PATENT POOLING BEHIND THE VEIL OF UNCERTAINTY: ANTITRUST, COMPETITION POLICY, AND THE VACCINE INDUSTRY

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INTRODUCTION

Consider the following recent outbreaks – one a threatened pandemic and one an actual pandemic. Each sickness was caused by a virus and for each, a vaccine was or is being sought. In each case, a vital portion of an essential upstream innovation was ostensibly subject to multiple patent applications or patents. Moreover, ownership of the respective upstream innovation in question was actually or possibly spread across multiple entities. These general facts describe both the Severe Acute Respiratory Syndrome ("SARS") outbreak in 2002[1] and the H1N1 outbreak in 2009.[2] In each instance there was much social hand-wringing attendant to the actual or possible patent fragmentation regarding vital intellectual property inputs necessary to combat the diseases. The proposed or actual resolutions to the fragmentation, however, differed tremendously between the two outbreaks. In one instance a patent pool was proposed, and in the other a single for-profit secured exclusive licenses from the other patent holders.

The ability of humanity to combat pandemics often entails the navigation of intellectual property rights and, in particular, patents. These rights are frequently fragmented among multiple owners or, to further complicate matters, multiple potential owners. Perhaps not surprisingly, patent pooling has been proposed as a mechanism to help address the possible pitfalls of fragmentation. Given the exclusivity inherent in patent rights (and with it the potential for market power) as well as the potential for interactions among competitors, patent pools and other collective approaches to addressing these global public health threats increasingly raise possible antitrust questions.[3]

[1] *See* Matthew Rimmer, *The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines*, 5 MELB. J. INT'L L. 335, 336 (2004) (indicating that the SARS epidemic "had a significant impact upon the global economy" and that it "has been variously described as a medieval plague, a medical disaster and an economic blight"). In the first eighteen months after SARS's identification, the World Health Organization reported 8098 known cases of infection and attributed 774 deaths to the virus. *Id.*

[2] *See generally* Seth J. Sullivan et al., *2009 H1N1 Influenza*, 85 MAYO CLIN. PROC. 64 (2010). "Within 2 months of its discovery [in April 2009] a novel influenza A virus (H1N1) . . . caused the first influenza pandemic in decades. . . . By June 11, 2009, nearly 30,000 cases of 2009 H1N1 had been confirmed across 74 countries . . . ." *Id.* Shortly thereafter, in July 2009, resource limitations prompted the CDC and WHO to stop reporting confirmed and probable cases of H1N1 infection. *Id.* at 67.

[3] Professor Brodley's observation regarding the unique intellectual puzzle that joint ventures pose provides a valuable perspective for this inquiry into patent pooling. Brodley asks, "Why is it that normally competitive firms would join in a mutual enterprise?" Joseph F. Brodley, *Analyzing Joint Ventures with Foreign Partners*, 53 ANTITRUST L.J. 73, 73 (1984). He further writes:

Unfortunately, clear answers to such questions are not forthcoming to the extent that current antitrust guidance regarding patent pools, whether in the form of judicial rulings or agency pronouncements, is directed almost exclusively to the very distinctive factual context of standard-setting organizations.

This Article begins with "a tale of two diseases" which briefly discusses the global health threats SARS and H1N1 pose. As becomes readily apparent, however, the real story is much broader and concerns the suitability of patent pools for overcoming the challenge that fragmented upstream patent rights pose to downstream innovation.[4] Society's understanding of the antitrust consequences of patent pools has developed primarily in the context of standard-setting. While vaccine development and such standard-setting activities in the computer, electronics, and telecommunication industries are both characterized by fragmented upstream patent rights, they differ significantly along at least two key dimensions. First, the standard-setting process itself creates market power for particular technologies which are then frequently pooled, whereas in the vaccine context the bottleneck technologies have market power absent the pool. Second, the design of a standard creates a high level of certainty regarding the relationships among the relevant pieces of intellectual property. Such certainty is frequently absent in the case of vaccine technologies where, for example, the significance of an input (e.g., essentiality) may be unclear at the time of licensing. This Article employs vaccine development as a concrete setting through which to explore the antitrust aspects of pools for which essential inputs are less discretionary and, perhaps counterintuitively, more uncertain.

In Part II, key aspects of the vaccine industry's patent, regulatory, and competitive landscapes are described. Given those parameters and suspending antitrust analysis, Part III applies basic economic reasoning to a series of hypotheticals to analyze the relative value, if any, of patent pooling to ameliorate challenges that patent fragmentation and technological uncertainty pose. Part IV then reintroduces antitrust law as a possible constraint on pooling arrangements, identifies two specific areas of the antitrust law (the

> The task of antitrust policy is to separate the usual, economically desirable joint venture from the occasional, anticompetitive joint venture. The fact that this is sometimes difficult to do is what gives the subject of joint ventures its intellectual fascination. The challenge is that the very quality that makes the joint venture economically desirable, the fact that it brings together otherwise independent firms in a common endeavor, can also create antitrust risk.

Id.

[4] *See generally* Joseph F. Brodley, *The Economic Goals of Antitrust: Efficiency, Consumer Welfare, and Technological Progress*, 62 N.Y.U. L. REV. 1020 (1987). Professor Brodley forcefully advocates that the promotion of "innovation efficiency" should be among the foremost goals of antitrust policy. *Id.* at 1025. "Innovation efficiency is achieved through the invention, development, and diffusion of new products and production processes that increase social wealth." *Id.*

pooling of substitutes and the exclusive licensing of pools) that warrant reconsideration, and offers recommendations. Current antitrust law and agency guidance is seen to have both too much and too little to say about patent pools within this particular context. While pooling is not the panacea that some would make it out to be, its value to date arguably has been limited by a lack of clarity regarding antitrust treatment of technological uncertainty.

I. A TALE OF TWO DISEASES

With regard to SARS, ownership of the relevant building blocks of the virus necessary for creation of a vaccine could potentially be held by several intellectual property rights holders. Four separate entities each "filed patent applications that incorporated either parts, or the whole, of the genomic sequence of SARS."[5] This circumstance was not surprising given that these, and other, entities were engaged simultaneously in sequencing the SARS virus.[6] Multiple, potentially blocking patents, could, therefore, encumber the genomic sequence that researchers need to develop a vaccine.[7] Furthermore, near simultaneous discovery of a single essential technology made priority of invention (and hence ownership) uncertain. When those key applicants indicated their desire to create a patent pool, the issue became how the antitrust authorities would assess such an undertaking.[8] Fortunately, the SARS outbreak turned out to be more mild and short-lived than expected. Consequently, the antitrust issues were not resolved.

In contrast to SARS, humanity has been less fortunate with regard to the H1N1 influenza outbreak that the World Health Organization ("WHO") officially declared a pandemic.[9] Interestingly, the intellectual property rights landscape relating to H1N1 bears a certain similarity to that characterizing SARS. With regard to H1N1, however, the reaction to the fragmentation of highly relevant intellectual property has not been to create a patent pool. Instead, rights to a vital set of intellectual property rights, so-called "reverse genetics" technology, were consolidated when a single, for-profit entity (MedImmune, Inc.) obtained exclusive licenses to key patents.[10] Perhaps more

[5] 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).

[6] *Id.* at 708.

[7] *Id.* at 709.

[8] *Id.* The law firm of Morgan Lewis and Bockius is providing pro bono services "for discussions with the antitrust authorities." *Id.*

[9] Press Release, Dr. Margaret Chan, Dir.-Gen., World Health Org., World Now at the Start of 2009 Influenza Pandemic (June 11, 2009), *available at* http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/index.html.

[10] Press Release, MedImmune, MedImmune Expands Patent Estate for Reverse Genetics with New Rights from Mount Sinai School of Medicine (Dec. 7, 2005), *available at* http://www.medimmune.com/news_pressroom.aspx?NID=793603.

telling than this exclusive licensing scheme itself is the reaction, or lack thereof, it has received from any number of key entities. The American antitrust agencies do not appear to have offered any resistance, and the WHO's Initiative for Vaccine Research seemed pleased that the exclusive rights-holder has proclaimed that it will act benevolently.[11]

An effective response to a disease outbreak requires the immediate mobilization of scientific resources. Great forethought should be given to identifying and, when possible, mitigating or even eliminating legal obstacles to such mobilization. This Article critically assesses the role of antitrust law and policy within this context. Would or should competition-related considerations have impeded the formation of a potential SARS patent pool? Would such issues have resulted in the SARS pool being structured or restructured in a manner that satisfies the antitrust laws but is suboptimal along other dimensions? What are the broader implications for deterring or encouraging patent pool formation more generally? Conversely, ought competition policy or antitrust considerations have impeded MedImmune's acquisition of exclusive rights to this important reverse genetics technology at issue? What are the relative strengths and weaknesses of each of these (and still other) intellectual property arrangements on innovation? Answering those questions is highly fact-dependent. Nonetheless, this Article's efforts to address those questions within the context of vaccines reveals important market dynamics and tradeoffs that can help inform antitrust analysis in all industries in which innovation requires access to potentially critical patents with diffuse ownership and whose technological relationship to each other is uncertain.

II. AN OVERVIEW OF THE VACCINE INDUSTRY

As a foundation for exploring the potential role of patent pools within the vaccine industry, this Part introduces the key features of the industry's patent, regulatory, and competition landscapes. While distinguished for ease of

[11] For example, the Initiative for Vaccine Research ("IVR"), part of the World Health Organization, described MedImmune's acquisition of the four patents believed critical to development of the vaccine in order to combat the "highly pathogenic" strains of influenza in the following manner:

> Negotiating access to these [disparate patents] used to be complex, however these have now been licensed exclusively to MedImmune Inc. (USA). This patent portfolio is highly relevant to the issue of access to pandemic influenza vaccines . . . . MedImmune, Inc., has taken steps to ensure that its patent rights do not inhibit the development and commercialization of a pandemic influenza vaccine.

IVR, MAPPING OF INTELLECTUAL PROPERTY RELATED TO THE PRODUCTION OF PANDEMIC INFLUENZA VACCINES 18 (2007), *available at* http://www.who.int/vaccine_research/diseases/influenza/Mapping_Intellectual_Property_Pandemic_Influenza_Vaccines.pdf. The IVR discussion document then acknowledges that "MedImmune has recently been acquired by Astra Zeneca. It is not yet known what effect, if any, this acquisition will have on the access to the reverse-genetics intellectual property." *Id.* at 19.

discussion, these three dimensions are interrelated facets of the industry's overall operating environment. Several key themes emerge from this overview that subsequent sections will explore including: vaccine development frequently requires access to multiple patents; ownership of key patents is often fragmented; and, particularly during the early stages of research and development ("R&D"), significant uncertainty exists regarding the value of specific technologies. These factors can impede timely vaccine development by creating transaction costs in licensing negotiations. In addition, fragmented ownership can lead to inefficient cumulative licensing fees, which can discourage development and/or end-use sales.

Before addressing the vaccine industry specifically, it is useful to place it within the more general context of the pharmaceutical industry. Although an oversimplification, the pharmaceutical industry colloquially can be divided into at least two primary sectors: "drugs and bugs."[12] "Drugs" refers to the small-molecule arm of the pharmaceutical industry; that is, products that are chemically synthesized. The majority of pharmaceutical products fall in this category. "Bugs" refers to the biologics arm of the pharmaceutical industry; that is, products that are created from living organisms such as antibiotics, vaccines, and rDNA products. While this Article focuses upon vaccine development, the relevant actors in the field are frequently intertwined with, and increasingly dominated by, the drug industry. As such, the vaccine landscapes delineated herein bear a strong resemblance to those characterizing the drug industry.

A. *Patent Landscape*

America's intellectual property regimes were created in response to the keen, albeit rudimentary, recognition of the potentially deleterious effect of competition upon innovation.[13] Exclusivity enhances an innovator's ability to generate returns on investment sufficient to justify undertaking oftentimes costly R&D. Patents, the primary focus here, constitute both a response to competition and, in turn, influence the nature of competition. Central to the patent regime are key statutes that are relatively broad in nature and for which common law development through fact-specific applications is of paramount importance.[14] To the extent useful generalizations can be drawn, they must often function at the industry level.

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[12] I am grateful to my colleague Geoffrey G. Dellenbaugh, Ph.D., for numerous valuable conversations and, more specifically, for this apt metaphor.

[13] *See generally* Hillary Greene, *Afterword: The Role of the Competition Community in the Patent Law Discourse*, 69 ANTITRUST L.J. 841, 844-47 (2002) (arguing that patent protection "can have a range of effects on innovation").

[14] *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1577 (2003) ("[D]espite the appearance of uniformity, patent law is actually as varied as the industries it seeks to foster. A closer examination of patent law demonstrates that it is

Patents play a central role in the pharmaceutical industry with regard to both bugs and drugs. This Section briefly considers the role of such intellectual property rights specifically within the vaccine industry in terms of the types of innovations being patented, the number of patents being conferred, and important consequences of those patenting trends. In so doing, it underscores how such exclusive rights can both incentivize and deter innovation. The complex relationship between exclusivity and innovation comes to the fore given the existence of fragmented patent ownership and the importance of sequential innovation.

Patent protection within the context of vaccines assumes numerous forms including patents on various biologic products and methods of creating or administering those products as well as future improvements.[15] Like their drug-based counterparts, these bug-based patents confer valuable exclusivity.[16] In fact, "[p]ioneer biologic drugs are covered by more and varied patents, including manufacturing and technology platform patents, than small-molecule branded products [drugs]."[17] License agreements generally include a range of provisions including: payment terms (e.g., royalty rates, upfront fees, or some combination thereof), the term or length of the license, and other elements such as whether the license is exclusive and whether it is restricted to particular uses. License fees primarily allow the patent holder to recoup its R&D investment, rather than reflecting some direct cost associated with the transactions between licensee and licensor, since the marginal cost of giving access to the actual intellectual property contained in a patent does not increase with the use of the patent.

The manufacture of biologic products often necessitates a substantial number of licenses which, in turn, "result[s] in significant 'stacking' of patents (or royalties) compared to the small-molecule patent [products]."[18] One scholar observed, "In the biotech and pharmaceutical industries, where [the royalty for] a non-exclusive license to a 'must have' technology averages

unified only in concept. In practice the rules actually applied to different industries increasingly diverge."). For a discussion of the biotechnology industry, see *id.* at 1676-87.

[15] MICHAEL A. GOLLIN, DRIVING INNOVATION: INTELLECTUAL PROPERTY STRATEGIES FOR A DYNAMIC WORLD 298 (2008) (delineating these different avenues of seeking patent protection); *see also* EDWARD HAMMOND, SUNSHINE PROJECT, SOME INTELLECTUAL PROPERTY ISSUES RELATED TO H5N1 INFLUENZA VIRUSES, RESEARCH AND VACCINES 4 (2007), http://www.sunshine-project.org/flu/patent_report.pdf (delineating patent applications relating to H5N1 which include claims that "relate to adjuvants or other formulation technology, sequences, production, or a combination thereof").

[16] "[T]here is no evidence that patents claiming a biologic drug product [bug] have been designed around more frequently than those claiming small-molecule products [drugs]." FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION, at vi (2009) [hereinafter FTC FOLLOW-ON BIOLOGIC REPORT], *available at* http://www.ftc.gov/os/2009/06/P0083901biologicsreport.pdf.

[17] *Id.*

[18] *Id.* at 35 n.139.

between 1-4% of net sales and [that of] an exclusive license averages between 6-10%, royalties can easily stack-up to 20% of net sales."[19] The presence of such royalties is significant because, "[o]ften, a burden of 8% versus 4%, for example, can make the difference as to whether the vaccine is commercialized at all."[20] Equally important, some of these necessary patents frequently lack substitutes and, therefore, could directly block development of a particular vaccine.[21]

The most important biologic patents will oftentimes cover research tools whose applicability extends beyond a single virus or vaccine and into broader areas dealing with "reverse genetics and cell culture systems."[22] Even those patents with more highly specific uses can significantly constrain R&D. For example, "the holder of a gene patent can control any use of the gene for the life of the patent [and as such,] the holder effectively has a monopoly over diagnostics, prophylactics and treatments based on the sequence."[23] Stated alternatively, the patentee controlling a gene sequence "can prevent others from engaging in research involving the sequence."[24] This should be viewed

[19] Anthony Williams, Governing the Innovation Commons: Private Ordering of Intellectual Property Rights 11 (Mar. 2005) (unpublished working paper), *available at* http://anthonydwilliams.com/wp-content/uploads/2006/08/Governing_the_Innovation_Commons.pdf; *see also* Keith J. Jones et al., *Problems with Royalty Rates, Royalty Stacking, and Royalty Packing Issues*, *in* IP HANDBOOK OF BEST PRACTICES, 1122 (Anatole Krattiger ed., 2007), *available at* http://www.iphandbook.org/handbook/chPDFs/ch11/ipHandbook-Ch%2011%2009%20Jones-Whitham-Handler%20Royalty%20Stacking.pdf (positing an example of vaccine development wherein "[w]hen the vaccine is ultimately ready for use, it may be subject to royalty obligations of 6%-20%, or more, of the selling price of the product").

[20] Jones et al., *supra* note 19, at 1122.

[21] Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 418 (2002) ("The foundational character of natural biochemicals and the necessity of understanding and experimenting with them for the development of modern medical diagnoses, vaccines, and therapies results in monopoly power for the patent holder. It is usually impossible to 'invent around' a discovered gene, protein, or cell line in order to avoid the licensing fee any more than one could invent around carbon, sodium, or any other base chemical. This fact distinguishes biochemical patents from most other kinds of patents." (citation omitted)).

[22] HAMMOND, *supra* note 15, at 2. These two proprietary technologies have contributed to the recent "wave of influenza-related corporate takeovers and technology deals inked in the last two years." *Id.*

[23] Lori B. Andrews & Laura A. Shackelton, *Influenza Genetic Sequence Patents: Where Intellectual Property Clashes with Public Health Needs*, 3 FUTURE VIROLOGY 235, 236 (2008).

