate to electronics products such as DVDs and MPEG-2.[27] Patent pools may thus be a response both to external pressures as well as internal development pressures.

In our view, the situation in genomics has given rise to an additional source of motivation to form a patent pool. Suitably structured patent pools might be used by patent holders to create arrangements more commensurate with the norms of open science than with standard corporate individualistic patent ownership. On this view and in the appropriate context, pooling the necessary patents arguably makes them more available to all comers and potentially drives the competitive, commercial patenting downstream, thus preserving the upstream research sphere as a place largely free from the restrictions that can confound research and development. As we suggest in this article, creating a space for open science was one of the key rationales for the proposal to establish a pool of patents relating to the SARS genomic sequence. To be clear, this suggested motivation is certainly not exclusive; rather a number of aims can work in tandem. For example, in the area of genomics there may be a threat of compulsory licensing when there is a threat of a pandemic, and this too can add to the rationale for forming a pool.

Others have posited additional rationales for patent pools for medicines, food and other products in the international arena. In the field of biomedicine for example, some have argued that patent pools could be an instrument for increasing access to proprietary medicines and other products:

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[25] National Human Genome Research Institute, Intellectual Property and Genomics, http://www.genome.gov/19016590 (last visited Nov. 6, 2009).

[26] MANON RESS, KNOWLEDGE ECOLOGY INT'L, IGWG SUBMISSION ON COLLECTIVE MANAGEMENT OF INTELLECTUAL PROPERTY – THE USE OF PATENT POOLS TO EXPAND ACCESS TO NEEDED MEDICAL TECHNOLOGIES 2 (2007), http://www.iprsonline.org/ictsd/Dialogues/2007-10-22/17%20Ress-PatentPool.pdf.

[27] Serafino, *supra* note 4, at 21.

> Proponents of patent pools for pharmaceutical products suggest that the pooling will: 1) Foster the development of new combinations or formulations that meet developing world specific needs, for example heat-resistant formulas or child-appropriate doses; and 2) Reduce prices for medicines through increased competition.[28]

More recently the Chief Executive Officer of GlaxoSmithKline, Andrew Witty, proposed in an address to Harvard Medical School that a patent pool may be one means of improving global public health:

> One idea we are proposing is a Least Developed Country (LDC) Patent Pool for medicines for neglected tropical diseases. We would put our relevant small molecule compounds or process patents for neglected tropical diseases into the pool, allowing others access to develop and produce new products. The pool would be voluntary so as to encourage others to participate and any benefits from the pool must go in full and solely to LDCs.[29]

In this paper we will focus mainly on the sorts of arrangements that would qualify as pools under current U.S. guidelines and thus will not explicitly address these other proposals. Nevertheless, we believe that many of the challenges and reasoning we invoke at least bear indirectly on these additional structures, which we refer to as "patent ponds."[30]

Before examining the rationales for forming patent pools further, we turn first to the legal parameters guiding the formation of patent pools in the United States. This discussion underlines the fact that development and use of patent pools for genomics is still at an early stage. The question of how to apply some of the key antitrust notions to the genomics arena has not yet been entirely resolved.

III. PATENT POOLS

A. Under U.S. Guidelines

According to the USPTO, a patent pool is formed by two or more patent

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[28] RICHARD GOLD ET AL., THE INNOVATION PARTNERSHIP, SUBMISSION TO WHO'S SECOND PUBLIC HEARING ON PUBLIC HEALTH INNOVATION AND INTELLECTUAL PROPERTY 2 (2007), http://www.who.int/phi/public_hearings/second/contributions_section1/Section1_MorinJeanFrederic-tIP.pdf.

[29] Andrew Witty, CEO, GlaxoSmithKline, Speech to Harvard Medical School: Big Pharma as a Catalyst for Change (Feb. 13, 2009), at 1, http://www.gsk.com/media/Witty-Harvard-Speech-Summary.pdf.

[30] As we shall see in the technical discussion below, the distinction between pools and ponds hinges on structure, not on jurisdiction. There are patent pools outside the U.S. and there are patent ponds within the U.S.

holders assigning or licensing their individual IP rights to one another or to a specifically created administrative entity.[31] The pool of patents is then made available for licensing non-exclusively, usually at a pre-established rate, to all comers. In addition, income from licensing fees is allocated to each member according to a pre-set formula or procedure.[32] Patent pools differ from cross licensing agreements in that cross licenses are agreements between two or more companies to grant each other the rights to use the technology under the other's patents, whereas patent pools go further and allow third parties to gain access to the pool's patents *without* an exchange of patent rights.[33]

As horizontal agreements among patent holders, each of which having the quasi-monopoly rights afforded by patent ownership, patent pools are subject to antitrust oversight and are regulated by competition authorities. The relations between antitrust law and patents have changed significantly over time:

> In the early 1900's, courts gave such sweeping deference to the licensing of patents that such activities were practicably immune from the Sherman [Antitrust] Act. Patent pools' freedom from any scrutiny under the antitrust laws ended in 1912 with the Supreme Court's decision in *Standard Sanitary Manufacturing Co. v. United States* which dissolved a patent pool because of antitrust violations. In 1945, the Supreme Court dissolved one of the most notorious patent pools in *Hartford-Empire Co. v. United States*. This patent pool of major glass manufacturers covered ninety-four percent of all the glass made in the United States, which allowed its members to sustain glass prices at unreasonably high levels.[34]

In recent years three important documents have expressed U.S. government positions about patent pools in light of antitrust concerns: (1) "Antitrust Guidelines for Licensing Intellectual Property"[35] [hereinafter "*Guidelines*"], which was jointly issued in 1995 by the DOJ and the U.S. Federal Trade Commission ("FTC"); (2) a White Paper entitled "Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?"[36] [hereinafter, "*Solution?*"],

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[31] CLARK ET AL., *supra* note 1, at 4.

[32] 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).

[33] Shapiro, *supra* note 5, at 127.

[34] CLARK ET AL., *supra* note 1, at 5.

[35] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (1995), http://www.justice.gov/atr/public/guidelines/0558.htm [hereinafter GUIDELINES].

[36] CLARK ET AL., *supra* note 1.

which was issued in 2000 by the USPTO; and (3) the DOJ and FTC's 2007 report, "Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition," which in essence endorsed the *Guidelines*.[37] None of these documents create laws or regulations that are legally binding on those forming patent pools. However, as documents expressing the views of the administrative bodies responsible for, respectively, assessing any antitrust issues and issuing the patents, the *Guidelines* and *Solution?* can be treated as definitive.