[24] *Id.* at 236; *see also* Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 463 (2004) (indicating that "upstream" patents in biotechnology "cover not just product markets but also innovation markets – . . . the ability to carry out fundamental research. They cannot be

as particularly troubling because step one in development of a vaccine is sequencing the viral gene.

Within the influenza vaccine context more specifically, it has been argued that there is "a much more complex and limiting field of intellectual property claims than has ever before existed . . . . And it is going to get worse."[25] The following statistics are revealing: "23% of all [patent] applications since 1983 for influenza vaccines (61 of 267)" were filed in the eighteen months spanning 2006 through mid-2007.[26] Half of those applications were filed in the United States.[27]

Another noteworthy characteristic of the intellectual property environment for vaccine development is the particularly pronounced uncertainty surrounding patents that are pending or have been recently issued. Such uncertainty can be usefully divided into two categories: uncertainty regarding patent ownership of intellectual property rights and uncertainty regarding the scope of patent rights which, in turn, determines in part whether a patent does or does not have substitutes.

In the United States, patent ownership is based on who is the "first to invent" rather than who was the "first to file" a patent application.[28] Therefore, patent applications filed by contemporaneous innovators can give rise to a priority contest called an "interference." Interferences are "elaborate . . . proceedings and legal standards" undertaken by dueling inventors to establish legal priority.[29] These priority contests are both time consuming and expensive. The average pendency of an interference before the Patent and Trademark Office ("PTO") is 30.5 months and "there are certain infamous interferences that [have] continued for decades."[30] The average legal cost associated with an interference proceeding has been estimated to range from "$100,000 to as high as $500,000."[31]

While the high profile of the SARS interference is relatively uncommon, the mere fact of its occurrence is not so aberrational. "The greatest number of interferences . . . originate from Group 1600 (biotechnology)."[32] More specifically,

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invented around: for instance, any scientist who wants to study the genetics of breast cancer needs to utilize the BRCA 1 test").

[25] HAMMOND, *supra* note 15, at 3.

[26] *Id.* at 4.

[27] *Id.*

[28] *Id.*

[29] Mark A. Lemley & Colleen V. Chien, *Are the U.S. Patent Priority Rules Really Necessary?*, 54 HASTINGS L.J. 1299, 1299 (2003).

[30] *Id.* at 1331 n.99.

[31] Ryan K. Dickey, *The First-to-Invent Patent Priority System: An Embarrassment to the International Community*, 24 B.U. INT'L L.J. 283, 291 (2003) (citations omitted).

[32] *Current Patent Interference Statistics*, ASS'N OF PATENT LAW FIRMS, http://www.aplf.org/mailer/interference-02.html; *see also* JAMES BESSEN & MICHAEL J.

> the rate of interference declaration involving TC 1600 . . . was at least 2.5-fold the rate of declaration in any other technology area and was about 6.5-fold the average rate of all other technologies for the 5 year period . . . .
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> . . . [S]taff in TC 1600 estimate that about 75% of interferences declared in the center involve biotechnologies . . . .[33]

This data is consistent with the "very high levels of competition and, in some cases, outright races for genetic discoveries . . . [including] most recently the quest for the sequence of the SARS virus."[34]

Interference proceedings provide insight into one aspect of the uncertainty that characterizes the patent landscape – that of priority of invention. In addition to timing-related issues, another source of uncertainty is a more pervasive ambiguity regarding the scope of issued patents and, by implication, whether any individual patent effectively offers market power because of the absence of viable substitute technologies. Patents are often characterized as establishing "the 'metes and bounds' of [an] invention in a manner analogous to real property deeds."[35] This analogy, however, is inapt since "[t]hose who are intimate with the patent system have long understood that it is simply impossible to define boundaries of invention with the physical or descriptive precision of defining the boundaries of real property."[36] Consequently, disagreements regarding the scope of issued patents are "pandemic."[37] These disagreements are extremely difficult and expensive to resolve. As Professors Burk and Lemley have observed:

> It seems no exaggeration to say that no one reading the average patent claim can begin to guess what that claim may be held to cover; that can

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MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 251 (2008) ("Research on interferences shows that a disproportionately large fraction of interferences involve chemicals, including pharmaceuticals. 'The interference rate for chemicals is 1.46 times greater than the average and drugs are interfered at over three times the average.'" (quoting Linda R. Cohen & Jun Ishii, *Competition, Innovation and Racing for Priority at the U.S. Patent and Trademark Office* 12 (Univ. of Cal., Davis, Dept. of Econ., Working Paper No. 050604, 2005))).

[33] Jon F. Merz & Michelle R. Henry, *The Prevalence of Patent Interferences in Gene Technology*, 22 NATURE BIOTECHNOLOGY 153 (2004) (citation omitted). The TC 1600 group encompasses drugs, herbicides, pesticides, cosmetics, bioinformatics, and other organic compounds, so this rate is not purely attributable to biotechnologies, much less human genetics. *Id.* Detailed data that would permit greater discrimination of technology involved or historical comparisons is unavailable. *Id.* (citing personal communication with George Elliott, TC 1600, USPTO).

[34] *Id*.

[35] Dan L. Burk & Mark A. Lemley, *Fence Posts or Sign Posts? Rethinking Patent Claim Construction*, 157 U. PA. L. REV. 1743, 1748 (2009).

[36] *Id.*

[37] *Id.* at 1750.

> only be known once the claims have been construed by [a district court judge] and, realistically, only after the Federal Circuit has reviewed the findings of the district court judge . . . .[38]

Consequently, even duly issued patents not plagued by questions regarding priority have been characterized as constituting nothing more than "a license to sue." Uncertainty may attach to issued patents as a result of not only questions regarding scope but also more fundamental questions as to validity.

Licensing within biotechnology may be particularly challenging because the uncertainty regarding the contours of specific patents is further exacerbated when, as is often the case, the needs of prospective licensees are also difficult to ascertain. Innovators undertaking R&D often cannot anticipate which technologies and, therefore, which licenses they will need. This uncertainty looms particularly large when the R&D is in its earliest stages. Given the high degree of patent proliferation characterizing biotechnology and the vaccine industry, and with it the potential for fragmented ownership of technologies, successful vaccine development (from both a scientific and economic perspective) is likely to be a function, in no small part, of how successfully innovators navigate the intellectual property realm. Unfortunately, "[u]ncertainty over the prospective costs of licenses, royalty 'stacking' that creates uncompetitive costs, delays in obtaining licenses . . . are all inhibiting biotechnology R&D in many areas."[39]

B. *Regulatory Landscape*

Vaccine development is an extremely time-consuming and expensive undertaking in part because of federal regulations. Federal law requires that all drugs and biologics, such as vaccines, must be evaluated and approved by the Food and Drug Administration ("FDA") before they can be marketed in the United States.[40] Through its review, the FDA seeks to ensure the "safety, efficacy, purity and potency" of all approved products.[41] This Section explores key aspects of how the FDA evaluates vaccines. While the FDA's goal is to ensure safety and efficacy, its regulations also have consequences for the economics of the vaccine industry and, by implication, the value of patent protection and the nature of competition.

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[38] *Id.* at 1791-92. "The Federal Circuit reverses more than one-third of the claim-construction cases presented to it on appeal, a far larger percentage than its general reversal rate." *Id.* at 1751.

[39] Anatole Krattiger et al., *Intellectual Property Management Strategies to Accelerate the Development and Access of Vaccines and Diagnostics: Case Studies on Pandemic Influenza, Malaria and SARS*, 2 INNOVATION STRATEGY TODAY 67, 74 (2006).

[40] David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 469 (2008).

[41] *Vaccines, Blood, Biologics*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/BiologicsBloodVaccines/Vaccines/default.htm (last updated Mar. 29, 2010).

Vaccines fall into the category of biologics and, as such, the FDA review process varies in significant ways from that for drugs. While both drug and vaccine manufacturers must comply with "good manufacturing practices," the manufacturing requirements imposed upon biologics are "particularly rigorous."[42] As a result, when the FDA approves a biologic such as a vaccine it is, in effect, approving a plant for manufacture. One key consequence of this approach is that a vaccine developer undertaking Phase III clinical trials to develop statistically significant data regarding safety and efficacy must use vaccines that were actually "produced in a facility that will be used for commercial production if the vaccine is approved. As a result, manufacturers must frequently invest more than $30 million in a production facility prior to product approval."[43]

The FDA's particularly stringent review of vaccines occurs not only during the initial stages of vaccine production, but also through ongoing inspections and testing. Vaccines, which are "produced from or use living cells and organisms, as well as complex growth materials taken from living sources," must be monitored carefully for "purity and quality."[44] Further, "[e]ach batch must be carefully tested for composition and potency through a batch release process. Unlike other drugs, vaccines are used on healthy people to prevent disease; and as a result, vaccine production is subject to higher standards of safety than is the case for pharmaceuticals."[45]

The high sunk costs associated with the FDA review process are an important reason for the emphasis upon the patenting of pharmaceutical products generally. When the patent on an FDA approved drug expires, generic manufacturers seeking to enter the market have historically encountered a far less demanding regulatory review process. For a generic drug, the FDA focuses primarily upon assessing bioequivalence between the original product and generic drug. Until extremely recently, no federal regime for generic biologics or "biosimilars" existed. Therefore, in addition to any patent protection attached to a vaccine, the pioneering inventor was further insulated from competition because any "generic" seeking to enter the vaccine

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[42] Lars Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. REV. 371, 380 (2002).

[43] INST. OF MED., FINANCING VACCINES IN THE 21ST CENTURY: ASSURING ACCESS AND AVAILABILITY 114 (2004) (citation omitted) [hereinafter IOM, FINANCING VACCINES], *available at* http://books.nap.edu/catalog.php?record_id=10782.

[44] *Id.* at 126.

[45] *Id.* Vaccines, such as that for H1N1, have received expedited reviews because the vaccine in question is considered part of a class of vaccines (e.g., it addresses a different strain of virus) that have already been reviewed. Perceived urgency may also play a role. *See* Letter from Dr. Margaret A. Hamburg, Comm'r of Food & Drugs to Healthcare Professionals (Nov. 10, 2009), *available at* http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm189691.htm. In highly unusual situations where an extreme emergency need for a vaccine exists, a government could, at least theoretically, threaten direct regulatory intervention to obtain pricing and distribution concessions.

market would need to undertake the full FDA approval process. While this Article was in press, a sweeping healthcare reform bill passed that would allow biosimilars. More specifically, Title VII(A), Biologics Price Competition and Innovation, requires the FDA to create an "approval pathway for biosimilar biological products" though no biosimilars have yet been approved.[46]

The regulatory review process is a critical aspect of the vaccine industry. The indirect, but nonetheless profound, effect of that process increases both the risk and the expense associated with vaccine development, which, in turn, reduces the expected return from development and commercialization. For vaccines with limited demand (e.g., because the value is for only one season or for only a small segment of the population), the increased fixed costs may make development contingent on lower prices or exclusive access. Despite the centrality of the regulatory review process to vaccine development, it is not directly implicated in this Article's analysis of patent pools.

C. *Competitive Landscape*

Professors Burk and Lemley characterize the biotechnology industry as "properly described in part by the anticommons theory (too many narrow patents must be aggregated to produce a viable product) and in part by prospect theory (a long and uncertain post-invention development process justifies strong control over inventions)."[47] This extremely apt characterization provides insight into the interrelated patent and competition landscapes. The anticommons aspect reflects the plethora of upstream R&D entities that create and patent important biotechnologies required as inputs for further downstream R&D. In contrast, the prospecting dimension implies that actual downstream drug or vaccine development is likely to involve many fewer market participants. This Section briefly discusses these key features of the vaccine industry, focusing primarily on its cost structure and its implications for market concentration and pricing. The discussion begins with the upstream R&D portion of the market then examines the production and sales characteristics of the downstream vaccine development and then manufacturing.

The upstream R&D portion of the vaccine market consists of a wide variety of organizations. These include integrated vaccine developers and manufacturers and an important and growing sector of the biotechnology industry which consists of small R&D firms and academic (and government) entities.[48] These entities invest heavily in research and development and

[46] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7002 (2010) (amending 42 U.S.C. § 262).

[47] Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RES. L. REV. 691, 738 (2004).

[48] Walter W. Powell et al., *Network Position and Firm Performance: Organizational Returns to Collaboration in the Biotechnology Industry*, *in* 16 RESEARCH IN THE SOCIOLOGY OF ORGANIZATIONS: NETWORKS IN AND AROUND ORGANIZATIONS (Steven Andrews & David Knoke eds., 1999), *available at* http://www.stanford.edu/~woodyp/papers/Rso1.pdf

produce innovations which are intangible and typically involve extremely low, if not negligible, marginal cost to disseminate. Such innovations are generally patented when possible. The intellectual property contained in these patents may be useful across a wide range of downstream applications (vaccines generally) or may be specific to a small class of R&D firms. Firms license their patents either exclusively or nonexclusively. Such licenses can involve a fixed fee and/or royalty payments. From the viewpoint of the vaccine manufacturer, royalty payments to upstream R&D licensors represent a marginal cost for each unit of sales.

Ownership of relevant patents may be spread across parties with widely varying interests. This may influence licensing decisions and, in particular, their (in)ability to form collective organizations such as pools.[49] For example, MedImmune's reverse genetics technology is a combination of technologies that originated with a for-profit, a research hospital, a medical school, and a university.[50]

The economics of development and manufacture has contributed to the downstream vaccine market's increasing vertical integration and consolidation. Several primary forces contributing to this evolution include the extremely high fixed costs characterizing further R&D and the manufacturing and regulatory approval processes as well as the limited revenue prospects for the vaccine industry, and the high level of complexity attendant to vaccine manufacturing.

The Federal Trade Commission ("FTC") indicates that: "Biotechnology innovation is costly and unpredictable, requiring significant amounts of investment to test and commercialize new drug products."[51] Patents "prevent[] rival firms from free riding on discoveries."[52] With that state-conferred exclusivity, the innovator can try to "recoup the substantial capital investments made to discover, test, and obtain regulatory approval of new drug products."[53] These general features characterize the pharmaceutical industry as a whole as well as the vaccine industry in particular: "Total development costs of bringing a vaccine to market are roughly similar to those for drugs and can be higher."[54] The cost of taking a new vaccine from "initial research to commercial

(observing that the biotechnology field "is not only multi-disciplinary, it is multi-institutional as well" and includes "research universities and both start-up and established firms, government agencies, nonprofit research institutes, and leading hospitals").

[49] *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 700 (1998).

[50] These institutions include MedImmune, St. Jude's Children's Research Hospital, Mt. Sinai School of Medicine, and Wisconsin Alumni Research Foundation.

[51] FED. TRADE COMM'N, FOLLOW-ON BIOLOGIC REPORT, *supra* note 16, at 1.

[52] *Id.* at 30.

[53] *Id.*

[54] IOM, FINANCING VACCINES, *supra* note 43, at 113 (citation omitted).

production" has been estimated at $700 million.[55] Moreover, "[o]nce a vaccine has been approved, the production process involves high fixed costs relative to variable costs. Fixed production costs, exclusive of up-front R&D and sales labor, represent 60 percent of total production costs for vaccines."[56]

Despite the fact that vaccine production costs "have generally been increasing," their sales revenues "have remained relatively constant."[57] Several factors appear to limit a vaccine's revenue potential. One factor is the limited nature of the demand as only a "small number of vaccinations [are] usually required" and most of those vaccines are "administered between one and four times over a lifetime."[58] Another contributing factor is that "vaccine production costs do not necessarily decline over time."[59] Vaccine production is subject to a "rigid batch inspection process, which makes it difficult for companies to achieve more efficiency through a learning curve and to enjoy cost reductions related to process improvements."[60] Finally, vaccine pricing has been profoundly affected by the market power exercised by the U.S. government qua purchaser including: "the CDC's ability to negotiate discounted federal contract prices, federal price caps on certain vaccines since 1993, the gradually increasing public share of vaccine purchases (at discounted prices), and the addition of price competition to the government contracting process."[61]

These overall trends regarding costs, sales, and the high risk associated with vaccine development, have contributed to the declining number of manufacturers in the vaccine industry: "[T]he number of companies making vaccines has decreased from twenty-six in 1967 to seventeen in 1980 and to five in 2004 . . . ."[62] This contraction reflects both exit and consolidation.[63]

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[55] *Id.* at 114 (citation omitted). Vaccines often require greater upfront investment in production facilities than do drugs. *See supra* notes 42-43 and accompanying text. But, "vaccines tend to have higher success rates than pharmaceuticals and may be characterized by faster development times." IOM, FINANCING VACCINES, *supra* note 43, at 114 (citation omitted).

[56] IOM, FINANCING VACCINES, *supra* note 43, at 114 (citation omitted).

[57] *Id.* at 116.

[58] *Id.*

[59] *Id.*

[60] *Id.* (citation omitted).

[61] *Id.* ("The principal exceptions to this revenue picture relate to two fairly new vaccines – varicella and pneumococcal conjugate – which are priced higher than earlier vaccines.").

[62] Paul A. Offit, *Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?*, 24 HEALTH AFF. 622, 624 (2005).