The position expressed in all of these documents is that a patent pool must on balance be procompetitive rather than anticompetitive. As such, a patent pool in the United States can operate without running afoul of antitrust law. The aim of the documents is first to identify the key factors on which the government is likely to base judgments of pro- vs. anticompetitiveness, and then to analyze the substance and boundaries of these components. We cannot canvass all the factors that bear on how this balance is judged, but we will examine some of the main elements. One of the key factors relating to procompetitiveness is that a patent pool "integrates complementary technologies,"[38] which means that all the patents in the pool must be judged to be "essential" to the technology under consideration.[39] Essentiality connotes that no realistic alternative to the technology under patent is available to produce end products.[40] Thus, in the case of a pool formed around DVD technology, a patent is regarded as essential if, in meeting the DVD standard specifications, it is "necessarily infringed" or "there is no realistic alternative" to it.[41] The phrase "integrate complementary patent rights" also captures the notion that patents in the pool must be *complementary* as opposed to *competitive*.[42] Complementarity suggests in turn that the inclusion of patents that provide alternative approaches to the same end – and thus compete with one another – are considered to be an *un*acceptable reduction of competition if included in the same patent pool.[43] The rationale for such a restriction is clear:

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[37] *See generally* U.S. DEP'T OF JUSTICE & FED. TRADE. COMM'N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION (2007), http://www.justice.gov/atr/public/hearings/ip/222655.pdf [hereinafter PROMOTING INNOVATION]; *see also* CLARK ET AL., *supra* note 1, at 3.

[38] CLARK ET AL., *supra* note 1, at 6.

[39] Patrick Gaulé, *Towards Patent Pools in Biotechnology?*, 2 INNOVATION STRATEGY TODAY 123, 128 (2006), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1427751 (last visited Jan. 5, 2010).

[40] *Id.*

[41] PROMOTING INNOVATION, *supra* note 37, at 69.

[42] CLARK ET AL., *supra* note 1, at 7.

[43] Anatole Krattiger et al., *Intellectual Property Management Strategies to Accelerate the Development and Access of Vaccines and Diagnostics: Case Studies on Pandemic Influenza*,

if there are multiple means to the same end but all means are incorporated into a pool, the pool limits alternatives for developers.[44]

It is important to note that these considerations about the scope and content of a patent pool are tied to a *product* or the *products* the patents are meant to enable. Traditional patent pools are "product-based."[45] Essentiality, for example, is determined with respect to particular products, and more particularly in recent cases, judgments about essentiality turn on whether the patent is required for the product to meet highly specific standards such as those governing the operation of electronic equipment. As we shall see, the product basis of patent pools poses a challenge to the formation of genomics patent pools because the patents in the latter case can be so far upstream that they do not relate to particular, identifiable products in the same concrete ways that we see in traditional cases.

In addition to the frameworks and factors outlined in *Guidelines*, *Solution*?, and the 2007 Report, another source for understanding the U.S. government's position on patent pools can be found in Business Review Letters issued by the DOJ. A Business Review Letter is the DOJ's response to a group of patent holders that has exercised its option to request examination of its (proposed) pool structure and operating principles for any antitrust concerns.[46] The most favorable possible response from the DOJ is that it is not currently inclined to initiate antitrust enforcement against the conduct described by the applicant. Between 1997 and October 2008 there have been five Business Review Letters on patent pools, all relating to products in the area of consumer electronics, including the MPEG-2 pool and two pools centered on DVD technology.[47] Here is a succinct comparison and summation of the conclusions of the letters regarding these three particular pools:[48]

> Like the MPEG-2 pool, the Antitrust Division concluded that two recently-formed pools for DVD technology were not likely to be

Malaria and SARS, 2 INNOVATION STRATEGY TODAY 67, 83 (2006), *available at* http://web.archive.org/web/20071011155236/www.biodevelopments.org/innovation/ist5.pdf (last visited Jan. 5, 2010).

[44] *Id.* at 74.

[45] The term "product-based" emerged both from authors' notes and comments from readers of the manuscript. We do not claim to have originated the term.

[46] *See* 28 C.F.R. § 50.6 (2008).

[47] Letter from Thomas Barnett to William Dolan & Geoffrey Oliver, *supra* note 12; Letter from Charles A. James, Assistant Att'y Gen., Dep't of Justice, to Ky P. Ewing, Esq., Vinson & Elkins L.L.P., (Nov. 12, 2002), http://www.usdoj.gov/atr/public/busreview/200455.pdf; Letter from Joel Klein to Carey Ramos, *supra* note 12; 1998 Letter from Joel Klein to Garrard Beeney, *supra* note 12; 1997 Letter from Joel Klein to Garrard Beeney, *supra* note 12.

[48] The two letters not mentioned here are generally aligned with the other three.

> anticompetitive. Indeed, it would have been quite a surprise had Justice concluded otherwise, given the many similarities between the MPEG-2 and DVD pools. The pools for both include only essential patents – those required to implement a widely-accepted technological standard. Also in both, an independent patent expert determines "essentiality" on the basis of objective evaluation procedure. Both pools call for royalties that are small relative to the total costs of manufacture. In addition, licensing is nondiscriminatory, and individual licensees are free to strike deals with each patent holder. Finally, because of the structure and scope of the pool, innovation does not appear to be hampered.[49]

Two of the factors cited as similar in the three cases deserve elaboration as they demonstrate the complexity of establishing a patent pool that will satisfy regulatory guidelines. First, it is worth noting that all three pools employ an expert individual or panel that will determine, *inter alia*, whether candidate patents are essential and complementary.[50] The Department expresses concerns that the expert be truly arms-length and objective: the expert will have to have "full and sufficient knowledge and skill in the relevant technology;"[51] its decisions will be "conclusive and non-appealable;"[52] it will repeat the comprehensive review of patents in the Pool and will vet new candidates; and the only reasons for which the expert can be dismissed are "malfeasance and nonfeasance."[53]

Second, the DOJ statement suggests that licensing and royalties are established by the pool while their implementation may be contracted to a pool licensing administrator. Notably, all of these patent pools allow for freedom on the part of individual participants even while they provide for licensing of the entire pool. In all the cases so far, pool members are permitted to license their patents bilaterally, i.e., outside of the pool structure.[54] Additionally, "a typical pool makes all pooled patents available to each member of the pool. Pools also usually offer standard licensing terms to licensees who are not members of the pool. In addition, the typical patent pool allocates a portion of the licensing fees to each member according to a pre-set formula or

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[49] Merges, *supra* note 32, at 47.

[50] *See*, *e.g.*, Letter from Joel Klein to Carey Ramos, *supra* note 12, at 4.

[51] *Id.* at 4.

[52] *Id.* at 5.

[53] *Id.* at 13.