[63] *See* Stanley A. Plotkin, *Why Certain Vaccines Have Been Delayed or Not Developed at All*, 24 HEALTH AFF. 631, 631-32 (2005) ("The absorption of vaccine producers by pharmaceutical [drug] companies has been inexorable, and it is argued that this arrangement provides greater capital and synergy between pharmaceuticals [drugs] and vaccines."). Plotkin, however, argues that other financing options may be "preferable" including: "vaccine companies were the subject of public offerings"; "governments could also invest in

Another important feature of the vaccine industry that results from characteristically high fixed-costs is the desire of manufacturers to maintain high margins to recoup development costs. Since competition makes maintaining such margins difficult, it is unsurprising that "[c]apturing entire markets for specific vaccines is one of the goals of manufacturers, which are expending sizable resources to develop new and unique vaccines. Monopoly markets tend to have higher profits because the developer does not have to share sales (or profits)."[64] Anticipated competition also means that

> potential entrants [into specific vaccine markets] have little incentive to invest in developing similar products [which are expected to have small or modest sized demand] since they could not hope to recoup their R&D costs unless they have a sufficiently superior product to command a higher price or capture a dominant market share.[65]

These aspects of the vaccine market have led some to conclude that, "given the cost and demand conditions of most vaccine markets, long-term equilibrium is likely to be one supplier or at most a few suppliers of each vaccine type at any point in time."[66] It is important to recognize, however, that even having a single developer does not mean that there are not multiple potential developers vying to become the ultimate supplier. Consequently, licensing negotiations for key patents held by upstream R&D organizations are likely to involve one-on-one negotiations between the patent holder and a small number of somewhat differentiated potential licensees.

III. INNOVATION, MULTIPLE TECHNOLOGIES, AND UNCERTAINTY

The vaccine industry brings to the fore – in a very concrete manner – the nexus between uncertainty, intellectual property, and innovation. Part III explores that relationship through a series of hypotheticals, loosely based on actual circumstances, which illustrate the antitrust issues associated with patent pooling in the vaccine industry. It begins with a simple example of a pure priority dispute which underscores the significance of uncertainty regarding timing issues. It then addresses increasingly complex settings characterized by uncertainty regarding multiple technologies that are potentially relevant to the creation and commercialization of a vaccine. Finally, Part III addresses settings involving uncertainty regarding the technological relationships amongst various patents. The analysis of each example begins by identifying the particular challenges that the intellectual property environment presents to

companies that provide the vaccines for their populations"; and "special bond issues could be issued for projects that reach the costly Phase III stage." *Id.*

[64] Margaret S. Coleman et al., *Factors Affecting U.S. Manufacturers' Decisions to Produce Vaccines*, 24 HEALTH AFF. 635, 641 (2005).

[65] Patricia Danzon & Nuno Sousa Pereira, *Why Sole-Supplier Vaccine Markets May Be Here to Stay*, 24 HEALTH AFF. 694, 695 (2005).

[66] *Id.* at 695.

vaccine developers and then explores the extent to which either patent pooling or individual licensing could address the challenges posed by actual or threatened upstream intellectual property fragmentation. The evaluations of pooling and individual licensing hinge largely upon their respective implications for transaction costs[67] and pricing efficiency.[68] The analysis of these elements, in turn, indicates that patent pools are not a general panacea for the transactional problems associated with individual licensing in non-standard-setting situations characterized by the fragmentation of essential property rights.[69] While there are some potential benefits that pools may create through more efficient pricing, such benefits will often be offset by transaction costs that are special to pools and pool formation.

A. *Uncertain Timing*

The challenge prospective vaccine developers frequently encounter is how to acquire reliable access to essential patents swiftly. While society wants such developers to act quickly, they may not do so if the property rights regarding the underlying technologies are uncertain. One source creating uncertainty deals with timing or, more specifically, priority of invention. As discussed previously, patent ownership in the United States is determined by priority of invention, rather than by priority of filing. Since priority of invention is difficult to ascertain, ownership issues can easily arise. The fear of delayed vaccine R&D owing to uncertain priority figured prominently in arguments favoring pooling within the SARS context. This Section explores a hypothetical involving a "pure" priority dispute in which the pending patent applications are essentially identical. More specifically, it considers how individual licensing, as well as patent pooling, could be deployed to address this uncertain priority. Individual licensing is addressed because the extent to which the parties could meaningfully account for the uncertainty at issue through individual contract negotiations creates an important baseline for transaction costs and pricing efficiency against which the pros and cons of any pooling arrangement ultimately must be evaluated.

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[67] *See infra* Part III.A.1 (discussing transaction costs).

[68] *See infra* Part III.A.2 (discussing pricing efficiency).

[69] The value of patent pooling within the biotechnology and related fields has received considerable attention, primarily by commentators, owing to the perceived promise of improved social welfare (including decreased transaction costs, increased pricing efficiency, and faster innovation) and despite the acknowledged potential for antitrust issues. *See generally* Krattiger et al., *supra* note 39; Simon et al., *supra* note 5; Willard K. Tom, *A Field Guide to Antitrust Issues in Standard Setting and Patent Pooling*, 14 COMPETITION: J. ANTITRUST & UNFAIR COMPETITION L. SECS. ST. B. CAL. 13, 28-29 (2005); Courtney G. Scala, Note, *Making the Jump from Gene Pools to Patent Pools: How Patent Pools Can Facilitate the Development of Pharmocogenomics*, 41 CONN. L. REV. 1631 (2009); Patrick Gaulé, *Towards Patent Pools in Biotechnology?* 9 (École Polytechnique Fédérale de Lausanne, Coll. of Mgmt. of Tech., CDM Working Papers Series, CEMI-Report-2006-010, 2006).

Consider a setting in which several potential vaccine developers exist and each requires access to the same upstream innovation. The innovation is the genomic sequence encoding the virus for which a vaccine is highly coveted. Three upstream, non-vertically integrated,[70] for-profit entities[71] have pending patent applications concerning the innovation in question. Each applicant claims essentially the same invention and has an equal probability of prevailing in the priority dispute. The applicant that filed its patent application first has an advantage but is at risk of losing in a priority contest. Clearly, only one pending application can be issued a patent.

Based on the profile of the vaccine industry, several other characteristics reasonably can be inferred. With regard to downstream developers, only a relatively small number of potential licensees are likely to exist. Also, any prospective developer is unlikely to undertake the upfront investment required to develop and commercialize the patented technology unless it has secured licenses for *all* the essential intellectual property. Finally, owing to the nature of the market (high sunk costs and relatively lower marginal costs), prospective developers may be willing to pay a premium for an exclusive license.

Given the uncertainty posited regarding ownership of the essential patent, the interested parties could defer negotiations and decisions until after priority has been resolved. At that point, each prospective licensee would seek to acquire a license from the party prevailing in the interference proceeding. The urgency to develop a vaccine, however, renders this approach untenable. Thus, the question becomes how, if at all, could prospective licensees attain sufficient legal comfort regarding technology access *prior to* the resolution of the interference proceeding? Stated alternatively: would either a patent pool or a series of individual licenses address the uncertainty in a manner that avoids unduly stymieing innovation? The pros and cons of these two approaches are best understood in relative terms. As such, this Section discusses the transaction costs and price efficiency of each approach.

Prospective licensees could individually negotiate licenses with each patent applicant. Such agreements typically provide for relatively small payments upfront prior to resolution of the interference proceeding. Those licenses may also provide for the transfer of know how or trade secrets from the patent applicant to the licensee. More importantly, such agreements also contain provisions detailing the terms for use if a patent ultimately issues.[72] The

[70] *See infra* Part III.C (discussing possible implications of vertically-integrated licensees).

[71] *See infra* Part III.A.2 (discussing characteristics of non-profit settings).

[72] *See generally* Daniel L. Reisner, *Patent Licensing and Misuse Issues*, *in* DEVELOPMENTS IN PHARMACEUTICAL AND BIOTECH PATENT LAW (PLI Patents, Copyrights, Trademark & Literary Property, Course Handbook Ser. No. 944, 2008) (describing how "pre-issuance royalties" can be structured as to avoid patent misuse). Reisner also indicates

licenses with the unsuccessful patent applicants could effectively terminate upon resolution of the priority contest. If a prospective licensee can procure all necessary licenses, it can undertake the R&D investment with sufficient comfort that even after the patent issues, it will not be subjected to either downstream holdups on price or exclusion from the market altogether.

An alternative approach to individual licensing would involve the prospective licensors forming a patent pool or, more accurately, a patent *application* pool. The patent applicants would allow their pending applications to be combined within a pool and licensed collectively rather than to be licensed individually by each applicant. Given the purpose of and circumstances surrounding such a collective undertaking, the pool contract would be contingency-based. It would establish the terms for the licensees while the priority dispute is ongoing and the terms for use when a patent ultimately issues. Sharing know-how is likely to be more difficult within a pool setting given that the pool participants may be competitors.

The likelihood that either approach, individual licensing or pooling, will emerge in response to the intellectual property-related uncertainty at issue is a function of not only the antitrust law but also the respective consequences of each approach for transaction costs and price efficiencies. In the case of pure priority disputes, it will be shown that contingent contracting can mitigate the costs to individual licensing caused by uncertainty over priority, making use of pools unnecessary.

1. Transaction Costs

Kenneth Arrow has defined transaction costs as the "costs of running the economic system."[73] These costs are "the economic equivalent of friction in physical systems"[74] and are invariably sought to be minimized. More

that "post publication/pre-issuance" royalties are justified in light of 35 U.S.C. § 154(d) (2006). *Id.*

[73] Kenneth J. Arrow, *The Organization of Economic Activity: Issues Pertinent to the Choice of Market Versus Non-Market Allocation* 1 (1969), *available at* http://www.econ.ucsb.edu/~tedb/Courses/UCSBpf/readings/ArrowNonMktActivity1969.

[74] OLIVER E. WILLIAMSON, THE ECONOMIC INSTITUTIONS OF CAPITALISM 19 (1985). Williamson elaborates:

> In mechanical systems we look for frictions: Do the gears mesh, are the parts lubricated, is there needless slippage or other loss of energy? The economic counterpart of friction is transaction cost: Do the parties to the exchange operate harmoniously, or are there frequent misunderstandings and conflicts that lead to delays, breakdowns, and other malfunctions?

Id. at 1-2. Instead of focusing on production costs, transaction costs concern the "comparative costs of planning, adapting, and monitoring task completion under alternative governance structures." *Id.* at 2 (emphasis omitted). Further, "[t]ransaction cost economics poses the problem of economic organization as a problem of contracting. A particular task is to be accomplished. It can be organized in any of several alternative ways. Explicit or

specifically, transaction costs can be divided into "four separate costs related to transacting: (1) search costs, (2) contracting costs, (3) monitoring costs, and (4) enforcement costs."[75] These costs can manifest themselves in terms of delay (time costs) as well as actual expenditures. Within the patent pool context, transaction costs include not only the costs associated with individual transactions between licensors and licensees, but also the costs associated with establishing and governing collective organizations which may participate in such licensing transactions. The prospect of transaction cost savings through pooling, as compared to individual licensing, is extremely well-trod ground within the context of standards-related pools. Despite rather pronounced differences from the vaccine market at issue herein, understanding the standard-setting context is critical because it invariably constitutes either an explicit, or at minimum implicit, point of reference for any antitrust analysis of patent pools.

Standards-related settings are typically characterized by a very large number of potential non-exclusive licensees requiring licenses to a large number of patents held by numerous patentees. As such, the sheer number of potential individual negotiations suggests that pooling could yield significant savings. Moreover, the additional cost of establishing royalty arrangements within the pool are lessened since the standard-setting process itself typically requires identification of key patents and some general agreement, albeit extremely vague, regarding royalty rates.

Within the vaccine context, however, it remains unclear whether pooling would cause transaction costs to decrease in absolute terms or merely to manifest themselves differently. One would need to compare the combined cost of negotiating the pool formation and the pool's subsequent negotiations with potential licensees with the sum of the costs incurred through individual negotiations between disparate licensors and licensees. The magnitude of transaction costs reflects in part the number of parties; to wit, the greater number of individual negotiations, the greater the potential for transaction costs savings with pooling. But as the number of negotiations in the priority hypothetical, and arguably within the vaccine context more generally, is likely small, one should be skeptical regarding the significance of *volume-based* transactions as traditionally understood.

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implicit contract and support apparatus are associated with each. What are the costs?" *Id.* at 20. Ex ante and ex post transaction costs

> are often difficult to quantify. The difficulty, however, is mitigated by the fact that transaction costs are always assessed in a comparative institutional way, in which one mode of contracting is compared with another. Accordingly, it is the difference between rather than the absolute magnitude of transaction costs that matters.

Id. at 21-22.

[75] Jeffrey H. Dyer, *Effective Interfirm Collaboration: How Firms Minimize Transaction Costs and Maximize Transaction Value*, 18 STRATEGIC MANAGEMENT J. 535, 536 (1997) (citations omitted).

A second important dimension for assessing transaction costs is the complexity of the terms to be negotiated. As will become apparent, even license negotiations involving a small number of parties may be extremely complicated owing to the terms of the license agreement itself or the extent to which one license's terms depend on the results of other simultaneously negotiated agreements. The potential for significant delay associated with complex negotiations has arguably been underappreciated in the patent pool literature. This shortcoming is particularly unfortunate in the vaccine context where development is frequently a race against both marketplace competitors and the spread of disease, delay may be the most critical transaction cost. However, in the pure priority hypothetical, there is no link across the licenses since only one license will effectively be operational. Hence, any transaction cost advantage, associated with priority uncertainty, that a pool enjoys relative to individual licensing is not likely to be substantial.

2. Pricing Efficiency

How, if at all, will the mechanisms to address upstream fragmentation of patent rights impact the efficient allocation of resources, i.e., the price efficiency, in the market? Revisiting the hypothetical involving three for-profit entities seeking to patent a single, essential technology, further assume the technology has no substitutes and requires no complements. Therefore, regardless of whether the licensors (patent applicants) price through a patent pool or through individual negotiations, each should, in theory, seek a monopoly price if it is awarded priority.[76] As a practical matter, pricing at the monopoly level might not be easy as it requires, among other things, understanding the elasticity of demand. While a pool could facilitate information sharing along this and other dimensions, it is unclear whether this would result in the price being set more accurately at the monopoly level or at a level that increases or decreases social welfare relative to the individual market price.

Through positing for-profit entities this and all subsequent hypotheticals assume that market participants are profit maximizing. Some industry participants, especially amongst those engaged in more upstream R&D are non-profit entities such as universities or not-for-profit hospitals which frequently invoke broader objectives such as the creation of knowledge for its own sake, the dissemination of that knowledge, and/or improving social welfare. These objectives may lead such organizations to pursue undertakings that for-profit organizations deem poor investments owing to the anticipated

[76] *But see* Tom, *supra* note 69, at 28-29, who argues that a pool involving sellers who have patent applications that are contending for priority is welfare superior to independent bargaining because independent bargaining will involve an inefficient price due to double marginalization. He also argues that a group of patent applications, only one of which will be granted, should be treated as functional complements for the purposes of antitrust analysis.

difficulty of appropriating much of the value from such projects. In terms of pricing, such social objectives can emerge in a non-profit's willingness to forego some profit if, by doing so, one of the organization's broader goals is met. Non-profits do, however, usually have a strong incentive to maximize their revenues on existing patents. To the extent that such an incentive dominates, non-profits will essentially act as though they are profit maximizing and will be indistinguishable from for-profits along many dimensions. The implications of such diverse objectives for individual pricing warrants further study.[77] What are the pricing dynamics in pools consisting of both for-profit and non-profit entities? Could, for example, non-profits act as moderating influences or would for-profit incentives override such influences?

In sum, the uncertainty problems both the upstream and downstream firms encounter in this hypothetical appear amenable to resolution through individual licensing. No clear benefit inures to either licensors or licensees through pooling the priority claims. Furthermore, any possible transaction cost reductions attainable through pooling seem relatively modest given the number of parties implicated and the ease with which individual licensing can be implemented. Thus, in this setting a pool does not confer any advantages on either the market participants or society.[78] The hypothetical illustrates how contingent contracting can mitigate various potential problems arising in transactions involving uncertain priority. As will become apparent, however, such contracting cannot solve all the problems that surface in vaccine development markets.

B. *Multiple and Uncertain Technologies*

In the pure priority dispute hypothetical, the uncertainty was extremely circumscribed as it was solely a function of timing.[79] Another key source of uncertainty vaccine industry participants encounter concerns the technological relationship between patents (are they substitutes? complements?) and the relationship between the patents at issue and the overall technology involved (which, if any, patents are essential?). Such technological uncertainty is likely to be greatest during the early stages of development which, unfortunately, is oftentimes when licensing arrangements must be forged for development to proceed.

To illustrate how uncertainty regarding technological relationships affects the vaccine industry, this Section modifies the priority hypothetical along two dimensions. First, more than one patent will now be required for vaccine

[77] Antitrust law applies to the actions of both for-profits and non-profits. While there has been some recognition in antitrust law and policy that non-profits have somewhat different incentives than for-profits, analysis usually begins by treating the two types of organizations similarly.

[78] There is a possibility that pooling patents may have some useful social incentives and economic effects on parties that are not driven primarily by a profit motive.

[79] *See supra* Part III.A (hypothetical positing three co-pending patent applications).

development. Second, the technological relationship amongst the patents at issue may or may not be fully understood during licensing negotiations. In the priority hypothetical, *A* was not only an essential technology but it was also the only patented technology required (the "single essential patent scenario"). The modified hypothetical posits that three issued patents (*A*, *B*, *C*) are potentially relevant to a vaccine's development. *A* is essential, but the technological relationship between *B* and *C* is uncertain. To simplify the analysis, it is also assumed that if *B* and *C* are substitutes, a licensee gains no additional value from licensing both of the substitutes rather than only one of them. Patents designated as substitutes are both technologically and economically equivalent. Given this framework, the two possible scenarios this Section primarily focuses upon are:

- *A* + *B* + *C*: All three patents are complementary and essential ("complements scenario").
- *A* + (*B* or *C*): *A* is essential and either *B* or *C* is also necessary but *B* and *C* are substitutes vis-à-vis each other ("substitutes scenario").

During negotiations, the prospective licensors and licensees are uncertain as to which of these two technological relationships obtains. Presumably, that technological uncertainty will be largely resolved over the course of R&D, although legal uncertainty may persist.[80] These two scenarios reflect a realistically cabined uncertainty in that profound uncertainty may exist regarding certain technologies (*B* and *C*), while little or no uncertainty may exist regarding other technologies (*A*). While the hypothetical pool is assumed to include all potentially critical patents, in practice pools may contain only a subset of such patents. Although many other combinations and permutations are possible, reliance upon these two technological relationships is sufficient to illustrate the key market dynamics.

This Section explores how prospective licensors and licensees could proceed, given technological uncertainty, whether through patent pooling or through individually-negotiated contracts. For expositional convenience, this inquiry sometimes assesses, as an intermediate step, how the licensors and licensees would interact if multiple *known* technologies were required. As with the priority hypothetical, this analysis assesses the transaction costs and pricing implications of pooling and individual licensing.

1. Transaction Costs

The two primary sources of transaction costs, discussed previously, are the volume and the complexity of the interactions.[81] This Section discusses the

[80] *See supra* notes 37-38 and accompanying text. The analysis of the modified hypothetical assumes technological uncertainty will be resolved by the time payments are made under the license. However, the basic lessons of the analysis are applicable to settings in which technological uncertainty persists.

[81] *See supra* Part III.A.1.

nature of those costs and the potential ability of contingent contracting to mitigate them within settings characterized by multiple technologies. In particular, it explores how the combination of multiple technologies with uncertain technological relationships exacerbates transactional frictions.

a. *Multiplicity and Certainty*

The specific challenges attendant to navigating numerous licensing agreements are illuminated by first considering a setting characterized by multiple required patents with *known* technological relationships (i.e., complements or substitutes scenarios). For instant purposes, assume a hypothetical for which those relationships correspond to the complements scenario described (three essential patents *A*, *B*, and *C*) and further assume that each market participant recognizes this technological relationship exists. Under this scenario, any firm intending to develop a vaccine needs to secure a license from each of the three patent holders. Assuming individual licensing, the number of licenses to be negotiated is the same as within the priority hypothetical. While a pool aggregating *A*, *B*, and *C* would reduce the number of individual licensor-licensee contracts, establishing the pool would require negotiations amongst the patent holders. Under either pool or individual licensing, the number of negotiations is not large, so again significant volume-based transaction cost savings for patent pooling relative to individual licensing is unlikely under the complements scenario.[82]

Transaction costs are not, however, merely a function of the number of negotiations involved. Negotiations can vary considerably in their complexity with those that are more complex incurring greater transaction costs. As such, it is important to recognize the extent to which the necessity of acquiring multiple licenses, even if it is only a small number, can increase the complexity of negotiations and, as a result, transaction costs.

Focusing solely upon the *process* of price formation, it is important to recognize that the licensing terms emerging from one transaction may well affect the course of related negotiations. For example, when a licensee requires multiple licenses, its primary focus is on the sum of the royalty rates rather than on the specific payments to any individual patent holders. As such, under individual licensing, a licensee's negotiation with one licensor will be driven to varying extents by earlier agreements between the licensee and other licensors or the licensee's anticipation of what those agreements will entail. The linkages across licenses in this hypothetical complicates negotiations and starkly contrasts with the priority hypothetical where resolution involved only one patent and, consequently, no interaction among license negotiations. The complexity introduced through such indirectly linked transactions increases

[82] This analysis applies to both exclusive and nonexclusive license settings, though in the former only one firm needs to secure the three licenses.

with the number of required licenses, but it is difficult to assess the significance of such costs in the absence of specific facts.[83]

The primary difference between individual licensing and pooling is that, in the latter, the licensing negotiations regarding multiple technologies are coordinated. This coordination reduces the transaction costs associated with individual negotiations, but entails governance and pool negotiation costs. It seems likely that as the number of coordinated technologies increases, the market transaction costs which involve the number of interactions will generally increase faster than the costs associated with pool governance which is a function of the number of participants and licenses.

b. *Multiplicity and Uncertainty*

Negotiating licensing terms given uncertain technological relationships is potentially problematic as the parties may want to establish different royalty rates or royalty divisions in response to different conditions. Uncertainty may attach to both the question of which general technologies are implicated and whether any specific technology is essential or has substitutes. This Subsection explores the relative merits of individual licensing and pooling given such uncertainty and, in particular, the relative abilities of these two approaches to mitigate uncertainty through the incorporation of contingency provisions.

Uncertainty regarding the underlying technologies increases the likelihood of disagreement between the negotiating parties regarding royalty rates. Such disagreement may, for example, increase the time needed to reach an agreement. Because the parties recognize that basis for their disagreement may become partially or fully resolved over time, contract provisions that are contingent upon the future resolution of this uncertainty make a current

[83] However, if exclusivity or near exclusivity is critical to induce vaccine development, the negotiation frictions could multiply rapidly with even modest increases in the number of buyers. *See* JEFFREY L. PRESSMAN & AARON B. WILDAVSKY, IMPLEMENTATION, at xi-xviii (1973). A situation involving the negotiation of a series of exclusive contracts brings to mind the point that "[t]he longer the chain of causality, the more numerous the reciprocal relationships among the links and the more complex implementation becomes." *Id.* at xxiv. "Experience with the innumerable steps involved in program implementation suggests that simplicity in policies is much to be desired. The fewer the steps involved in carrying out the program, the fewer the opportunities for a disaster to overtake it." *Id.* at 147; *see also* Stephen A. Hansen et al., AM. ASS'N ADVANCEMENT OF SCI., THE EFFECTS OF PATENTING IN THE AAAS SCIENTIFIC COMMUNITY (2006), *available at* http://sippi.aaas.org/survey/AAAS_IP_Survey_Report.pdf. A survey of the American Association for the Advancement of Science regarding the "time taken to negotiate acquisition of technology" revealed that the fastest technology acquisitions involved nonexclusive licenses of which 39% were "completed in under one month." *Id.* at 19. Whereas of those transactions for which negotiations lasted more than six months, 33% were for exclusive licenses. *Id.* Additionally, "biomedical science (26 percent) had the highest proportion of transactions taking over six months." *Id.*

agreement more likely. For example, a contingency provision that specifies one royalty rate if the relevant patent later turns out to be essential and another rate if it does not, offers a compromise that parties in disagreement may accept more readily than a single (non-contingent) royalty rate. More quickly consummating a licensing agreement is especially important if, as in the vaccine case, delay is particularly costly.

One pervasive contingency-based clause in patent licenses is the antistacking provision. Such provisions establish different royalty rates for a particular license depending on the extent to which the licensee must acquire additional patent licenses. The intent of these provisions is to mitigate the present consequences of the uncertainty (and with it potential disagreement) regarding what technologies will be needed. Consider the following example illustrating how such an antistacking provision could be incorporated into an individual license with *A*. The licensee agrees to pay the licensor, *A*, a prescribed royalty rate which acts as a baseline. If the licensee needs to secure additional licenses complementary to *A* (such as *B* or *C*) to practice *A*'s technology, then *A* agrees to permit a fractional offset in light of these additional licenses. Oftentimes, such provisions permit a fractional offset against the royalty rate, e.g., 30-50%, up to a maximum permissible amount.[84] Antistacking provisions may also be useful in pool situations when, for example, the pool does not contain all the necessary intellectual property.

While these contingency provisions generally will be quite useful, they are less effective when addressing uncertain technology than when addressing uncertain ownership as exemplified by the priority hypothetical. Recall that the priority hypothetical addressed the underlying uncertainty through a contract contingent upon whether a patent was awarded. Ex ante the parties to the transaction (whether through individual licensing or pooling) establish one royalty rate if the licensor is granted a patent and a different royalty rate (zero) if the licensor is not granted a patent. Once the single patent at issue is awarded, the uncertainty is resolved and the licensee's obligations under each contract become clear. Resolution of the uncertainty is time-consuming but is eventually clear-cut as only one applicant receives the coveted patent.

Resolving the residual technological uncertainty (and the oftentimes closely related legal uncertainty), which would occur by the time payments are to be made, may result in downstream transaction costs in the form of arbitration, litigation, or settlement activities. Unfortunately, the determination of the appropriate contingency can sometimes be influenced or obscured by the actions of the licensee, thereby increasing transaction costs. Consider, for example, an ex ante setting in which three scenarios are deemed as possible outcomes: *A* and *B* are essential (*C* is unnecessary); *A* and *C* are essential (*B* is unnecessary); and *A* is essential and both *B* and *C* are actually substitutes (one

[84] Jones et al., *supra* note 19, at 1122. If the licensor permitted the licensee to offset entirely any additional royalties paid to third party licensors, then the licensee's incentive to negotiate effectively would decrease.

is necessary, the other is unnecessary). Now assume that *B* and *C* are substitutes in that a vaccine developer, the licensee, could theoretically choose between two paths (with comparable costs and likelihood of success) with one approach using *B* and other approach using *C*. During manufacturing, however, only *B* is used and *C* is no longer a potential substitute for *B* (they are not plug-in substitutes). Stated alternatively, specific investments during the development phase convert *B* into an essential input ex post despite it having been a substitute ex ante.[85] In this case, under individual licensing the developer has an incentive to argue that *B* and *C* are substitutes and, therefore, lower royalties should be paid to *B*, whereas *B* has an incentive to argue that it is essential and that higher royalties are warranted. There likely would be no hard evidence in support of the proposition that *C* was a viable alternative as development did not proceed with *C*. Litigation or arbitration is a likely outcome.

The interests of the licensors and the licensees are in opposition with respect to identifying the applicable contingency. This opposition increases the transaction costs associated with resolving the technological uncertainty. Importantly, however, because these costs arise subsequent to the license agreement, as long as such contingency provisions expedite the license agreement such provisions should prove valuable in situations where delay in development is the primary transaction cost.

Technological uncertainty has different effects on pool licensing and individual licensing. Unlike individual contracts, pool contracts can offer access to all the pool patents regardless of their respective essentiality or uniqueness for a single royalty.[86] Such an all-inclusive price would greatly reduce disagreements between the licensor and licensee stemming from technological uncertainty, e.g., the licensee is indifferent as to whether *B* or *C* are essential or are substitutes.[87] However, this inter-organization advantage would be traded off against potential intra-organization disputes regarding the division among pool members of payments received by the pool as a whole. In much the same manner that deftly deploying contingency provisions could expedite agreements in individual licensing cases, they could also facilitate pooling if profit division depended on a subsequent determination about technological relationships.

It is difficult to assess the absolute size of transaction costs associated with profit division within a pool. However, it is likely that such costs will be greater when the patent pool contributors diverge in terms of the essentiality of their respective patents. For example, the transaction costs may be lower when

[85] *See generally* WILLIAMSON, *supra* note 74.

[86] It is also possible for pool contracts to contain contingencies based on need and essentiality.

[87] *But see infra* Part IV.B.2 (discussing how the prospect of renegotiation may render even a pool licensee interested rather than indifferent to the resolution of such technological uncertainty).

the complements scenario is more likely than if the substitutes scenario is more likely because, in the former context, price negotiations are likely to be less contentious (all are essential) than amongst patent holders in the substitutes setting, where there is likely to be heated dispute over the probability and degree to which some of the patents are potential substitutes.

Ultimately, there does not appear to be any general rule that can establish a relative advantage of a pool over individual licensing with respect to transaction costs stemming from uncertain technology. Key questions in determining relative advantage are the extent to which technological uncertainty is a major obstacle to coming to an agreement (e.g., between licensors and licensees or among pool members), how effective contingency provisions are in reducing this obstacle, and the likely size of ex post disagreement costs. Contingency provisions help in both cases and the pool will not have the transaction costs associated with linkages across license contracts. The latter observation suggests that when there are many technologies that would be included in a pool, transaction costs will generally be lower for a pool than for individual licensing. Nonetheless, the answers to these questions and the advantage of one form over the other will be situation specific.

2. Pricing Efficiency

To evaluate the relative abilities of individual licensing and patent pooling to address technological uncertainty involving multiple technologies, it is also critical to understand their respective impacts upon pricing outcomes. Under individual licensing, pricing is established through market interactions in which each party seeks to maximize its individual profit. Patent pooling alters the pricing dynamics by coordinating licensors so as to maximize their joint profit which is then allocated internally. After expanding upon these different pricing dynamics, this Subsection examines the relative efficiency of the price outcomes under each regime.

This Section's treatment of pricing efficiency contains two simplifying assumptions. First, it focuses solely upon royalty-based licenses rather than payments in the form of lump-sum transfers or lump-sum transfers combined with royalties. Second, it assumes that individual licensees (buyers) lack the market power to influence pricing. While the licensees are assumed to behave competitively, the licensors (sellers) may enjoy varying degrees of market power. These assumptions, discussed below, do not affect the conclusions drawn. As with the preceding transaction costs discussion, this Section first explores pricing within the context of multiple, known technologies (the complements and substitutes scenarios) and then introduces the complication of uncertain technological relationships.

a. *Multiplicity and Certainty*

Assuming the presence of multiple technologies with certain relationships, the hypothetical developed allows for two possible scenarios: the complements

scenario wherein *A*, *B*, and *C* are each essential and the substitutes scenario wherein *A* is essential along with either *B* or *C*.

The complements scenario under individual licensing, with the interdependence of *A*, *B*, and *C*, illustrates what the economic literature refers to as "Cournot complements." The problems of pricing within that setting are well recognized.[88] Each patent holder has market power and could, in theory, charge a royalty rate (a "monopoly" rate) which reflects its essentiality. According to the Cournot model, if a series of such individual licenses were negotiated, the licensors would charge rates reflecting their respective monopoly power. The resulting combined royalty rate would be greater than both the rate that maximizes the licensors' joint profits and the rate that maximizes social welfare. Thus, a reduction of the de facto joint price would increase joint profits while also reducing the price distortion induced by the licensors' market power.[89] The licensors' prices are excessive because any individual licensor accounts only for the effect of its price increase on its own profits (increase in price per unit traded off against a decrease in the number of units sold). However, the individual licensor does not account for the effect of its price increase on the other licensors' profits, which are always negatively affected. That is, no licensor gains additional per unit profits from another's price increase, but each licensor does experience a loss in unit sales.[90]

Pooling helps mitigate inefficient Cournot pricing because the pooling firms internalize the effect that an increase in price has on the profits of all licensors. Since pricing is chosen to maximize joint profits, the possible net benefit of a price increase is calculated for the entire group of licensors. Pooling, therefore, will lead to a lower overall royalty relative to individual licensing.[91] Furthermore, economic analysis indicates that the profit-maximizing pool price will be the same price that a single monopoly input provider (e.g., only *A* is essential) would charge.[92] Increasing the number of essential inputs does not increase the ability of a single entity to extract profits from the downstream licensee, since there is a single monopoly profit. Henceforth, this Article will refer to this profit-maximizing pool price as the "single monopoly price."

While this Article invokes the single monopoly profit theory within a horizontal context, it is most commonly associated with contexts involving vertical integration such as tying. Within such contexts, "[a] firm with a

[88] Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 2013-14 (2007).

[89] *Id.* at 2011 ("[T]he aggregated or stacked royalty rate is not simply the sum of the royalty rates that would be negotiated bilaterally by each patent holder in the absence of the other patent holders.").

[90] *Id.* at 2013.

[91] *See* Richard J. Gilbert, *Antitrust for Patent Pools: A Century of Policy Evolution*, 2004 STAN. TECH. L. REV. 3, ¶¶ 25-26.

[92] *Id.* ¶ 25 (demonstrating that a patent pool maximizes revenue at the single monopoly price).

monopoly at one level of the chain gets all of the monopoly profit if it charges a monopoly price and everyone else in the chain charges a competitive price."[93] The licensor, therefore, would not benefit from extending its monopoly within a given supply chain because it would be unable to increase its profits.[94] Regardless of the context, the underlying theory turns upon identifying those circumstances *not* susceptible to monopoly leveraging. Over time, extensive analysis in the economics and legal literature has led to a clearer understanding of the conditions under which this theory does or does not apply. The most frequently cited prerequisite for its applications is that the inputs, whose control is at issue, must be required in fixed proportions.[95] This condition is clearly met by the circumstances at issue herein where essential patents are required for vaccine development. That is, every unit of output requires access to each essential patent.

What are the implications of the single monopoly profit theory for pricing under the substitutes scenario? Clearly, this scenario also contains a complementary element because it is essential that either *B* or *C* supplement *A*. Therefore, individual pricing will reflect both the complementary relationship between *A* and *B* or *C* and the substitute relationship between *B* and *C*. As such, aspects of the pricing dynamics characterizing the previous complements scenario have continued relevance within this altered setting. The new element warranting consideration is the degree of competition between *B* and *C*.

A's profit maximizing royalty rate reflects the competition between *B* and *C* as well as the interaction of *B* and *C* with *A*. The outcome of the pricing interactions reflects the degree of competition between *B* and *C*, which could range from minimal to intense. A full economic analysis of this wide range of competitive interactions falls beyond the scope of this Article. However, one can glean the key dynamics by comparing pricing outcomes at the two extremes of competition between *B* and *C*.

Recall from the Cournot complements pricing discussion that individual licensing in the presence of complements results in each patent holder reducing its own royalty rate to a level below its own monopoly price.[96] *A*'s royalty, under the substitutes scenario, will also be less than the single monopoly price because a complementary input is still necessary. However, *A*'s royalty will increase as the competition between *B* and *C* intensifies and, in any event, will be greater than it would have been under the complements scenario ($A + B + C$). Competition between *B* and *C* forces each to lower its royalty relative to what they would have charged if their inputs were essential complements. If the competition between *B* and *C* is sufficiently intense, it is possible that they

[93] David S. Evans & A. Jorge Padilla, *Designing Antitrust Rules for Assessing Unilateral Practices: A Neo-Chicago Approach*, 72 U. CHI. L. REV. 73, 77 (2005).

[94] *Id.*

[95] *See generally* Einer Elhauge, *Tying, Bundled Discounts, and the Death of the Single Monopoly Profit Theory*, 123 HARV. L. REV. 397 (2009).