[54] 1997 Letter from Joel Klein to Garrard Beeney, *supra* note 12, at 4; 1998 Letter from Joel Klein to Garrard Beeney, *supra* note 12, at 6; Letter from Joel Klein to Carey Ramos, *supra* note 12, at 6; Letter from Charles James to Ky Ewing, *supra* note 47, at 7; Letter from Thomas Barnett to William Dolan and Geoffrey Oliver, *supra* note 12, at 4.

procedure."[55]

It is clear from these considerations that in the view of the United States DOJ, establishing a patent pool that does not raise antitrust concerns is a rigorous undertaking that requires detailed external evaluation as well as a highly complex internal licensing structure.[56]

B. Variants of Patent Pools: Patent Ponds

In addition to those patent pools that conform to the specifications outlined in the *Guidelines* and *Solution?* documents and are designed specifically to meet U.S. antitrust concerns, there are "patent pools" proposed that use the terminology somewhat differently. For example, the term "patent pool" has been applied to co-operative efforts among multiple parties to ensure access that falls outside of what the current U.S. legal conception of patent pools involves. In order to distinguish these arrangements from "patent pools" described above and addressed in the *Guidelines*, we call these other collective arrangements "patent *ponds.*" In this paper, our focus is primarily on patent pools, i.e., those that aim to satisfy the U.S. Guidelines in a manner similar to the pools in the electronics sector and that provide "one stop shopping" for both researchers and developers whatever their goals may be, though the licensing conditions may vary depending on the nature of use.

The main conceptual distinction between pools and ponds is that membership in pools is determined in terms of technical standards, and the arrangement is meant to facilitate the commercialization of products whose identities are known in advance of, or concurrent with, the establishment of the pool. In contrast, ponds are composed of patents that relate much more loosely to one another. It is far from clear that the U.S. would only look favorably upon structures that are based on standards the way the electronics pools are. Indeed, the very fact that the USPTO raised the possibility that pools could be useful in biotechnology suggests a willingness to consider types of structures that differ from the arrangements employed in the electronics pool.[57] Thus, it could come to pass that both pools and (some) ponds might be subject to favorable review by the FTC or DOJ under the parameters set out in the *Guidelines.*

In his survey of historical and recent patent pools, Serafino's category, "Recent Pools (and proposals for pools) involving biomedical and agricultural

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[55] James Love, Presentation at the 14th Annual AIDS Conference in Barcelona: Essential Inventions, Inc. on Collective Management of IP Rights: Patent Pool (July 8, 2002), http://www.essentialinventions.org/docs/eppa/whatisapatentpool.html.

[56] *See* Letter from Joel Klein to Carey Ramos, *supra* note 12.

[57] *See* CLARK ET AL., *supra* note 1.

technologies," includes eight entries.[58] As far as we can determine, the only one among them that aimed to satisfy U.S. guidelines is the SARS pool.[59] However, since the SARS pool has not gotten as far as requesting a Business Review, we do not know what structure it would have proposed or whether that would have been acceptable to the FTC or DOJ.

For clarity, we briefly survey below some of the more prominent patent ponds that have been formed or proposed in order to illustrate the concept.

1. Medicines Patent Pool (MPP)

UNITAID is a multinational organization hosted by the World Health Organization ("WHO") and initially formed to facilitate drug purchases for the developing world.[60] In June 2006, three months before UNITAID's official launch, UNITAID and the government of France were approached by Médecins Sans Frontières ("MSF") to support the establishment of a Medicines Patent Pool, which would be targeted at providing HIV/AIDS anti-retroviral medication in the developing world. MPP would be "designed to address the fact that patent-holders are not producing either the fixed-dose combinations (FDCs) or the new formulations required by developing countries [to treat HIV/AIDS] and that anti-retrovirals are not affordable in those countries."[61] According to the original proposal, holders of patents essential to the production of anti-retrovirals would be invited to join the pool and accept capped royalties; otherwise, compulsory licenses would be sought.[62] The creation of MPP was endorsed by UNITAID's board in July 2008 and was approved by UNITAID's Executive Board in late 2009.[63] Although the exact structure of the pool is still subject to deliberation, some of the likely features are contained in a preliminary legal review conducted by Richard Gold and associates.[64] They recommend that the MPP consist solely

[58] *See generally* Serafino, *supra* note 4.

[59] *See generally id.*

[60] UNITAID, How UNITAID Came About, http://www.unitaid.eu/en/How-UNITAID-came-about.html (last visited Nov. 30, 2009).

[61] E. RICHARD GOLD ET AL., THE INNOVATION PARTNERSHIP, PRELIMINARY LEGAL REVIEW OF PROPOSED MEDICINES PATENT POOL iv (2007), http://www.theinnovationpartnership.org/data/documents/00000003-1.pdf.

[62] UNITAID ANNUAL REPORT 2008 27 (2008), http://whqlibdoc.who.int/unitaid/2008/annual_report_2008_en.pdf; *see also* Letter from Essential Innovations, Inc. to WHO, UNAIDS, & The Global Fund (Jan. 17, 2005), http://www.essentialinventions.org/docs/eppa/cover17jan05.pdf; Gaulé, *supra* note 39, at 124.

[63] *See* UNITAID ANNUAL REPORT, *supra* note 62, at 26; "UNITAID Approves Patent Pool", http://www.unitaid.eu/en/20091215237/News/UNITAID-APPROVES-PATENT-POOL.html.

[64] *See generally* GOLD ET AL., *supra* note 61.

of patents voluntarily contributed, that it operate as a Swiss not-for-profit corporation or association, and that it be focused on about a half dozen developing countries.[65] Given the jurisdictions under consideration, there is no reason why it would be designed to conform to U.S. regulations. Nevertheless, some of the same concerns about competiveness and other legal constraints would apply.

2. CAMBIA/BiOS

In a comprehensive paper on the potential of an open source licensing approach for genomics, Katharine Nolan-Stevaux makes the claim that the sharing inherent in open source licenses may *de facto* involve participants in a patent pool.[66] Specifically, Nolan-Stevaux points to the open source licenses designed by Biological Innovation for Open Society ("BiOS"), an affiliate of the Center of Applications of Molecular Biology to International Agriculture ("CAMBIA"), an independent, non-profit research institute in Australia. "In return for the right to use the BiOS patents and know-how, the BiOS licenses include a grant-back clause, giving CAMBIA a worldwide, non-exclusive, royalty-free, fully paid-up license to any improvement patents or any improvements."[67] Accordingly, Nolan-Stevaux concludes, "the BiOS approach explicitly creates a patent pool" which resides with BiOS and is then available to other comers through open source licenses.[68] She later describes the BiOS open source license as a "patent 'plus' pool," given that the license allows the licensee access to the licensed patent *in addition to* a "pool" of other improvements and know-how.[69]

3. Research Consortia

The term "patent pool" has been used very loosely to refer to the practices of consortia which have come together to share patents. The aim of the companies involved is generally to work together to prevent further patenting of the shared material. For example, in 1999 a group of ten pharmaceutical companies and a British charity formed the Single Nucleotide Polymorphism ("SNP") consortium in order to share information on SNPs in a public database. This effort effectively undercut any ability to patent and hence, has been referred to as an "anti-patent" pool.[70]

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[65] *Id.*

[66] Katharine M. Nolan-Stevaux, *Open Source Biology: A Means to Address the Access & Research Gaps?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 271 (2007).