[96] *See supra* Part III.B.2.a.

will license their respective patents at or near marginal cost (the competitive outcome). Under such circumstances, *A* should be able to negotiate a royalty rate that equals or approximates the single monopoly price. Competition is bad for *B* and *C* but good for *A*. The combined royalties a licensee pays will exceed the single monopoly price and hence the joint profits will likely increase with increases in competition.

Consider now a pool that includes all three patents and in which *B* and *C* are substitutes ("substitutes scenario"). Such a pool would be problematic under current antitrust law.[97] Nonetheless, consideration of such a pool is necessary to understand whether (assuming no legal prohibition) such pools would form, the potential consequences if they did, and the basis for their prohibition.

Antitrust discourages the pooling of substitutes owing primarily to the concern that it would provide a mechanism for collusion between competitors. This price-fixing concern is particularly well-founded if the pool contains only *B* and *C*. The presence of essential patent *A*, however, helps mitigate the negative price effect. Assuming the conditions exist that support the single monopoly profit theory, then a pool consisting of the three patents (*A*, *B*, *C*) would license the pooled technology (including the substitutes) at the same price that would obtain if there were only one monopoly input.[98] This price will be lower than the combined prices under individual licensing. The lower pool price also represents a social welfare improvement over individual licensing.

Thus far, this Article has focused primarily upon the overall price efficiency of pools once they are formed. Additional factors warranting consideration include how pool profits will be divided among the members, whether a pool will form, and what are the competitive consequences of failed pool negotiations.

Assuming voluntary participation, each pool member must receive at least as much profit through the pool as it would have earned through individual licensing. Within the substitute scenario, all of the prospective pool members will not want to divide the profits equally. *A*'s interests run counter to the incentives of *B* and *C* to cooperate to raise their share of the pool profits at *A*'s expense. This results because, as discussed within the individual licensing analysis, *A*'s individual royalty increases as *B* and *C* compete more intensely. Thus, as the individual licensing situation is more competitive for *B* and *C* than the pool, *A* will require the more competitive *B*/*C* pricing (in terms of profit division) as a condition of its participation. Nonetheless, a profit division satisfactory to all participants should be possible because when the profit-maximizing pool price is the single monopoly price, there are some additional profits will accrue under pooling versus individual licensing. Furthermore, these profits do not come at the expense of social welfare because *B* and *C*

[97] *See infra* Part IV.B.2 (discussing the antitrust implications of pooling substitutes).

[98] *See supra* notes 91-92 and accompanying text.

cannot price fix in a manner that simultaneously decreases social welfare but increases their respective profits.

Contentiousness regarding profit division has some potential to increase the transaction costs associated with pool formation. This is especially true as the likelihood of the substitutes scenario increases. Part of the problem is that pool formation depends on agreement regarding profit allocation. However, the appropriate allocation depends on the degree to which *B* and *C* compete which is likely to be a point of disagreement between *A* (arguing for significant competition) and *B*/*C* (arguing for little competition).

In sum, pooling confers a pricing benefit upon both the licensors and society vis-à-vis individual licensing when there are multiple essential technologies with known relationships (whether the complements or substitutes scenario obtains). This pricing efficiency increases as the number of essential patents increases. The next Subsection introduces the further complication of uncertain technological relationships.

b. *Multiplicity and Uncertainty*

The effect of technological uncertainty on pricing efficiency can be explored by modifying the hypothetical with the additional assumption that at the time of licensing the parties to the license are uncertain whether the relationship amongst the various patents corresponds to the complements or the substitutes scenario. Contingency provisions can mitigate not only the problems associated with the uncertainty regarding timing demonstrated in the priority hypothetical analyzed previously, but also the uncertainty regarding technological relationships. For example, a license can specify different royalties depending on whether *B* and *C* are found to be complements or substitutes. Using contingency provisions to mitigate uncertainty problems, however, does not alleviate the pricing inefficiency that is fundamental to the individual licensing of complementary patents.

The magnitude of the salutary effects attendant to contingent contracting depends, in part, on the extent to which resolution of the technological uncertainty is clear-cut and easily verified by third parties. If resolving the relationship between *B* and *C* is difficult, it creates the potential for future disputes. Such disputes may reflect somewhat more contrived positions. These considerations greatly complicate predicting ultimate pricing outcomes, which this Article does not attempt.[99] Nevertheless, this Article next explores

[99] The transaction costs discussion remarked that the interests of the owners of the potential substitutes *B* and *C* conflict with the interests of the licensee. It then explored how *A* prefers strong competition between *B* and *C* and, hence, *A* would also prefer to argue for the substitutes outcome (which has some competition between *B* and *C*) over the complements outcome (no competition between *B* and *C*). These tensions, of course, underscore that there are no disinterested parties involved in the transactions. Moreover, the parties involved are likely to be the best informed about the underlying technologies. To the extent that these ex post disputes may also be resolved through renegotiating royalties, this

some of the consequences flowing from contingent contracts and residual uncertainty.

With regard to individual licensing, if a downstream dispute seems reasonably probable, then it will likely be reflected in the ex ante licensing negotiations. More specifically, increased transaction costs may characterize the ex ante negotiation because when greater latitude for disagreement exists, greater attention is warranted when specifying the contingencies. The pricing effect is less clear. If the parties incorporate contingency provisions, the pricing terms underlying each contingency should reflect each party's assessment of the anticipated dispute and its resolution. Pricing in the license contract may be distorted as each party seeks to establish a superior downstream negotiating position or to move each price in the direction of the "average" price across the contingencies to reduce risk. At the extreme, some parties might choose to eschew contingency provisions, in effect, sacrificing some profits to enhance predictability and avoid downstream disputes.

Similar disputes would exist between a pool qua licensor and a licensee if the pool license were contingent upon the technological relationship. But if a single monopoly price is the optimal pool price under either technological relationship, then contingency provisions are unnecessary and the uncertainty will not affect pricing and transaction costs regarding the licensor-licensee contract. While the pool, relative to individual licensing, will reduce disputes between the licensors and licensees, the nature of the technological relationship still has potential implications for the division of pool profits. As discussed, the share of profits that the owner of essential patent *A* can legitimately claim will increase in the substitutes scenario relative to the complements scenario.[100] Also, because the internal profit division will not impact the amount of profits overall (i.e., the division does not distort the number of units sold given a single monopoly price), the pool can likely establish a single division of profits ex ante more easily than a licensee and differently motivated licensors could agree to a single royalty price for each contract regardless of technological relationship.

In sum, pool licensing involves *different* transaction costs than individual licensing. At its most basic, pooling becomes relatively more attractive when the transaction costs of individual licensing exceed the costs of pool formation and governance. Even if volume-based transaction costs are unlikely to be significant, as the complexity of the individual transactions increases; this value will increase nonlinearly with the number of transactions. The pool enables coordinated pricing, which can translate into price efficiencies that benefit both pool members through increased profit and consumers through

alters the welfare effects associated with the pricing. As prices can increase or decrease, there is no obvious prediction regarding the welfare effects of the renegotiation.

[100] One difference between the licensor-licensee group and within the licensor group disputes is that the licensors are likely to have less special information advantages relative to each other about the technology relationships than would the licensee.

lower prices. For small numbers of essential patents, the costs of pool formation and governance could be large enough to more than offset the advantages pools have over individual licensing. On the other hand, pools involving large numbers of patents would appear to offer some benefit over individual licensing.

These general observations regarding pricing efficiency reflect, in part, several underlying assumptions. The remainder of this Section will address two of them. The first assumption is that licenses will be heavily weighted to royalties rather than a combination of royalties and an up-front payment. The second assumption is that the licensee (buyer) market power is insignificant relative to licensor (seller) market power.

This Article's pricing analysis assumes that payments to licensors are made via royalties rather than as upfront payments. Within the biopharmaceutical industry, while royalties are not the most efficient mechanisms as a matter of economic theory, they are clearly the most important mechanism as a matter of practice.[101] Within the vaccine context at issue it is technically more efficient for the royalty rate to be set at marginal cost and for the profits to be conveyed through an up-front payment that is independent of unit sales. This pricing scheme avoids the resource allocation inefficiencies that would otherwise result from end-user demand distortions caused by royalties that exceed marginal cost. In practice, however, most of the upstream profits come through royalty payments.[102] This reliance results in large part from the sizable risk involved with predicting future demand and profits on a product that has not yet been developed and for which demand may also be unknown. If most of the payments to upstream patent holders came via a lump sum payment, then even if the vaccine was not successfully developed or if demand was weak, the manufacturer would still have to pay the lump sum whereas with a royalty-based contract there would be little or no payment.

For a given level of licensor profit, higher up-front payments and lower royalties yield more socially efficient pricing. Up-front payments also enable the licensor to extract rents from the licensee more efficiently because the licensor can profit without inducing a reduction of end-user sales (which would otherwise occur with an increase in the royalty rate). This analysis applies to both individual licensing and pool licensing. Further study would be valuable to understand how increased reliance upon up-front payments would affect the

[101] ASS'N OF UNIV. TECH. MANAGERS, AUTM U.S. LICENSING ACTIVITY SURVEY: FY 2008 SURVEY SUMMARY 38 (2010) (indicating that running royalties accounted for approximately 80% of total payments for university licenses in FY 2008); LICENSING EXECS. SOC'Y, BIOPHARMACEUTICAL ROYALTY RATES & DEAL TERMS REPORT 67 (2008) (surveying biopharmaceutical deals in the mid-2000s and collecting responses from about twenty-one deals for which the average up-front payments was 15% of the net present value of the deal with a median of 7%).

[102] *Id.*

relative differences between pooling and individual licensing in terms of price and transaction cost efficiencies.

This Article has not specifically delineated what, if any, downstream market power exists within the hypothetical. The potential licensees, as described in Part II, are firms in an oligopolistic industry and hence might be expected to have some market power, albeit less than that possessed by an essential patent holder.[103] As a general matter, licensee market power should exert a downward force on royalty rates in both the individual and pool licensing situations. If there are many essential patents, then the combined royalty is likely to exceed the single monopoly royalty rate even when the licensees have substantial market power. For example, assume that licensee market power is quite strong and, as a result, the negotiated royalty for each license lies halfway between the monopoly and the competitive levels. Under those circumstances, and further assuming numerous required licenses, the combined individual royalties would exceed the single monopoly royalty. As such, while a patent pool would still offer superior price efficiency relative to individual licensing, the size of the efficiency would be less than if there was no licensee market power. In contrast, if licensee market power is substantial and there are very few patents at issue, then it is possible that the combined individual royalty rate would be below the single monopoly royalty rate. In this case the price efficiency advantage of the pool is unclear, because the licensors' single monopoly royalty rate is greater than the sum of the individual licensing royalty rates. The pool has an incentive to try to raise the pool royalty rate higher, towards their ideal monopoly rate, but the market power of the licensees will still be a countervailing force. Much depends on whether the pool somehow increases the relative market power of the licensors. This situation requires further analysis that is beyond the scope of this Article.

C. *Exclusivity*

This Article has explored a series of hypothetical licensing arrangements wherein the relationship between the licensor and licensee was either non-exclusive or unspecified. The insights developed, however, are generally applicable to exclusive licenses as well. Acquiring exclusivity over inputs often facilitates a licensee obtaining exclusivity in the output market, which is a common objective in the vaccine industry. This Section explores some unique issues regarding both transaction costs and pricing efficiency, that exclusive licensing can introduce regardless of whether that exclusivity is

[103] The standard Cournot complements model assumes that the downstream purchasers of the intermediate good have no market power. This is the simplest circumstance to analyze because it involves no negotiation between the upstream and downstream firms. Price is set by either a monopolist patent holder or through upstream competition and the licensees are price-takers. At the other extreme is a setting in which an upstream monopolist faces a downstream monopsonist. Price negotiations would ensue and the outcome is indeterminate.

achieved through individual licensing or patent pooling. These additional issues are the effect of exclusivity on decreasing licensee competition, the increased risk to a licensor of relying on a single developer when development success is not certain, a coordination problem that manifests when there are multiple essential technologies, and the foreclosure incentives of a licensor of an essential patent who is also a downstream developer and licensee of other technologies. The contours and wisdom of antitrust law and policy regarding exclusivity are addressed in Part IV.

The vaccine developers, the licensors in the hypotheticals, may seek exclusive contracts which offer the prospect of higher profits by eliminating competition for vaccine sales. Eliminating such competition both raises the final good's price and ensures that the entire market's sales go to the exclusive developer. Reducing competition generally harms consumers unless market demand is insufficient to support more than a single development effort.

As discussed in Part II.C, vaccine markets have a number of characteristics that favor exclusivity. Oftentimes the markets are quite small and the demand may be highly uncertain especially when vaccine development (for a disease such as influenza) is based upon the projected size and severity of the anticipated outbreak. Two additional characteristics of the vaccine market more generally warrant further consideration. First, the purchasers are often governments who wield substantial market power owing to volume purchasing. With such buyer power, prices may be forced substantially below monopoly levels. Second, the vaccine markets appear susceptible to tipping in the sense that the better of multiple vaccines, even if it is only slightly superior, may effectively dominate the market despite substantial discounting of the comparatively inferior vaccine.[104] While this winner-take-all scenario still offers equally situated developers the same expected sales, it increases the risk the developers bear.[105] Overall, these factors decrease the risk-adjusted profits that a developer can expect and, therefore, reinforce the need for greater market demand to justify multiple development efforts given the substantial R&D costs.[106]

[104] That is a function of multiple factors, including the paramount importance of inclusion on the Advisory Committee on Immunization Practices ("ACIP") list. *See* Danzon, *supra* note 65, at 695; *see also* Dep't of Health & Human Servs. & Ctrs. for Disease Control & Prevention, *General Recommendations on Immunizations: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 55 MORBIDITY & MORTALITY WKLY. REP. 1, 3-4 (2006), *available at* http://www.cdc.gov/mmwr/PDF/rr/rr5515.pdf.

[105] An offsetting factor is that a market that tips to monopoly has greater profit potential than does a duopoly market.

[106] Even if licensees do not need exclusivity, the licensees may attempt to acquire at least one exclusive contract to ensure themselves of a bargaining chip to gain access to other essential technologies. Furthermore, because successful product development is uncertain, a vaccine monopoly may emerge despite non-exclusive contracts for inputs when only one vaccine developer succeeds.

From the social standpoint, therefore, exclusivity can be competitively justified when the anticipated market demand is less than necessary to cover fixed R&D costs for multiple developers.[107] Unfortunately, as costs are private and demand subject to debate, arguments favoring exclusivity can also be proffered disingenuously where demand is sufficient to support more than one developer and exclusivity is merely a means to achieve higher profits.

One method to obtain exclusivity in the output market, assuming successful development, is by acquiring exclusive access to at least one essential patent as well as non-exclusive access to all other needed patents. But gaining such rights requires that at least one licensor of an essential patent be willing to license its patent on an exclusive basis. Licensors should prefer exclusive to nonexclusive contracts because the anticipated licensee profit associated with exclusivity is greater than the sum of the profits from multiple licensees and, therefore, a licensor should expect a larger payment with an exclusive contract. However, two factors involving development risk may mitigate against such a licensor preference. First, if the licensor's compensation is based primarily upon royalty payments and successful development is uncertain, then the licensor will favor nonexclusive agreements in order to maximize the probability that at least one development effort will be successful. For example, if a single developer's probability of success is modest, then the total expected profits available from multiple nonexclusive licenses may exceed the expected profits from a single exclusive license. Second, the licensee's relative unwillingness to make noncontingent (e.g., lump sum) payments reduces the upper limit of overall payments (royalty and lump sum) that the licensee would be willing to offer to obtain exclusivity. For example, if royalty rates for nonexclusive licenses are already at the monopoly level, the premium a licensee would pay for exclusivity would have to be channeled through lump sum payments, which exposes the licensees to additional risk that they may be reluctant to accept.[108]

If one assumes that developers want exclusive rights and that licensors are willing to award such contracts, the question becomes not whether the license is negotiated as an exclusive but rather which licensee receives the exclusive rights. Given the uncertainty attendant to such R&D efforts, the licensor would likely choose (assuming the same royalty) the licensee with the highest likelihood of success.

When multiple essential technologies are implicated, exclusivity can introduce additional negotiation frictions if licensors differ in their assessments

[107] Because each licensee is differentiated, competition between the licensees will not bid away all of their profits.

[108] Comparatively large lump sum payments appear to be uncommon in practice, perhaps because licensees are unwilling to make large certain payments for even large uncertain outcomes. *See supra* note 101. There is greater scope for increasing royalties when the licensees have market power which counters at least some of the market power of the monopoly licensors. One would expect to see more exclusive contracts in such situations.

regarding the merits of the prospective licensees. To illustrate this dynamic within the context of individual licensing, consider a simplified version of the complements scenario: *A* and *B* are both essential parties and there is no additional party *C*. Prospective licensees *X* and *Y* each want exclusive rights to at least one of the two technologies and, at a minimum, nonexclusive rights to the other technology. Consequently, a coordination issue arises that does not exist with nonexclusive licensing. Licensors negotiating exclusive licenses will try to identify the licensee most likely to develop the technology successfully. If the licensors differ in their assessments regarding the buyers' relative abilities, each licensee could acquire an exclusive license to a different complement (recreating the underlying blocking situation). Moreover, a licensor's assessment regarding the licensee's capabilities may vary over time as additional information is acquired. If *X* licensed *A* exclusively and *Y* licensed *B* exclusively, then various contingency provisions may be triggered or a round of sublicensing may ensue. Such a negotiation thicket has the potential to delay significantly the consummation of the licenses necessary for vaccine development. The possibility of delay increases if the two prospective licensees each want exclusive rights to both of the essential inputs. Controlling more than one essential patent provides insurance against the possibility that a patent thought "essential" was actually not essential, either because a substitute for it is subsequently uncovered or because a rival manages to invent around the single blocking patent.