[67] *Id.* at 305.

[68] *Id.*

[69] *Id.* at 308.

[70] David B. Resnik, *A Biotechnology Patent Pool: An Idea Whose Time Has Come?*, 3 J.

IV. PROPOSED SARS PATENT POOL

The efforts involved in SARS research have been hailed as a case study in international scientific collaboration.[71] In March 2003, several months after the outbreak of a form of severe atypical pneumonia, "WHO enlisted a network of laboratories from around the world to identify the etiological agent of the disease and to help contain it."[72] Very quickly the SARS coronavirus was identified, its genome was sequenced, and by early April several provisional patent applications were filed.[73] One of these, filed by the Genome Sciences Centre ("GSC") of the British Columbia Cancer Agency ("BCCA"), claimed the entire sequence.[74] These patents appear to claim rights in most diagnostic tests, drugs, or vaccines that have been or would be developed to cope with the outbreak.[75] Dr. Marco Marra, one of the leaders of the project at the BCCA, predicted the research would facilitate the development of antiviral treatments, including neutralizing antibodies and development of a vaccine to treat this emerging and deadly disease.[76]

The decision to seek patents on the SARS sequence was controversial within some of the filing institutions and among commentators at large.[77] In particular, some critics argued that the very fact that public institutions chose

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PHIL. SCI. & L., at Sec. 8 (2003), *available at* http://www6.miami.edu/ethics/jpsl/archives/papers/biotechPatent2.html.

[71] Matthew Rimmer, *The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines*, 5 MELB. J. INT'L L. 335, 337 (2004), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=603234.

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

[73] Rimmer, *supra* note 71, at 337.

[74] The first publicly available draft sequence was announced by scientists at the Genome Sciences Centre of the British Columbia Cancer Agency (BCCA) on April 12, 2003. Rimmer, *supra* note 71, at 340.

[75] *See* Coronavirus Isolated From Humans, U.S. Patent No. 7,220,852 (filed Apr. 12, 2004) (issued May 22, 2007); Human Virus Causing Severe Acute Respiratory Syndrome (SARS) and Uses Thereof, U.S. Patent No. 7,375,202 (filed Mar. 30, 2004) (issued May 20, 2008); SARS Virus Nucleotide and Amino Sequences and Uses Thereof, U.S. Patent App. No. 20070258999 (filed Apr. 28, 2004).

[76] Rimmer, *supra* note 71, at 340.

[77] *See* E. Richard Gold, *SARS Genome Patent: Symptom or Disease?* 361 THE LANCET 2002 (2003), *available at* http://cmbi.bjmu.edu.cn/cmbidata/SARS/pdf/113.pdf; Peter K. Yu, *SARS and the Patent Race: An Introduction to the "Patent Law, Social Policy, and Public Interest" Symposium* 3 (Mich. St. Univ. DCL Coll. of Law, Pub. Law & Legal Theory Working Paper Series, Research Paper No. 01-17, 2004), *available at* http://ssrn.com/abstract=451640.

to file patent applications in this case shows that the patent system does not properly serve the public good and is in need of modification.[78] Within the BCCA, one of the main arguments in favor of seeking a patent was put forward by, among others, Dr. Sam Abraham, director of the BCCA Technology Development Office. In his view there was a need to engage in defensive patenting in order to control, protect, and expand research into the SARS virus.[79] The BCCA had already adopted a policy of "graduated licensing": non-commercial institutions and individuals would have non-exclusive royalty-free access to the patent for research purposes, while commercial developers of diagnostics, prophylactics, and therapeutics would, respectively, have increasingly stringent conditions for licensing.

During the same period when the BCCA was pursuing a patent application, the Center for Disease Control ("CDC,"), Hong Kong University ("HKU"), and Erasmus Medical College submitted provisional patent applications.[80] The CDC sequence was substantially identical to the BCCA's, differing by only 15 additional nucleotides. The CDC also claimed "its application was to prevent others from monopolizing the field."[81] The HKU produced a refined sequence and along with its technology transfer office, Versitech, also said they were engaged in defensive patenting.[82] A fourth party, Erasmus Rotterdam University Medical Centre ("EMC") in the Netherlands, also asserted IP rights over parts of the sequence. As a result of all this activity, the situation around the SARS IP became complex and uncertain and could potentially have resulted in a delay of the development of SARS diagnostic tools and vaccines.[83]

In 2003, Simon et al., working out of CoroNovative, the technology transfer office at a spin out company of EMC, proposed that the four parties known to own key patent applications form a SARS patent pool. Simon's aim was to pursue a patent pool as a way in which careful application of existing

[78] Gold, *supra* note 77, at 2002.

[79] Dirk Meissner, *SARS gene patent application will help cure research, says B.C. Cancer Agency*, CANADIAN PRESS, May 5. 2003, http://cmbi.bjmu.edu.cn/news/0305/71.htm.

[80] Rimmer, *supra* note 71, at 337.

[81] *Scientists Race to Patent SARS Virus*, MSNBC.COM, Nov. 4, 2003, http://www.msnbc.msn.com/id/3076748/; Interview with Dr. Sam Abraham, Vice President, Strategic Relations, British Columbia Cancer Agency, in Vancouver, B.C., Can. (Mar. 5, 2009) (according to Sam Abraham he urged the CDC to seek a defensive patent, comparing the situation to the case of the Hepatitis C patents, where CDC researchers made some discoveries relating to the sequence but the patents ended up in the private sector; s*ee generally* John Cohen, *The Scientific Challenge of Hepatitis C*, SCIENCE, July 2, 1999, *available at* http://www.sciencemag.org/cgi/content/full/285/5424/26.).

[82] Rimmer, *supra* note 71, at 339.

[83] Simon et al., *supra* note 72, at 708.

regulations would avoid a fragmented patent landscape and reduce IP risk that could adversely affect the development of diagnostic and therapeutic technologies, as well as vaccines.[84] In addition, one of Simon's aims was to further the goals of open science.[85]

In response to Simon's suggestion, the four parties expressed their willingness to form a patent pool and enable wide access to the SARS genome.[86] The concept of a patent pool for SARS gained further support from the WHO SARS Consultation Group and the National Institutes of Health Office of Technology Transfer in the United States.[87] In turn, the BCCA, HKU/Versitech, and Erasmus MC/CoroNovative and the CDC initiated discussions with U.S. regulatory authorities to determine how such a pool might be formed in compliance with regulations.[88]

It has taken an extended period of time to get approval for the patents intended to be included in the patent pool, craft an agreement about pool structure and licensing terms, and address all the usual technical matters any pool would face to ensure that antitrust and other regulations are met. The potential SARS patent pool has had additional challenges that historic pools generally did not encounter. First, in the case of the SARS pool there were only patent *applications* – and no actual issued patents – when the parties announced their intention to pool. Thus, the pool was proceeding without even the certainty that the patents would issue. This situation, of course, reflected the perceived urgency of making the IP available in the face of a possible pandemic. Second, in the SARS context, the relationship between the patents and specific commercial products that might incorporate the patents' teachings differed from the historical precedents. In the SARS case, as for genomics in general, commercial therapeutic and prophylactic products can be placed on the market only after a lengthy research and development process, and the range of possible commercial endpoints remains only partially defined until well into the development process. As a result – and as discussed above – determinations of essentiality and complementarity are difficult to make, unless perhaps the pool was strictly limited to patents specifying genomic sequences and their associated proteins. For this reason, it is not clear how membership in the pool would be determined and whether the regulators in the U.S. would agree that the basis for these decisions would be acceptable.

As of February 2009, only two of the sequence patents had been issued in

[84] *Id.*

[85] *See generally id.*

[86] *Id.* at 709.

[87] *Id.*

[88] *Id.*

the U.S.[89] and the SARS patent pool continues to be at the letter of intent stage.[90] There has been no public announcement as to the cause of the delay, but the diminution of the threat of an epidemic has been cited by some of the principals as the likely reason.[91] After the implementation of public health control measures to isolate cases and quarantine contacts of SARS patients, the last case of SARS was reported in Taiwan on July 5, 2003, and the WHO declared the end of the SARS pandemic.[92] Thus, in a very real sense, the urgency behind making the SARS patents available has largely receded, as has the economic driver. Still, research has continued, as evidenced by the number of recent patents that have been issued on SARS-related work.[93]

The SARS patent pool thus remains an incomplete story of how a genomics patent pool is formed and functions. The efforts to form the pool are, however, certainly suggestive of the kinds of issues and opportunities raised by patent pools for genomics. Yet questions remain about the fruitfulness of such patent pools. Is it unambiguous that a narrow patent pool such as the proposed SARS one, consisting solely of sequences and related proteins, is useful? Is it possible that upstream patent pools, such as the one proposed for SARS, are unnecessary, given the apparent ability of companies to continue vaccine research without access to all sequences? Perhaps it remains the case that broad questions about the potential potency of patent pools in genomics will only be answered where there is a need (e.g., an epidemic), as well as an opportunity.

V. THE POTENTIAL VIABILITY FOR PATENT POOLS IN GENOMICS

The difficulty in forming a genomics patent pool has, along with other concerns, given rise to many questions about the utility of pools in this context. In this section we consider some of the challenges for patent pools in genomics and offer some preliminary responses. In the succeeding section we present our versions of the strongest positive arguments for the use of patent pools for genomics in the appropriate circumstances.

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[89] *See* U.S. Patent No. 7,220,852 (filed Apr. 12, 2004) (issued May 22, 2007); *see also* U.S. Patent No. 7,375,202 (filed Mar. 30, 2004) (issued May 20, 2008); *c.f.* U.S. Patent App. No. 20070053878 (filed Apr. 28, 2004) (this patent has yet to be issued).

[90] *See* James Simon, *Dealing with Patent Fragmentation: The SARS Patent Pool as a Model*, *in* GENE PATENTS AND PUBLIC HEALTH 115, 119 (Geertrui Van Overwalle ed., 2007).

[91] Interview with James Simon, Chief Operating Officer Deputy Chief Executive Officer, ViroNovative BV, in Vancouver, B.C., Can. (Jan. 9, 2009).

[92] KENRAD E. NELSON & CAROLYN MASTERS WILLIAMS, INFECTIOUS DISEASE EPIDEMIOLOGY: THEORY AND PRACTICE 432 (Jones and Bartlett 2d ed. 2007).

[93] *See*, *e.g.*, '202 Patent; *see also* '852 Patent.

A. Genomics Discoveries do not Lend Themselves to Pool Creation

It is possible that the very nature of genomics makes it difficult to demonstrate that relevant patents are "essential." The intended end products of genomics research – whether drugs, diagnostics, or other health related products – are often only loosely defined in upstream research (e.g., a Vascular endothelial growth factor inhibitor), and thus in this context "essentiality" is a difficult concept to define. Further, it is possible that the inability to definitively know the end product of upstream genomics research, together with the generally long development cycles in genomics, makes it difficult to assemble the appropriate patents that will "integrate complementary patent rights."[94] This potential hurdle has not been well tested because to date, there has not been a cohort of upstream genomics patent pools to follow through to development. Further, it is unclear whether competition authorities, such as the U.S. DOJ or FTC, would accept genomics patent pools that include patents with a weaker degree of essentiality, as might be the case where downstream applications of discoveries/inventions are unclear.[95]

In the context of diagnostic genetics, some authors have argued for creating standards to facilitate patent pooling and to eliminate confusion over definitions of essentiality.[96] These authors explain that "the use of a standard will benefit U.S. and European companies because it will provide them with guidance in deciding which patents should be included in the pool [to satisfy the 'essentiality' requirement and help them avoid] antitrust and unfair competition challenges."[97] Other authors suggest that with a defined field of use the absence of standards need not be of consequence.[98] Our limited review of the SARS patent pool suggests that while the parameters of essentiality are not clear, it is also not clear that a standard would help make this determination. This problem arises largely because of the upstream, non-product related status of the SARS patent pool material. Another possible approach to resolving this challenge is to attempt to employ something other than a product as the organizing principle of a patent pool. One candidate is to have all patents in a pool relate to a particular disease or type of therapy.[99]

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[94] CLARK ET AL., *supra* note 1, at 7.

[95] *See, e.g.*, Rochelle Seide et al., *Biotechnology*, 27 LICENSING J. 28, 29 (2001).

[96] Ted Ebersole et al., *Patent Pools and Standard Setting in Diagnostic Genetics*, 23 NATURE BIOTECH. 937, 937 (2005).

[97] *Id.*

[98] Larry Horn, *Alternative Approaches to IP Management: One-stop Technology Platform Licensing*, 9 J. COM. BIOTECH. 119, 124 (2003).