Patent pools can theoretically reduce transaction costs because each individual licensee would not have to negotiate to acquire exclusive licenses. A closely related advantage of pooling is that participants can share information and force an internal decision as to which exclusive buyer to endorse, thus reducing some of the negotiational breakdown and coordination problems that can plague independent licensing. This is not to argue that the pool is always more efficient, of course, as the pool has its own formation and internal governance issues. However, it seems quite plausible that the individual licensing coordination problem grows faster than the pool formation/governance problem as the number of essential patents increases and that this problem could prove an obstacle to society's desire to act quickly.

The forgoing discussion assumed that each licensor sought only to maximize its direct profits from an exclusive license deal. In many industries, including the vaccine industry, one or more licensors may also be potential licensees. In such cases a vertically integrated licensor who holds an essential patent can legally block any potential licensee from successful development. In theory, if that licensor sought only to maximize profits, it would still award exclusivity to the most efficient potential licensee.[109] But there will be cases in

[109] Sole ownership does, however, offer a potential pricing efficiency that renders it attractive for profit and social welfare reasons. That efficiency derives from avoiding the double-monopolization problem under fixed proportions that would emerge with

which the vertically integrated firm instead uses its blocking power to help establish itself as the exclusive developer, perhaps to avoid shutting down otherwise underutilized facilities or laying off excess staff. Such considerations have the potential to further complicate negotiations and increase transaction costs. It is unclear whether such costs would be higher for individual licensing or for pooling.

The analysis in the previous sections of this Article regarding the relative transaction costs and price efficiency associated with individual licensing and pools also holds under exclusivity. However, because exclusivity further increases the interrelatedness among license negotiations, it is likely to increase the negotiational transaction costs for individual licensing faster than it increases the joint pool negotiation costs. The interrelatedness costs are exacerbated when the licensors prefer nonexclusive contracts while the licensees prefer exclusive contracts, and when the licensors have different assessments regarding which licensee is most likely to succeed in its development efforts. While negotiational transaction costs associated with exclusivity will vary greatly across licensing settings, and hence are unlikely to always favor one licensing arrangement, in general the costs would appear to be somewhat greater with individual licensing than with pools.

IV. RETOOLING POOLING

Industry standard-setting endeavors provide the most common contemporary context in which patent pools are formed. This Article explores the potential role for pools in industries characterized by very different patent and competition landscapes. In particular, Part II described the key patent and market features of the vaccine industry which is an exemplar of a very different industry setting in which patent rights are frequently fragmented and the market power associated with the patents is not created through joint activities such as a standard-setting process. Given those industry characteristics, Part III applied basic economic theory to a series of hypotheticals characterized by varying degrees of technological uncertainty in order to illuminate the relative competitive pros and cons of pooling versus individual licensing. This Part combines those practical and theoretical insights to underscore the inadequacy of contemporary antitrust law and policy to address contexts such as the vaccine industry. It identifies two areas (substitutes and exclusivity) that warrant revisiting and offers general recommendations with the goal of instigating and guiding further analysis. This Part concludes by situating antitrust issues regarding patent pools within the broader discourse between the patent and competition communities.

fragmented independent ownership of monopoly inputs and monopoly control of the end-user market.

A. *An Assessment of Individual Licensing Versus Pooling*

Part III explored how individual licensing and patent pooling differ in the degree to which they efficiently address the problem of fragmented property rights. The relative effectiveness of each form of licensing depends on at least two key factors: the extent to which each approach incurs significant transaction costs and how well each fares in terms of pricing efficiency. Performance on these dimensions is highly fact-specific. Nonetheless, several observations regarding their relative merits are possible.

In many settings, such as patent licensing associated with a technological standard, pooled licensing is preferable to individual licensing owing to the sheer volume of licenses to be negotiated. Such is not likely to be the case with vaccine development, for example, because the transaction costs at issue relate primarily to the complexity of the negotiations and the effect of that complexity in slowing time sensitive R&D. Complexity increases when the technological relationships among the various patents relevant to the R&D at issue are uncertain, appropriate and desired pricing is interrelated across the technologies to be licensed, and exclusivity is highly coveted. Interrelatedness considerations become more important at an increasing rate as the number of technologies to be licensed increases. Further, transaction costs considerations become increasingly significant as the premium for delay increases. Thus, the one-stop characteristic of pools relative to individual licensing gives pools a potentially significant advantage for dealing with such transactional complexities. This advantage may be offset, however, if pool formation and maintenance costs are significant or the absolute level of the transaction costs that complexity introduces is not particularly significant. In the vaccine development setting, technological uncertainty is commonplace, urgency is great, and pricing is frequently interrelated. In this setting, therefore, transaction costs are likely an important factor in determining the relative attractiveness of individual licensing even assuming a relatively small number of licenses.

The pricing efficiency of pools is likely to be welfare superior to individual licensing when the conditions favoring pool selection of the single monopoly price are present and the sum of the individual licensing prices exceeds this single monopoly price. This comparative advantage increases as the gap between these two widens. The combined individual licensing price can greatly exceed the single monopoly price when licensees require access to multiple essential patents. A key value of patent pools, then, is the pool's ability and incentive to set a more efficient combined price than would emerge from individual licensing. As discussed in Part III, by internalizing the profit incentives of the individual pool members, pricing is more socially efficient (e.g., the pool sets a combined license at the single monopoly price) while, at the same time, more profitable. These advantages do not accrue, however, in the absence of a clearly essential patent. If a pool did not include an essential patent but did include some substitute technologies, the pool becomes, in part, a mechanism to give such potential substitute technologies market power,

possibly resulting in a higher pool price relative to the sum of the individual licensing prices. Furthermore, the price benefits to efficient pricing through the pool diminish as the dominant source of payment shifts from royalty payments to lump sum fees.

In light of these dynamics, the relative price efficiency of pooling vis-à-vis individual licensing hinges, in large part, upon the existence of an essential patent input (or at least the very strong likelihood that at least one of a group of pooled technologies will ultimately be found to be essential) and the use of royalties as the primary source of license payments. Moreover, as the number of essential patents increases, the number of complements and the pricing advantage of the pool over individual licensing should also increase. Finally, the pure form of the single monopoly price argument assumes no licensee market power to offset the market power that many of the individual licensors may enjoy. As licensee market power increases, the sum of the individual license prices also decreases, rendering the pool less attractive for society.[110]

Given this general characterization of the relative pros and cons of pooling versus individual licensing in the vaccine setting at issue, the next Section offers some recommendations for improving antitrust law and the competition discourse regarding patent pools.

B. *Technological Relationships – Possible Substitutes*

Discerning the technological relationship between patents and identifying whether any are essential may be extremely difficult, particularly when the technology is in its early stages and further R&D is required. Willard Tom, former counsel to the SARS patent pool, observed that because some vaccine manufacturers may utilize only a portion of the viral genome while others may utilize the entire sequence, a single determination of complementarity or substitutability regarding any associated patents may not be possible.[111] That sentiment has been echoed within the context of biomedical research more broadly: it may be that "where patent pools would be of most interest, final products have yet to be developed. But when final products do not yet exist it may be *ipso facto* especially difficult to determine which patents are essential."[112] This difficulty of characterizing the underlying technological relationships may be compounded if the options available are overly simplistic ones such as complements, substitutes, or neither.

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[110] The analysis of market power on both sides of the market is complex and would also involve distinguishing how much additional market power a pool might have compared with the market power that already may exist with each individual licensor. For example, if the pool does not enhance the market power that already existed, it is not clear that the pricing via a pool would result in a higher combined license price than under individual licensing even when the pool price falls below the single monopoly price.

[111] Tom, *supra* note 69, at 28-29.

[112] Gaulé, *supra* note 69, at 9.

The extent to which patent pools play a meaningful role in facilitating R&D, given fragmented intellectual property, will reflect to some extent the manner in which antitrust handles technological uncertainty. Unfortunately, contemporary antitrust law and policy has been formulated largely upon the assumption (stemming from the standard-setting context) that technological relationships can be identified with virtual certainty and that only essential patents (complements without substitutes) can be included within a pool. The particularly prominent role of the antitrust agencies' policy pronouncements regarding pooling has contributed to this skewed perspective. This Section advocates an antitrust analysis incorporating the more nuanced tradeoffs, including the recognition of possible substitutes, required in circumstances such as those characterizing the vaccine industry.

1. Legal and Policy Pronouncements Regarding Possible Substitutes and Pools

Patent pools that contain substitute technologies pose the risk, in the extreme, of merely providing a mechanism for naked price fixing. A preoccupation with such collusion is readily apparent in the key agency pronouncements regarding patent pooling. Owing to the factual context (standard-setting) and practical context (policy statements and advisory opinions) to which that guidance has been primarily directed, the resulting guidance is incomplete. Additionally, the relative dearth of case law on this issue has contributed to the arguably excessive profile of these policy pronouncements. Fortunately, the antitrust regime is well-equipped to transcend its current shortcomings by applying the more nuanced competitive effects analysis that it routinely applies within other contexts.

The FTC and DOJ's joint guidelines, *Guidelines for the Licensing of Intellectual Property* ("*IP Guidelines*"), address numerous issues involving antitrust and intellectual property including those arising from patent pools.[113] Although such statements of enforcement policy do not formally bind either the agencies themselves or the courts, their influence, particularly in the absence of case law, can be considerable.[114] The *IP Guidelines* emphasize that the procompetitive benefits attendant to pooling derive from "integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation."[115] The language of the guideline provision itself is somewhat open-ended in that the inclusion of

[113] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY 27-30 (Apr. 6, 2005) [hereinafter IP GUIDELINES], *available at* http://www.justice.gov/atr/public/guidelines/0558.pdf.

[114] *See generally* Hillary Greene, *Guideline Institutionalization: The Role of Merger Guidelines in Antitrust Discourse*, 48 WM. & MARY L. REV. 771 (2006) (chronicling the adoption of "non-binding" agency guidelines and analyzing the use and effect of those guidelines on the evolution of antitrust merger law).

[115] IP GUIDELINES, *supra* note 113, at 28.

substitutes within a pool is not expressly prohibited. Nonetheless, it is worth noting that two examples which illustrate the relevant guideline are somewhat extreme. Example 9 in the *IP Guidelines* illustrates an anticompetitive joint assignment of patent rights, similar for instant purposes to a patent pool, which are close substitutes.[116] Example 10 illustrates a procompetitive patent pool in which the patents contributed are not only complementary but also blocking.[117]

In addition to general enforcement policy statements, the U.S. federal antitrust agencies each provide an important mechanism which enables private parties to receive an advisory opinion with regard to enforcement intentions. For the Antitrust Division within the Department of Justice that guidance takes the form of Business Review Letters.[118] Much of the current antitrust guidance on patent pools derives from a series of such letters involving standard-setting organizations.[119] These letters evaluate the potential procompetitive and anticompetitive effects of the proposed pools in much the same manner as the *IP Guidelines* delineate. Unlike the *Guidelines* which are extremely general, DOJ's business review letters address specific factual circumstances. The letters at issue explicitly recognize that each proposed pool will "exclude substitute technologies . . . by admitting to the pool only those complementary patents essential to manufacture products complying with the standard."[120] Two characteristics of the business review letters are particularly relevant. The first is merely a reflection of the administrative context in which the guidance is offered. If an antitrust agency is willing to state that it would not institute an antitrust action, there is a strong bias that the practices evaluated in this manner

[116] *Id.* at 25.

[117] *Id.* at 29-30.

[118] *See* 28 C.F.R. § 50.6 (2009) (delineating the procedure for requesting a business review letter from the Department of Justice).

[119] The relevant letters are: Dep't of Justice, Antitrust Division, *IEEE*, Business Review Letter (Apr. 30, 2007), http://www.justice.gov/atr/public/busreview/222978.pdf; Dep't of Justice, Antitrust Division, *VITA*, Business Review Letter (Oct. 30, 2006), http://www.justice.gov/atr/public/busreview/219380.htm; Dep't of Justice, Antitrust Division, *3G Patent Platform Partnership*, Business Review Letter (Nov. 12, 2002), http://www.justice.gov/atr/public/busreview/200455.pdf; Dep't of Justice, Antitrust Division, *Hitachi, Ltd., Matsushita Electric Industrial Co., Ltd., et al.*, Business Review Letter (June 10, 1999), *available at* http://www.justice.gov/atr/public/busreview/2485.pdf; Dep't of Justice, Antitrust Division, *Koninklijke Philips Electronics, N.V., Sony Corporation of Japan and Pioneer Electronic Corporation of Japan*, Business Review Letter (Dec. 16, 1998), *available at* http://www.justice.gov/atr/public/busreview/2121.pdf; Dep't of Justice, Antitrust Division, *MPEG LA, L.L.C., et al.*, Business Review Letter (June 26, 1997), *available at* http://www.justice.gov/atr/public/busreview/215742.pdf.

[120] *See* U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION 71 & n.91 (2007) [hereinafter DOJ/FTC REPORT] (identifying the relevant portions of the letters *supra* note 119: MPEG-2 Business Review Letter at 10-11; 3C DVD Business Review Letter at 10-13; 6C DVD Business Review Letter at 12-13; 3G Business Review Letter at 10).

will tend strongly towards the unambiguously permissible.[121] The second is the factual context, standard-setting, which they directly address.

Although the business review letters do not directly state that DOJ will challenge pools that include possible substitutes,[122] the absence of any letters nominally sanctioning pools with possible substitutes provides at least indirect evidence, potentially sufficient to have a chilling effect, that such pools raise competitive concerns. This is particularly true given that it is both common knowledge and common practice that business review letter requests likely to result in a DOJ challenge are withdrawn.[123]

While the antitrust agencies have long recognized that the rule of reason applies to patent pools, recently they have abstractly acknowledged the prospect that this may include countenancing inclusion of possible substitutes within a pool.[124] At the same time, these pronouncements regarding pools within the standard-setting contexts do not identify any concrete instances in which the inclusion of possible substitutes was permitted, thereby likely leaving potential pool participants wondering if the agencies' current appreciation for the net benefits of allowing possible substitutes into a pool remains at a more theoretical level.[125]

At a minimum, formal agency guidance on the issue of substitutes suggests that a pool that may include substitutes is subject to a substantial and potentially chilling prosecutorial risk. *Princo Corp. v. International Trade*

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[121] "Parties desiring a favorable business review often incorporate mechanisms designed to eliminate or minimize risk of anticompetitive effects in order to give the Department sufficient confidence in its assessment of the likely competitive effects of the proposed activity to permit the issuance of a favorable letter." DOJ/FTC REPORT, *supra* note 120, at 72. If an enforcement investigation is launched into an operating pool, "the failure to incorporate all the safeguards set forth in the pooling business review letters will not automatically lead to the conclusion that the pool is anticompetitive." *Id.* The agencies will evaluate whether the "actual conduct has an anticompetitive effect." *Id.* at 72-73.

[122] The antitrust agencies have consistently avoided condemning patent pools that include substitutes as being per se illegal (in the absence of an overt price-fixing scheme). *See id.* at 10. Thus,

> [The antitrust agencies] will continue to evaluate the competitive effects of cross licenses and patent pools under the framework of the Antitrust and IP Guidelines. Given the cognizable benefits and potential anticompetitive effects associated with both of these licensing practices, the Agencies typically will analyze both types of agreements under the rule of reason.

Id. at 9.

[123] James A. Keyte, *The Risks and Rewards of Business Review Letters*, 12 ANTITRUST 28 (1998). Business letter requesting parties may withdraw their letter requests or modify their proposed conduct in response to DOJ feedback. These options may explain why ninety-five percent of business review letters between 1994 and 1997 were letters indicating no intent-to-challenge the conduct at issue. *Id.*

[124] *See, e.g.*, Frances Marshall, *Patent Pools: Perspectives on Enforcement*, 867 PLI/PAT 367, 379-80 (2006); DOJ/FTC REPORT, *supra* note 120, at 76-78.

[125] DOJ/FTC REPORT, *supra* note 120, at 76-78.

Commission provides some salutary guidance.[126] In *Princo*, the Federal Circuit addressed the antitrust implications of pooling non-essential patents. The "central issue" was "whether Princo's admitted infringement of Philips's patents [was] subject to a patent misuse defense."[127] Princo proffered a misuse defense arguing that the patents it infringed were included in a pool despite the fact that they were not essential to the pooled technology.[128] The Administrative Law Judge ("ALJ") found that the pooled patents covered technology for which "a non-infringing, 'economically viable[] alternative technology existed.'"[129] The ALJ then ruled that the "tying arrangement constituted misuse."[130] The U.S. International Trade Commission ("ITC") adopted the ALJ ruling. A panel of the Court of Appeals for the Federal Circuit then reversed.

The Federal Circuit stated that the procompetitive efficiencies associated with patent pools "are not limited to situations in which a potential pool patent is, in fact, a blocking patent."[131] Extending this line of reasoning, the court further opined that, "[p]rohibiting the inclusion in a package license of a patent that is arguably essential, merely because it ultimately proved not to be essential would undercut, even eliminate, this potential procompetitive efficiency."[132] The court further wrote:

> We [the Federal Circuit] thus think that perfect certainty is not required to avoid a charge of misuse through unlawful tying. Rather, in this context a blocking patent is one that at the time of the license an objective manufacturer would believe reasonably might be necessary to practice the technology at issue.[133]

The Federal Circuit has, however, withdrawn this opinion pending rehearing en banc.[134] The facts of *Princo* are potentially instructive regarding how the

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[126] Princo Corp. v. Int'l Trade Comm'n, 563 F.3d 1301, 1302 (Fed. Cir. 2009), *reh'g en banc granted* 583 F.3d 1380 (Fed. Cir. 2009).