[99] This is the approach employed by the proposed UNITAID pool for AIDS medications. However, it also is centered on particular products that comprise fixed dose combinations. The MPP would then be product-based as traditional pools have been. However, unlike traditional pools in the U.S., it would also involve multiple products. Press Release,

Pursuing this suggestion further is beyond the scope of this paper.

B. Economic Incentives

Many have dismissed any possibility for patent pools for genomics because of the lack of apparent economic incentives to participate in any such pool.[100] The lack of incentives can be said to be especially poignant in the case of small biotech companies.[101] Especially for start-ups, the patent portfolio serves as the major – and sometimes only – tangible asset. And even for larger biotechs and big pharmaceutical companies, the optimal use of patents, from a commercial perspective, is usually to establish a favorable context for their own products that require other companies either to work around them or to seek to license. In either the small or large biotech scenario, the prospect of putting IP into a pool, and thereby ceding a degree of control and possibly realizing less revenue, could make this option less than attractive.[102]

Two major considerations that potentially undercut the notion that small and large biotech companies lack the incentives to engage in patent pooling are the threat of compulsory licensing and the possibility that the formation of a thicket would result in IP languishing.[103] Compulsory licensing was included in the Trade-Related Aspects of Intellectual Property Rights ("TRIPS")[104] Agreement, but up to now actual instances of invoking that measure have been relatively few.[105] Nevertheless, the very threat of compulsory licensing has the potential to realign the risk-benefit determination.[106] Historically, it was precisely the threat of compulsory licensing, exacerbated by wartime

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UNITAID, UNITAID Moves Towards a Patent Pool for Medicines, Jul. 9, 2008, *available at* http://www.unitaid.eu/en/20080709113/News/UNITAID-moves-towards-a-patent-pool-for-medicines.html (last visited Nov. 18, 2009).

[100] Resnik, *supra* note 70, at Sec. 8.

[101] *Id.*

[102] *See, e.g.*, Grassler & Capria, *supra* note 5, at 112 (discussing patentee hold-out power in the absence of a pool).

[103] Simon et al., *supra* note 72, at 708-09; Shapiro, *supra* note 5, at 120.

[104] World Trade Org., Compulsory Licensing of Pharmaceuticals and TRIPS, http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Nov. 29, 2009).

[105] *See generally* Carlos M. Correa, *Public Health and the Implementation of the TRIPS Agreement in Latin America, in* TRADE AND HEALTH: SEEKING COMMON GROUND (Chantal Blouin, Jody Heymann & Nick Drager eds., 2007).

[106] Countries have threatened to grant such licenses in order to obtain substantial price reductions for medicines, as seen in the case of South Africa. *See generally* Carlos M. Correa, *Refusal to Deal and Access to an Essential Facility: Balancing Private and Public Interests in Intellectual Property Law*, *in* MELANGES VICTOR NABHAN. (Yvon Blais ed., 2004).

conditions that led to the formation of the aircraft patent pool.[107] Arguably, the prospect of a pandemic such as SARS could similarly produce enormous pressure for compulsory licensing of IP and could tilt the risk-benefit analysis in support of voluntarily pooling relevant patents to reduce the threat.

In addition, if patent thickets or an anticommons were to develop in an area where a company has IP, then there is the real possibility that the development would be stymied and the value of the patents in that field could be substantially reduced. Under such circumstances, there might also be a very real reason to engage in patent pooling. That said, we recognize that there may be additional strategic reasons for obtaining patents – related to building or protecting tangible assets – where the actual portfolio of licenses may not be important. In this case, the attraction of a patent pool may not exist.

Finally, we note that economic incentives may not stand as the only priority for many of the universities and research institutions that would be candidates for forming patent pools, especially those institutions centered on upstream inventions. Some of these institutions have articulated a range of priorities in the manner that patents are handled, such as supporting the norms of open science, and these alternate priorities may be strong contenders to direct economic factors.[108] We return to an aspect of this point in the next section.

C. The Challenge in Forming Patent Pools

The perception that patent pools are difficult to form may also hinder pursuit of such arrangements. Indeed, it has been almost a decade since the USPTO published its *Solution?* document suggesting that patent pools may resolve some problems in biotechnology[109] and it has been five years since SARS sequencers announced their intention to form a SARS patent pool.[110] Yet, there has been little progress in forming genomic patent pools and to date, there is no SARS patent pool. There is no doubt many factors contributed to these extended intervals – e.g., in the case of SARS, the threat of an epidemic is now considered quite low and thus the sense of urgency has all but dissipated. Nevertheless, one factor that appears certainly to have played a role is the difficulty of knowing how to form a genomics patent pool that adequately conforms to the guidelines. Considerable resources are required to develop this structure and without the external pressures, as noted above, an investment of resources by potential patent pool participants or government

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[107] *See* CLARK ET AL., *supra* note 1, at 4.

[108] THE ASS'N OF UNIV. TECH. MANAGERS, IN THE PUBLIC INTEREST: NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY 1 (2007), http://www.autm.net/Nine_Points_to_Consider.htm [hereinafter NINE POINTS].

[109] *See* CLARK ET AL., *supra* note 1 at 8-10.

[110] *See generally* Simon et al., *supra* note 72.

reviewers may not be forthcoming. Certainly, after one or more genomics patent pools comes into being one can expect that this difficulty will diminish.

D. Fulfilling Stated Aims

One of the stated aims of patent pools is to increase access to information contained in IP.[111] There are numerous interpretations of "access." In the field of genomics IP, one of the most prevalent approaches to encouraging access occurs via "graduated licensing," which means that there is a sliding scale of licensing terms along several dimensions. As a general approach, most licensing parties formulate licensing terms for commercial entities that are more demanding in terms of costs and obligations than those for academic researchers. Such licensing terms are also often more stringent for therapeutic applications than for diagnostic ones. The aim is generally to ensure that the subject of the IP is available. Toward this end, the prospective members of the SARS patent pool have stated their intention to employ graduated licensing.[112] That said, in its Business Reviews, the U.S. DOJ has taken the position that patent pools must be licensed in a non-discriminatory manner,[113] an approach which might make the use of graduated licensing the subject of close attention by regulators.[114]

It is also possible that fulfilling the requirements of a patent pool articulated in the *Guidelines* and *Solution?* documents would cause the resulting pool to be too narrow and thus diminish its usefulness. As discussed above, the technical requirements for forming a patent pool in the U.S. are intended, in reflection of antitrust considerations, to minimize the number of patents that can legitimately be included. There are stringent rules, for example, to ensure that only "essential" patents are included in a pool.[115]

The challenge for genomics patent pools is that the candidates for pool inclusion may embody discoveries so far upstream that it might be difficult to discern exactly what products they relate to. There are also not likely to be discernible standards by which to measure essentiality. The net result may be to diminish the possible utility of the genomic patents pools as genomics pools that qualify may be too narrow to be useful for development. In the case of the proposed SARS pool, the strategy was to include only patents that covered the

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[111] *See* CLARK ET AL., *supra* note 1 at 10.

[112] In his article James Simon only mentioned non-exclusive licensing. *See* Simon et al., *supra* note 72, at 709. However, interviews have suggested that some form of graduated licensing was contemplated. Interview with James Simon, *supra* note 90.

[113] *See, e.g.*, Letter from Joel Klein to Carey Ramos, *supra* note 12, at 3.

[114] *See* Krattiger, *supra* note 43, at 74; *see generally* GUIDELINES, *supra* note 35.

[115] *See* Krattiger, *supra* note 43, at 74; Gaulé, *supra* note 39, at 128; *see generally* GUIDELINES, *supra* note 35.

SARS sequence and the proteins expressed. Thus, much of the development work relating to SARS – vaccines, diagnostics and therapeutics – would likely have recourse to the SARS sequence. Pooling sequence IP would then at least eliminate the growth of thickets in this crucial area.

E. Access to Medicines

In this discussion, it is important to acknowledge that, as conceived, patent pools will not in and of themselves solve the problem of access to medicines in the developing world. The possibility that patent pools could help solve this ongoing problem has been put forward mainly by those advocating a "pool" of patents relating to HIV/AIDS. As mentioned above, variants such as this are not intended to meet the requirements laid out by the *Guidelines* and *Solution?* documents. One can, however, wonder whether patent pools meeting those requirements could help with access to medicines in the developing world (or the developed world for that matter).

We believe that patent pools are useful *indirectly* in the sense that any measures that minimize the possibility of thickets or an anticommons promote access to information and therefore drug development in general. However, in this context, it is important to recognize that patent pools, whether they fit the U.S. definition or not, might also improve access in other ways. Thus, patent pools themselves can be combined with a wide range of licensing terms: for example they can employ graduated licensing terms or not. In this sense, patents pools can be one important element in a strategy that addresses questions of access. A clear example of this approach is contained in Nolan-Stevaux's notion of "patent 'plus' pools."[116] Nolan-Stevaux initially applies this term to describe the BiOS approach, which involves "pooling" patents and then using Open Source-type ("OS-type") licenses. The BiOS "pool" described by Nolan-Stevaux was originally formed in the field of agriculture and plant biotechnology. Given its apparent potential for increasing access to information, a number of authors have proposed using that approach and some form of OS-type licenses in the area of health biotechnology.[117] There is clearly much work to be done in considering how to formulate patent pools as part of an overarching access strategy. Current discussion suggests that, at a minimum, patent pools might be part of a strategy to address access to medications in the developing world.

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[116] *See* Nolan-Stevaux, *supra* note 66, at 308.

[117] Janet Elizabeth Hope, Open Source Biotechnology (Dec. 2004) (unpublished Ph.D. thesis, Australian National University) (on file with author), *available at* http://cgkd.anu.edu.au/menus/PDFs/OpenSourceBiotechnology27July2005.pdf.

VI. A ROLE FOR PATENT POOLS IN ADVANCING OPEN SCIENCE

Our discussion of patent pools in general and the SARS patent pool in particular makes clear that there are promises and challenges associated with this method of handling IP. As outlined earlier, we believe that in addition to solving problems around patent thickets and access, patent pools may have value in utilizing patents to preserve a zone of open science in certain upstream research contexts. To be clear, our aim is not to make the broad claim that patent pools are appropriate in every situation or for all upstream genomics research. Rather, we note that in certain limited circumstances, such as the SARS effort and at least some research areas, patent pools may achieve this limited end.

The special goals we have identified aim to demonstrate that genomics patent pools may be seen as a kind of alternative approach to IP that is closer in spirit to the norms of open science than to the norms of standard commercial patenting. Specifically, the fact that patent pools can function as a form of "extended" defensive patenting coupled with the practice of progressive licensing for patent pools support this view.

A. Extended Defensive Patenting

Defensive patenting is common among commercial firms. In those cases it provides a party with a repertoire of patents to prevent other parties from gaining a patent foothold in a technology. In addition, defensive patents can serve as counterclaim weapons if another party asserts patent invalidity. In this sense, such patents are also used as an offensive tool to build up protection around a patent portfolio to strengthen a firm's negotiating position with competitors (e.g., as in cross-licensing).

In the SARS case study, the research institutions contended that it was necessary to engage in "defensive" patenting to protect public access to important scientific research. By filing patent applications, they intended to pre-empt commercial applicants from obtaining patents that might hinder further research and development relating to SARS. The potential effectiveness of the pool would come about if, for example, the entire SARS coronavirus genome and associated proteins were in the pool. If a single patent licensed in a graduated manner is a strong defense against using patents to limit the scope and intensity of research on a technology, the idea was that a group of patents similarly licensed would be an even stronger defense.[118]

[118] Given the very limited number of patent pools that have even been attempted, much less completed successfully, it is difficult to gauge effects, but at least one of the principals in the SARS case believes that the large number of MTAs issued by his institution when the SARS genome was sequenced was facilitated by the announcement that it would be available to all comers at little or no cost. Interview with Sam Abraham, *supra* note 81.

B. Progressive Governance

We propose that patent pools incorporate progressive governance in order to help further the goals of open science. By "progressive governance," we mean that licensing and other terms of governance are at least directionally aligned with guidelines for licensing genetic inventions proposed by the Organization for Economic Cooperation and Development[119] and with cautionary points raised by influential managers of university technology.[120] Other components of progressive licensing could include graduated licensing so that, for example, research access could be obtained at little or no charge. If applied to patent pools, the pool would effectively establish an explicit research exemption in an area of upstream research.[121] In addition, one could structure progressive licensing so that, for example, diagnostic applications pay less than therapeutic ones.

It is important to note that adopting such an approach for patent pools is not straightforward. As Merges points out, in recent Business Review Letters the DOJ has explicitly stated that for patent pools "licensing is non-discriminatory."[122] The DOJ's sense of non-discrimination is strong and seems to preclude the ability of the pool, acting as a pool, to license in any graduated, or differentiated, way. Thus, for example, the MPEG-2 pool argued against having the pool manage the licensing of separate *components* of the pool. That is, MPEG-2, like the others, made provisions for pool members to license their patents without licensing all the patents in a pool, but the pool licensing administration itself would not be engaged in that process.[123] The pool itself

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The fact that multiple institutions were also submitting patents could have led some to shy away from a complex IP situation. The announcement that the key applicants intended to form a pool that would operate on the same principles ameliorated that concern.