[127] *Id.* at 1303. Patent misuse is a defense often raised, as within *Princo*, in the context of an infringement action. For instant purposes, a misuse defense is "tantamount to a defense" that the patent's owner used the patent in an anticompetitive manner. HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE § 5.5b (3d ed. 2005). Misuse has been found even in the absence of an antitrust violation. Nonetheless, the misuse and antitrust inquiries are often closely allied as they are within the context of tying. A successful misuse defense typically results in the patent being held unenforceable. *Id.*

[128] *Princo Corp.*, 563 F.3d at 1304.

[129] *Id.*

[130] *Id.*

[131] *Id.* at 1310.

[132] *Id.*

[133] *Id.*

[134] Princo Corp. v. ITC, 583 F.3d 1380, 1380 (Fed. Cir. 2009) (granting rehearing en banc and vacating panel opinion).

court will consider licensing under the dual conditions of urgency and uncertainty which characterize settings such as vaccine development. Though it is unclear whether the facts are likely to generate a legal ruling that either clarifies the standard and the definition of substitute or that suggests specific protocols regarding pool formation and operation that could help navigate the underlying tension between procompetitive efficiencies and anticompetitive harms.

2. Recommendations Regarding Possible Substitutes

Patent pools receive rule of reason analysis under the antitrust laws.[135] However, the practical consequences of applying that legal standard to pools such as those at issue herein are highly ambiguous. The antitrust agencies, through a combination of enforcement guidelines and business review letters, have largely dominated the discourse regarding the potential antitrust consequences of pooling substitute technologies. To the extent that the agencies' standard setting-derived aversion to pooling substitutes is actually imported or viewed as directly applicable to the industry contexts this Article addresses, efficiencies may be unduly sacrificed and, as a result, consumer welfare harmed. Towards that end, this Section advocates a more nuanced antitrust analysis which transcends the frequently unrealistic assumption of clearly known technological relationships and proposes a starting point for engaging in the balancing that is the hallmark of the rule of reason.

This Article advocates modestly relaxing the de facto standard regarding pooling to permit inclusion of what are likely essential patents[136] that, nonetheless, have a significant possibility of having substitutes (hereinafter, "possible substitutes"). This proposal is designed to capture the benefits while reducing the potential costs of pooling such technologies. In particular, the burden of proof for inclusion in the pool is sufficiently permissive to accommodate pool formation despite the technological uncertainty that frequently characterizes the early stages of R&D. The proposal addresses three related requirements regarding the inclusion of ostensibly essential patents (i.e., patents that are unique and required) within a given pool by establishing a tiered-threshold for the level of certainty regarding the fact of essentiality for patents that are candidates for being pooled and a mechanism for removing non-unique or unnecessary patents from a pool.

The proposal's first requirement is the inclusion of at least one patent for which essentiality is reasonably certain. The second requirement is that all

[135] *See supra* note 122 (discussing the rule of reason).

[136] *See* Gaulé, *supra* note 69, at 9 (recognizing both the challenges that the essentiality standard poses for biotechnology-related pools and the fact that it is "less clear [] whether competition authorities would be ready to accept patent pools that include patents meeting a weaker definition of complementary than essentiality or where essentiality is likely but difficult to prove"); Tom, *supra* note 69, at 29 (advocates in general terms "adjust[ing]" the essentiality standard within the biotechnology context).

other pooled patents must be substantially more likely than not essential.[137] The third requirement, given that these thresholds could result in the inclusion of non-essential patents, is an eviction procedure for patents that no longer meet the thresholds established for inclusion. Note that just as inclusion into the pool does not require complete certainty regarding essentiality, so too eviction from the pool does not require complete certainty regarding non-essentiality. After an eviction occurs, each licensee has the option to maintain the previous pool license including continued access to the evicted patents on the previously negotiated terms. Alternatively, each licensee can unilaterally terminate the existing contract and presumably negotiate new licensing agreements with all concerned. In the absence of any ostensibly essential patents, dissolution of the pool is warranted.

The determination of whether a patent meets the various standards will be made by an independent expert who will screen patents regarding inclusion in the pool and who will monitor the changing scientific and technological relationships among pool technologies to each other and to technologies outside the pool.[138] Such patent monitoring is commonplace among modern standards pools. The contributors to the pool are assumed to anticipate the transaction costs associated with pool formation and maintenance including patent screening, monitoring, eviction, and renegotiation. If the pool formation and maintenance involved transaction costs that more than offset the price efficiency benefits, the individual parties would not be expected to form the pool.

The importance of including at least one essential patent in a pool is the insurance it provides that even if the pool also contained substitutes, it would not set a price greater than that which would obtain from individualized licensing. Recall that if an essential patent were the only required input, it could obtain a monopoly price and if other patents are also essential or are partial substitutes, the combined total price to a licensee under individual licensing would likely exceed the monopoly price. But when the various

[137] These general requirements warrant liberal interpretation so that their intended goal, the inclusion of at least one essential patent, could be applied meaningfully across a wide range of fact patterns. For example, assume two technologies satisfy the second criterion ("substantially more likely than not essential"), but neither of them satisfies the first criterion ("essentiality is reasonably certain"). Additionally, one of the two technologies is essential but it is not known which one. Formation of such a pool should be permissible even though it fails to meet the literal requirements of the proposal.

[138] Many of the patents that the independent expert classifies as substitutes will not be "plug-in" substitutes in that they may not be interchangeable ex post once the vaccine development path has been chosen. The patent eviction process delineated is less effective in dealing with patents originally admitted into the pool that are of this type because previous licensees may have already been locked into a vaccine based on one of the (ex ante but not ex post) substitutes. Such licensees would, however, still benefit from the pool's incentives to set a single monopoly price (which would typically be lower than what the licensee would have obtained in individual market negotiations).

inputs are pooled, the pool (under a specific set of conditions that is likely met in the vaccine settings) will maximize profits if it charges a single monopoly price for the entire set of patents. Hence, the prospect of potential substitutes to price fix via a pool should be relatively less concerning as overall prices will be lower.

The foregoing argument regarding the monopoly pricing suggests that the inclusion of substitutes within a pool is not problematic if at least one essential patent is also included. Given the ostensible lack of harm attendant to pooling substitutes, why incorporate an eviction procedure? The eviction option serves to mitigate the costs attendant to pooling when the conditions for a single monopoly price do not all hold (the combined royalties exceed the single monopoly price), or when sufficient licensee power exists to force total prices, even with an essential patent, below monopoly levels.[139] This proposal's approach is consistent with that expressed in the now rescinded *Princo* ruling that pool legality should be based on ex ante assessments of essentiality. This proposal not only delineates the contours for such pre-pooling determinations, but also requires ongoing reassessments over the life of the pool.

What does "eviction" mean as a practical matter? Clearly, after removal of a patent, the pool would not offer new licenses under the previous terms. Instead, the pool would renegotiate terms with the remaining patent holders for a new pool license including a new profit division going forward. Existing licensees, however, could choose between continuing with the previous pool license and terminating that license during a prescribed time frame (for example, three months). The value of this option to the licensee lies in its ability to provide both security and flexibility. With regard to the former, the ability of licensees to continue under the existing contracts guarantees that regardless of how the technological uncertainty is resolved, the licensees could fare no worse than the terms they had already accepted. Consequently, the licensees need not fear, at the extreme, being shut out of the market because they no longer have a necessary license. Nonetheless, the licensees' ability to terminate the pool license may translate into potentially significant latitude for renegotiation. Because the evicted patent has a previously unrecognized substitute, the profits that the substitute patent(s) can subsequently earn in the market should be less than those the now evicted patent previously earned as part of the pool. The remaining pooled patents are now less constrained and may be able to earn more profits via their larger share of the new pool profits, but that can occur only if the new pool is able to renegotiate a new license with previous licensees. Those licensees, in turn, will agree only if the total price

[139] The single monopoly price argument taken to its logical extreme actually suggests that keeping substitute patents in the pool would result in a more efficient price if the substitute patents retain some level of differentiation or, equivalently, would be expected to be licensed at an oligopoly price in independent market negotiations. Willard Tom has argued that eviction has no negative consequences. *See* Tom, *supra* note 69. This would be true if competition among the evicted substitutes is extremely intense.

for the required patents is less than under the old pool license. A lower price for the evicted patents or their substitutes should be a force acting to lower end-user prices.

As an example of how the proposal would apply, consider the following scenario: Six patents (*A*, *B*, *C*, *D*, *E*, and *F*) are possible candidates for inclusion within a pool. An independent expert determines that *D* and *E* are substitutes and excludes them. *F* is found to be unnecessary and is also excluded. The expert also finds that it is almost certain that *A* is essential and that *B* and *C* seem considerably more likely than not to be essential. Thus, a clear recognition exists that *B* and *C* have a modest possibility of being substitutes or of not being necessary at all. Given those facts, the ability of a pool including *A*, *B*, and *C* to pass muster under the prevailing antitrust law and policy norms is highly suspect at best. Under this Article's proposal, however, *A*, *B*, and *C* can participate in a patent pool.

Assume the pool license price is $10 and *A* receives $6 while *B* and *C* each receive $2. Suppose vaccine developer *Z* takes a license. As the vaccine R&D progresses, the technological relationships among the pooled technologies become clearer and the independent expert determines that a new technology *G* is a substitute for *C*.[140] Patent *C* is evicted from the pool. Developer *Z* can either continue with its existing pool license or renegotiate licenses with *A*, *B*, and either *C* or *G*. Because *C* and *G* are substitutes, the individual license price for either of them is likely to be less than $2. Suppose that price is $1. If developer *Z* can license *C* for $1, it should be able to negotiate new licenses for *A* and *B* via the pool at a price that is less than $9. *Z*'s total license price, therefore, would be less than the original pool license price of $10 but greater than $8. Additionally, both *A* and *B* would receive greater profit than under the original license.

3. Concerns Regarding Failed Pool Negotiations

One critical transaction cost associated with patent pooling not yet discussed is the competitive risk associated with failed efforts to pool. If firms owning possible substitutes (e.g., *B* and *C* in the prior hypothetical) discuss pricing and profit division during pool negotiations and the negotiations fail, then the potential exists for such discussions to facilitate subsequent tacit price

[140] Alternatively, if patent *C* is found to be unnecessary and of no incremental value, *C* will be unable to command any royalty after it is evicted. The remaining pool members and the licensee can renegotiate such that all improve their positions relative to profit earned under the original pool license. A more difficult case arises when a patent originally included in the pool is found to be unnecessary but it offers incremental value over the other patents in the pool. The licensee can choose between licensing only the core essential patents and licensing the core patents plus the discretionary patent. Consideration of this further complication is beyond this Article's scope.

coordination[141] resulting in higher individual licensing prices.[142] Whether or what kind of competitive threat failed pooling efforts introduce reflects numerous factors. Two key factors are whether the market at issue is conducive to tacit collusion and, even if it is, whether pooling negotiations were conducted in a manner that mitigates or exacerbates any underlying competitive risk. The lack of recognition this issue has received by the courts, agencies and commentators is likely a function of the current legal regime's strong discouragement of price negotiations during pool formation.

An outright prohibition on price negotiations would, of course, diffuse the competitive threat unsuccessful pool formation may pose. Such prohibitions would also, however, severely undermine the prospects that the type of pools this Article addresses would form at all. When patents relevant to a pool vary considerably regarding essentiality and value, they would likely command differing royalty rates if individually licensed. Essential patents would command higher royalties than those that may have substitutes. Consequently, as a condition to pool participation, the essential patent holders, in particular, would require assurances that they would receive royalties at least equal to what they could otherwise obtain through individual licensing. In the absence of at least some preliminary price and/or profit division negotiations, those holding the most valuable patents will find pool participation to be particularly risky.

The significance of easing prohibitions on price discussions varies depending upon the context. As the likelihood that two patents included in the

[141] Section 1 of the Sherman Act prohibits "contracts, combinations, or conspiracies" in restraint of trade. "In determining whether such an agreement exists, courts have relied heavily on common law contract formulations, such as 'meeting of the minds' or 'mutual assent.'" HOVENKAMP, *supra* note 127, § 4.2. Tacit coordination or tacit collusion refers to "oligopolistic, interdependent behavior." *Id*. § 4.4a. Such behavior is concerted anticompetitive conduct for which "there is no direct evidence that it resulted from explicit agreement among competitors." *Id*. § 4.2. It has long been recognized that "firms in concentrated markets can increase their prices above the competitive level without . . . the need for anything resembling a 'conspiracy' or agreement among the parties." *Id.*

[142] In the standard-setting pool context, specific pricing discussion is not undertaken prior to pool formation owing to the concern it will be condemned as price fixing. *See, e.g.*, John J. Kelly & Daniel I. Prywes, *A Safety Zone for the Ex Ante Communication of Licensing Terms at Standard-Setting Organizations*, ANTITRUST SOURCE, Mar. 2006, at 1, 1-2. The type of patent pool this Article addresses is materially different from a standard-setting pool because even in independent negotiations, there is already "monopoly" market power that accrues to each of the essential patent holders – market power is not created as a result of the actions of the pool (e.g., to set a standard requiring use of some of the patented technologies held by pool members). Hence, price discussions are less troubling and are likely necessary to secure participation. However, even in the standard-setting context, some commentators have argued that potential pool members should be given more latitude to discuss pricing. *Id*. at 11 ("Unless appropriate safety zones [regarding ex ante pricing discussion for patent pools] are developed and approved, the antitrust laws may perversely become an impediment to efficiency and consumer welfare.").

prospective pool are substitutes decreases, the price effect of tacit coordination also decreases. For pure complements there should be no collusion issue. By restricting pool participation to essential patents for which a substitute is unlikely, the proposal limits the potential competitive hazard. Additionally, owners of essential patents offer some protection against tacit coordination. Essential patent holders have monopoly-like market power and prefer that other patent holders do not engage in tacit coordination to raise price because, if they do, the Cournot-complements pricing dynamic suggests that these essential patent owners would be worse off.[143] Then, anticipating a possible failure in negotiations, essential patent holders may choose not to negotiate exactly in industry settings where failed negotiations are believed to facilitate tacit collusion among the possible substitute patent holders. Finally, within the industry context this Article addresses, tacit coordination may be quite difficult because market transactions involve non-public prices and possibly large sale quantities, both of which are factors that greatly encourage cheating on any tacit or explicit agreement.[144]

These considerations notwithstanding, if failed pool negotiations pose a risk of increased individual license pricing, it is useful to consider whether the value of reductions of competitive risk through restrictions on pool negotiations (short of completely prohibiting price discussions) outweigh the additional costs or inefficiencies created by those restrictions. Pool negotiations could be conducted between a disinterested third party administrator and each prospective pool participant. This administrator would work with the independent expert to first address technology questions that determine which patents would be permissible to include in the prospective pool. Then, once it is established what technological relationships likely exist, the administrator would be the primary agent for division of profits and price negotiations. Individual patent holders would have no contact with each other, so the negotiations should do little or nothing to facilitate collusion should the pool fail to form.

A particularly dangerous situation regarding failed pool negotiations arises when pool and individual license negotiations occur simultaneously. Although a third-party administrator could mitigate the competitive risk in this situation, additional safeguards could be taken such as requiring parties involved with ongoing pool negotiations to suspend individual license negotiations. Alternatively, one could require the potential pool participants to fully segregate those negotiating the pool itself from those negotiating individual licenses.

A strong prohibition on price-related discussions during pool formation has come under increasing criticism within the standard-setting context where it is

[143] *See, e.g.*, Gilbert, *supra* note 91.

[144] *See, e.g.*, U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 2.12 (Apr. 2, 1992, rev'd Apr. 8, 1997), *available at* http://www.justice.gov/atr/public/guidelines/hmg.pdf

viewed as potentially counterproductive to the emergence of procompetitive pools. Historically, standards-related pools have avoided any price-related information exchange other than to require a general RAND (reasonable and nondiscriminatory) commitment by the owners of patents incorporated into the standard.[145] RAND, or FRAND (fair, reasonable, and nondiscriminatory) commitments require patent holders of technologies essential to implementation of a given standard to establish fair, reasonable and non-discriminatory terms if a standard incorporating their patent is established.[146] The purpose of such commitments is to avoid "unexpected hold-up by patent owners."[147] Owing to the self-evident imprecision of such RAND commitments, however, standard development organizations argue that they are vulnerable to patent holders who, despite a RAND obligation, then demand royalties that are "significantly higher than expected" and that may render the standard "commercially infeasible."[148]

In 2006, the standards development organization VITA sought DOJ's assessment, through the business review letter process, of a proposed policy which would require that patent holders seeking consideration for inclusion within a standard under development "must declare the maximum royalty rates and most restrictive non-royalty terms that the [patent holder] will request for any such patent claims that are essential to implement the eventual standard."[149] DOJ effectively approved this policy through its conclusion that it has "no present intention to take antitrust enforcement action against the conduct . . . described."[150] As discussed, the standard-setting context differs significantly from the setting this Article addresses. Additionally, the VITA proposal differs significantly from the price and profit division discussions at issue herein which, for example, generally requires specific royalty divisions. Nonetheless, it constitutes an important recognition that price and information sharing restrictions can profoundly and potentially adversely affect the value of pooling.

The antitrust risk that failed negotiations pose would seem particularly salient in the settings this Article addresses because price and profit allocation issues would likely be central to whether a pool would form at all. Despite strong indicators that tacit price coordination is very difficult in such markets, it is perhaps prudent to not be overly aggressive by permitting inclusion into a pool those patents which fail the substantially more likely to be essential test.[151] A conservative approach, vis-à-vis antitrust, would favor barring from the pool patents that are very likely to be essential but are possibly substitutes.

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[145] *See supra* note 142.

[146] *VITA* Business Review Letter, *supra* note 119, at 4.

[147] *Id*.

[148] *Id*. at 3.

[149] *Id*. at 4.

[150] *Id*. at 10.

[151] *See supra* note 139 and accompanying text.