[119] *See generally* ORG. FOR ECON. COOPERATION AND DEV., GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS (2006), http://www.oecd.org/dataoecd/39/38/36198812.pdf.

[120] *See generally* NINE POINTS, *supra* note 108.

[121] In most jurisdictions there are statutory or common law "research exemptions." However, the scope of the exemption is a matter of contention most everywhere, but especially in the U.S. where litigation outcomes appear to have severely narrowed the field of what qualifies as research. Madey v. Duke Univ., 307 F.3d 1351, 1360-61 (Fed. Cir. 2002). Despite this, at least one prominent commentator has noted that in practice, many researchers appear to use proprietary material with impunity, so much so that some scholars argue for reforming the patent system, as it leads otherwise law-abiding citizens to ignore the law. Rebecca Eisenberg, Presentation at the W. Maurice Young Centre for Applied Ethics Workshop, Alternative Intellectual Property and Technology Transfer Offices – Exploring the Evolving Landscape. (May 9, 2008).

[122] Merges *supra* note 32, at 47.

[123] *Competition and Intellectual Property Law and Policy in the Knowledge-Based*

licenses the entire pool to all comers; someone wanting to license only one or more patents in the pool has to deal directly with the relevant patent owner(s).

Proposals to introduce graduated licensing of a patent pool might put pool licensing administrators in a position where they would be required to discriminate among types of licenses and perhaps licensees. There are some "natural" measures that can achieve some degree of scaled licensing and would probably not raise anticompetitive issues. For example, royalties on product sales "naturally" discriminate between research and commercial institutions since research institutions generally do not engage in sales and marketing and thus would not pay royalties that could be built into licensing terms.[124] Nevertheless, there could be some terms that involve discrimination among types of applications and, given the degree of vetting of structural licensing terms, these would likely draw an additional level of scrutiny by regulators to ensure that the pool is *not* anti-competitive.

Notably, the notion of progressive governance is already in play: all the parties to the SARS pool are either public health research institutes or are closely linked to such organizations, and it is their announced intention to employ what we term progressive governance.

It may well be that pools formed by public institutions are good candidates for adopting progressive governance, but we wonder whether other institutions would adopt such an approach if they were to participate in a patent pool. The suspicion that progressive governance would not be widely adopted may be the basis for the proposal made by Caulfield and associates concerning independently governed patent pools that appear to build upon the arm's length expert bodies that are mainstays of modern pools:

> If structured appropriately, [an independently governed patent pool] could be given the explicit mandate to promote the public good in its decision making about access and licensing, thereby shifting the focus away from profit as the sole motivator. All decisions and rationales by the independent body would be open to public scrutiny and would balance the necessity of industry involvement, the interests of researchers, ethical issues, and the desire to keep licensing terms reasonable to ensure that the public has access to valuable technologies.[125]

Economy: Joint Hearings Before the United States Department of Justice Antitrust Division and the Federal Trade Commission (2002) (statement of Baryn S. Futa, CEO and Manager, MPEG LA, LLC), http://www.ftc.gov/opp/intellect/020417barynfuta.pdf.

[124] Thanks to James Simon for raising this point. Interview with James Simon, *supra* note 91.

[125] Timothy Caulfield et al., *Trust, Patents and Public Perceptions: The Governance of Controversial Biotechnology Research*, 24 Nature Biotech. 1352, 1353 (2006), *available at* http://www.nature.com/nbt/journal/v24/n11/full/nbt1106-1352.html.

Although this suggestion is provocative, it is unclear to us what exactly is being proposed. The extended mandate could of course be voluntarily adopted within the governance system established by members of a pool. However, if the extended mandate were imposed on the governing board by some governmental body by virtue of legislation or regulation, then we have a vastly different situation. Among many other things, such an arrangement could work against the voluntary formation of the pool itself. That is, the pool would in effect be subject to compulsory licensing, the avoidance of which is one possible motivator of pool formation, at least among commercial organizations. To be clear, we are not arguing against pools that aim explicitly and intentionally to serve the public interest. However, in our view this is best achieved by encouraging adoption of patent pools and progressive licensing, especially for upstream areas.

Finally, we hypothesize that if patent pools of the sort we describe were widely adopted, they could serve to drive competition for IP rights away from upstream areas and toward downstream development as James Simon pointed out in his proposal to form a SARS patent pool:

> It would enable wide access to the genomic sequence of SARS – a key building block for the development of vaccines – driving competition away from accessing such IP rights to areas downstream in development, resulting in more innovative products. Furthermore, the formation of such a patent pool would send a powerful signal to putative licensees . . . that patent owners mean to make their IP rights available from [sic] standard rates, reducing IP risks and licensing costs and in turn potentially stimulating greater and/or earlier investment in product development.[126]

Reducing IP competition at the upstream end would in effect bring the IP system more in line with the "openness" claimed for science. Pools of this sort would of course serve the purpose of avoiding thickets and anticommons effects. And they would do so without compromising the possibility of commercial development and perhaps without requiring a major overhaul of patent law, regulation, and practice.

However, the widespread adoption of patent pools of this sort faces challenges in addition to the ones we have canvassed. We have for example, envisioned the burgeoning of these patent pools at the upstream end, but it is far from clear just where upstream ends and downstream begins – there may well be clarity at the extremes, but the huge middle is much less clear. One natural approach to meeting this challenge is to let the system sort itself out. That is, let the requirements and practices of developers and researchers drive where pools are needed. Many researchers have claimed that the IP system is

[126] Simon et al. *supra* note 72, at 709 (emphasis added).

capable of adjusting itself, albeit more slowly than many would like.[127]

VII. CONCLUSION

On balance the considerations we have raised make us hopeful but cautious about the prospects for genomic patent pools. The possibility of public research institutions facilitating a move towards the norms of open science and public benefit still suggest that patent pools may have a role to play in this area in the future.[128] The SARS patent pool will likely never reach fruition as long as the public health threat, and thus the economic incentive, seem negligible. Yet a patent pool employing progressive governance is certainly one candidate for an alternative IP approach at a time when there is widespread desire for IP reform.[129]

[127] *See generally* Robert P. Merges, *A New Dynamism in the Public Domain*, 71 U. CHI. L. REV. 183 (2004).

[128] *See generally* Richard T. Mahoney et al., *The Introduction of New Vaccines into Developing Countries IV: Global Access Strategies*, 25 VACCINE 4003 (2007).

[129] *See* E. RICHARD GOLD ET AL., THE INNOVATION PARTNERSHIP, TOWARDS A NEW ERA OF INTELLECTUAL PROPERTY: FROM CONFRONTATION TO NEGOTIATION 3 (2008), http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP_Report_E.pdf.