Such an approach would sacrifice some of the price and transactional efficiencies that pools offer. For example, the greater the number of essential patents remaining outside the pool, the lower the social efficiency gains from pool pricing. This Article recommends requiring a strong showing that pooled patents do not have substitutes.[152] Price discussions among complementary patent holders do not pose nearly as troubling an antitrust concern and, at least until society gains experience with pool formation dynamics, a cautious approach seems warranted.

C. *Ownership Relationships – Exclusivity*

Section B explored how the ability of patent pools to facilitate R&D reflects, in part, antitrust treatment of uncertain technological relationships. Along similar lines, this Section explores how antitrust's treatment of exclusive licensing by patent pools could profoundly influence the development of efficiency enhancing pools.

Antitrust accepts as a given the exclusivity, and with it the potential for market power, attendant to legitimately conferred patents. As a result, individual patent holders are afforded wide latitude regarding unilateral disposition of their intellectual property rights via exclusive licensing. When two or more patents are aggregated, either through a series of exclusive individual licenses or through a pool with exclusive licensing rights, additional antitrust issues may arise. The relevant case law and agency policy pronouncements provide only high level guidance regarding the treatment of exclusivity in the patent pools this Article addresses. Hence, some uncertainty may exist regarding whether the courts and agencies will treat exclusivity the same in pools as in a series of individual licenses.

1. Legal and Policy Pronouncements Regarding Exclusivity and Pools

Antitrust analyzes exclusive licenses under the rule of reason. As applied, the rule of reason weighs the costs and benefits of allowing exclusivity in a manner consistent with the "principles and standards used to analyze mergers, particularly those in the 1992 Horizontal Merger Guidelines."[153] In the absence of any horizontal relationships between the parties, a patent holder can typically exclusively license another party because the agreement is viewed as essentially shifting an existing exclusive right from one entity to another entity. The underlying logic, as one commentator has observed, is that a patent provides the "right to exclude" and the threat to competition that an exclusive license poses is "no greater than the threat created by the exclusionary power of the patent itself."[154] The exclusionary power attendant to the patents at

[152] This standard arguably is more stringent than the "reasonably might be necessary" standard articulated in the subsequently withdrawn *Princo* ruling. The *Princo* court did not consider, for obvious reasons, the anticompetitive risk associated with failed pooling efforts.

[153] IP GUIDELINES, *supra* note 113, at 31.

[154] Reisner, *supra* note 72, at 97.

issue will be enhanced most directly if the acquired patents are substitutes rather than complements to the intellectual property the acquiring party already controls or is seeking to acquire.

Established guidance exists regarding the potential competitive risk that the aggregation of rights to substitute patents poses within both the individual licensing and pooling contexts.[155] Recently, greater attention and concrete guidance has emerged regarding a different potential competitive harm associated with the aggregation of exclusive licenses to even complementary technologies: the possible reduction in incentives to innovate. This guidance arises largely within the context of standards-related patent pools. The DOJ business review letters are uniform in their de facto approval of pools that all explicitly provide for nonexclusive licensing in which the patent holders expressly retain the right to license their respective patents independent of the pool.[156] The rationale underlying the antitrust agency's preference for nonexclusive licensing into a pool reflects, in part, concern about ongoing innovation. If the constituent patents for an industry standard are available for license individually, the prospect of a competing standard emerging is greater than if those constituent patents are unavailable for individual licensing. Though not expressly addressed by the business review letters, nonexclusive licensing out of the pool is assumed as standards-related pools seek to promote adoption of the standard through making the licenses widely available to all potential licensees.

The Agencies have opined on when the failure to establish nonexclusive pool licenses may raise antitrust questions. "A competitive concern would arise . . . if decisions on licensing outside a pool were part of a concerted attempt by the pool's licensor's to hinder the ability of others (outside of the pool) to offer a competitive product or process."[157] And yet, the Agencies have also recognized more generally that "[e]xclusive licenses may be desirable, and thus potentially procompetitive if they are necessary to provide a significant incentive for the licensees to invest in complementary assets. . . ."[158] The challenge for the courts when addressing exclusive licensing by pools, as well as the serial acquisition of exclusive licenses by a single entity, becomes how to accommodate these two potentially conflicting imperatives within the context of rule of reason balancing.[159]

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[155] *See supra* Part IV.B.1.

[156] DOJ/FTC REPORT, *supra* note 120, at 79.

[157] *Id*. at 80.

[158] *Id*. at 79.

[159] Settings in which pools only perform the licensing function are the easiest to analyze. Here, exclusivity means that the pool has the exclusive right to license the patents contributed to the pool. Non-exclusive licenses would represent the situation, for example, where the original patent-holders maintain the right to license their patents individually. Granting exclusive licensing rights to a pool does not imply that the pool will use this grant to license a single licensee; but without an exclusive licensing right, a pool cannot

As an example of an antitrust analysis involving a consolidation through a series of exclusive license agreements, consider the hypothetical discussed previously in which three essential patents, *A*, *B*, and *C* are owned by three different firms. These patents are assumed to lack substitutes and are assumed to be complementary as successful vaccine development ultimately requires all three technologies. The absence of any horizontal relationships among the underlying three patents suggests that their acquisition by a single entity would not further increase the level of exclusion that already existed.

Now consider whether the antitrust analysis changes if the patent-holders (*A*, *B*, *C*) exclusively licensed a patent pool. At least in theory, the same procompetitive effects which support permitting a single party to acquire exclusive rights to such a patent estate would also appear to justify an exclusive license grant to a patent pool. It is unfortunate, however, that no direct guidance presently exists regarding such patent pools. Moreover, all of the legal and policy guidance on patent pools concerns standards-based pools and that guidance appears to *discourage* exclusive licensing to pools. While it is possible, and well-recognized, that the exclusive licensing of complementary patents to a pool may reduce competition to innovate around those patents, the same possible anticompetitive effect (though not comparably or adequately acknowledged) also applies to consolidation through individual exclusive licenses.

Given the stark differences between standards-oriented pools and the vaccine-related pools at issue herein (e.g., market power created through the standard and significant volume-based licensing savings), legal guidance derived within the former context should not be merely imported into the latter context. Nonetheless, the prospect of such unwarranted legal spill-over requires attention. If the lessons from standards-oriented pools constitute the baseline for analyzing pools (but not individual licensing), a relative bias could be introduced against exclusivity in pools. Similarly, it is also possible that an analysis of the incremental competitive effects associated with the serial acquisition of multiple, individual exclusive licenses might differ from an analysis of the simultaneous acquisition (i.e., patent pool) of the same exclusive licenses.

2. Recommendations Regarding Exclusivity

At the highest level, rule of reason analysis is the applicable antitrust standard whether one is analyzing exclusive licensing within the context of patent pools (regardless of type) or the context of individual licensing. However, implementation of that rule may vary between contexts and, as a result, so too may the ultimate antitrust outcomes. The challenge, of course, is

unilaterally award a licensee an exclusive license. Whether an exclusive pool actually decides to license exclusively or non-exclusively may be unknown at the time of pool formation and may depend on the value that the potential licensees assign to exclusive versus nonexclusive licenses.

to ensure that nominally different outcomes reflect fidelity to the underlying antitrust principles. Within the context of exclusivity, successful application of a general standard like rule of reason balancing requires successfully navigating the oftentimes critical distinctions between different types of pools and recognizing important similarities between pools and the serial acquisition of multiple, individual licenses. A simple clarification of how the law would, or at least should, be applied specifically to the pools at issue would help in this regard. This clarification would also reduce any misperceptions that may exist in the practitioner community. Such misperceptions, if left unchecked, could unnecessarily discourage the use of patent pools, encourage the use of individual licensing even when pools are more efficient; and, in so doing, could reduce innovation and consumer welfare.

If, in fact, unduly harsh antitrust treatment of exclusivity occurred regarding the category of patent pools at issue herein, then it would potentially dissuade pooling which enjoys efficiency benefits relative to a series of exclusive individual licenses. For example, consider a situation in which value-added development through a joint venture (pool) is superior to development by an individual firm and exclusive in-licensing is necessary to incentivize development (in either form). If exclusive in-licensing is only permitted in the individual licensing case, a more efficient pool may be eschewed in favor of the less efficient single-firm consolidation. Furthermore, because a restriction against exclusive in-licensing by definition implies a restriction against exclusive out-licensing, there are also potential efficiencies that could be lost if exclusive licensing to buyers is prohibited. Transaction costs attendant to the pursuit of exclusivity might be lower with pools relative to individual licensing. As discussed previously, exclusivity increases the complexity of individual licensing either by increasing the interrelatedness of the nominally separate individual negotiations (e.g., exclusivity over one patent is only valuable if one has access to the other essential patents) or by increasing the number of negotiations needed (e.g., if two licensees separately negotiate exclusive contracts allowing access to one of two essential patents, these licensees would have to undertake an additional level of negotiations with each other). Moreover, if pools are discouraged from licensing exclusively, then the general potential transaction costs savings attendant to pooling would be lost.

The potential price efficiencies that pools offer are independent of whether the pool license is exclusive or nonexclusive. When exclusive out-licensing is contemplated, a distinct issue regarding which single licensee might be selected is introduced. That is, will individual licensing and pooling ultimately result in different exclusive licensees? A primary reason that the value of exclusivity may vary between licensees is their differing abilities to exploit the technology at issue successfully. If one assumes that both the individual patent holders and the pool seek to maximize their respective economic interests, then, if exclusive licensing was the best way to accomplish this, both avenues will result in an exclusive license being awarded to the party offering the highest expected return.

However, the licensee selection issue is complicated somewhat when a potential licensee (e.g., MedImmune) is also a patent holder; it is conceivable that a patent-holder who is also a potential licensee might refuse to license any third party regardless of merit in the hope of developing the technologies in-house. This hold-up problem potentially interferes with the selection of the best exclusive licensee and could arise in both the individual and pool licensing settings. Though, in the latter setting, the group decision dynamic may sometimes make it more likely to choose the best licensee. Regarding the other pluses and minuses of pools, note that a "pool" that is acquired will have all the out-licensing efficiencies that a conventional pool would have, but perhaps has somewhat less of a problem regarding the antitrust dangers attendant to failed pools. On balance, it seems that if allowing exclusive licensing is valued in the context of independent acquisitions of exclusive licenses, then it should also be valued in the patent pool context.

In summary, depending upon the circumstances, individual licensing and licensing through patent pools are likely to have different potential benefits, with one or the other being more efficient and/or faster depending on the individual situation. For contexts in which exclusivity is valuable and, perhaps, even essential, any extra impediments to offer an exclusive license may profoundly and adversely affect the relative attractiveness of patent pooling. If development is urgent, hampering the pool channel but allowing the individual licensing channel would not appear to be good social policy. Therefore, this Article recommends that the courts are careful that their approach to analyzing exclusivity in patent pools does not bias their analysis away from an even-handed approach to exclusivity.

D. *Legal Relationships – Antitrust and Patent Law*

At the risk of oversimplifying, the patent system seeks to promote innovation through restraining competition. The antitrust system seeks to promote innovation through protecting competition. A misstep within either regime (whether it is an improvidently granted patent or an improvidently instituted antitrust action, for example) can thwart innovation. To what extent can questionable policies or practices in one regime undermine, or at least be in tension with, the operation of the other? This last Section discusses key Patent & Trademark Office ("PTO") pronouncements regarding the examination of gene-related patents and the formation of gene-related patent pools. These two milestones provide a useful point of reference for a broader analysis of the discourse between the competition and patent communities.

In 1999, the PTO issued "Revised Interim Utility Examination Guidelines" which it then adopted (largely without change) in early 2001.[160] The PTO's press release heralded that it had "published [the] final guidelines for

[160] Utility Examination Guidelines, 66 Fed. Reg. 1092, 1092-99 (Jan. 5, 2001).

determining utility of gene-related inventions."[161] It noted that "[t]he Utility Guidelines are applicable to all areas of technology. However, they are particularly relevant in areas of emerging technologies, such as gene-related technologies . . . ."[162] In particular, the 2001 guidelines introduced a more rigorous standard for assessing the utility of gene-related patents than the prior version in 1995.[163] The 1995 guidelines had been widely criticized as too lenient with respect to the utility requirement as applied to gene-related technologies. The 2001 reform constituted "a start" in remedying the PTO's improvident issuance of patents on gene fragments without known functions.[164] The ongoing debate (Is the utility standard too harsh? Too lenient?) regarding the 2001 guidelines is beyond the scope of this Article.

In late 2000, the PTO issued a white paper in which it explicitly acknowledged concerns regarding the capacity of patents to thwart innovation in biotechnology.[165] According to the PTO,

> One of the biggest public concerns voiced against the granting of patents by the [PTO] to inventions in biotechnology, specifically inventions based on genetic information, is the potential lack of reasonable access to that technology for research and development of commercial products and for further basic biological research.[166]

The PTO's response to those concerns, at least within its white paper was: "One possible solution lies in the formation of patent pools."[167] The white paper did not even mention the PTO's own extensive efforts to revise the utility guidelines, despite the fact that the final guidelines would be issued less than two weeks after the white paper's release.

The white paper's discussion of patent pools within the biotechnology context is strikingly devoid of any concrete examples of actual, proposed, or possible pools. The absence of such examples has particular consequences for the PTO's effort to convey multiple important, albeit arguably misguided, messages – one concerning the law and the other concerning the marketplace more generally.

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[161] Press Release, U.S. Patent and Trademark Office, USPTO Publishes Final Guidelines for Determining Utility of Gene-Related Inventions (Jan. 4, 2001), *available at* http://www.uspto.gov/news/pr/2001/01-01/.jsp.

[162] *Id.*

[163] Anna E. Morrison, Note, *The U.S. PTO's New Utility Guidelines: Will They Be Enough to Secure Gene Patent Rights?*, 1 J. MARSHALL REV. INTELL. PROP. L. 142, 143 (2001).

[164] *Id.* at 153.

[165] JEANNE CLARK ET AL., U.S. PATENT & TRADEMARK OFFICE, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? 2-3 (2000), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf.

[166] *Id.* at 2.

[167] *Id.*

The white paper itself is fairly short and largely amounts to the PTO's restatement of the general principles that had already become conventional antitrust wisdom regarding the pro- and anticompetitive effects of patent pools. It aptly recounts key features of the *IP Guidelines* and relevant DOJ business review letters. The PTO's conclusion, drawn without any meaningful biotechnology-specific antitrust analysis, was that "the social and economic benefits of [the pooling of biotechnology patents] outweigh their costs."[168] The white paper fails to acknowledge the myriad difficulties, which this Article delineates, attendant to merely importing the existing legal guidance from a standard-setting context in the computer, electronics, and telecommunications industries to a non-standard setting context involving biotechnology.[169] Given this significant omission, perhaps the PTO's conclusion that antitrust should not unduly impede patent pool formation within the biotechnology sector should itself be interpreted as an advocacy statement rather than as merely a description of the state of the law.

The PTO, and the patent community more broadly, clearly has an important role to play in the broader discourse regarding the impact of competition policy in the same manner that the competition community has an important role to play in the discourse regarding substantive and procedural patent policy considerations.[170] Given the centrality of innovation to not only the economy but also society as a whole, these varied discussions must proceed concurrently. Nonetheless, in that din, it is important to maintain a realistic perspective on what patent pooling can and cannot accomplish.

This Article has identified at least two key problems characterizing antitrust's treatment of patent pools. Or, more accurately, it identified how the antitrust law has not yet been applied to address a particular type of patent pool (illustrated through various vaccine industry hypotheticals) and it argued that merely importing existing norms developed within the standard-setting context would be a mistake. Has this pocket of legal uncertainty chilled the development of patent pools within the biotechnology industry?[171] That is certainly a possibility and the competition community and antitrust law can and must continue to evolve to address this and many other issues. It is, however, also important to consider whether antitrust has failed to evolve in this manner owing, in part, to the absence of any strong clamor from the

[168] *Id.* at 8.

[169] *See, e.g.*, Tom, *supra* note 69, at 28 (commenting that biotechnology-based pools are a "misfit for the existing model" of guidance that is addressed to standards-related pools).

[170] *See generally* Greene, *supra* note 13.

[171] *See, e.g.*, Josh Lerner & Jean Tirole, *Efficient Patent Pools*, 94 AM. ECON. REV. 691, 691 (2004) (questioning whether, though not addressing specifically the biotechnology industry, "the reluctance to form pools may be due to the ambiguities surrounding the manner in which proposed pools will be evaluated"); Deborah Platt Majoras, Chairman, Fed. Trade Comm'n, Recognizing the Procompetitive Potential of Royalty Discussions in Standard Setting 7 (Sept. 23, 2005), *available at* http://www.ftc.gov/speeches/majoras/050923stanford.pdf.

biotechnology sector to engage in such pooling activities. The competition community has long recognized what the patent community appears to be increasingly recognizing, namely, the value of economic reasoning in helping to inform some of the key tradeoffs within its legal regime. It is also worth considering whether the frequency with which patent pooling is discussed within the context of biotechnology is excessive and whether it deflects attention from more basic concerns that would be better addressed through other channels.

CONCLUSION

Battling pandemics is, at its core, a matter of science. Waging such battles also implicates, for better or worse, matters of intellectual property and perhaps antitrust. While developing vaccines frequently entails a high degree of uncertainty within the laboratory, society should attempt to minimize the level of uncertainty regarding antitrust exposure of that development. While the current rules of thumb provide some unambiguous guidance, they do so only when little or no technological uncertainty is present. Whether antitrust seeks to promote innovation or, at a minimum, it merely seeks to avoid impeding innovation, the competition community must turn a critical eye upon its own practices. Antitrust's first foray into patent pools took the form of condemning those which were mere shams used to facilitate price fixing. Its second foray into this arena largely took the form of identifying a set of patent pools that were more or less unambiguously procompetitive. Antitrust now has an obligation to enter into the grey middle zone.