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MPEG LA'S USE OF A PATENT POOL TO SOLVE THE CRISPR INDUSTRY'S LICENSING PROBLEMS

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Abstract

Since 2012, CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) technology has revolutionized how scientists approach gene editing. CRISPR allows for easier modification and alteration of the genome. This technology has potential applications ranging from correcting genetic defects to the treatment and prevention of diseases—CRISPR's potential upside is unquestionable. However, CRISPR's current patent landscape presents a variety of roadblocks for research, innovation, and profit. This Note discusses the potential use of a patent pool to alleviate some of these roadblocks. This Note begins with a discussion of the independent administrative body attempting to create such a patent pool, MPEG LA, before discussing the current patent landscape. Next, it discusses the licensing issues biotech products face when attempting to create a patent pool. Finally, this Note analyzes the prospects of MPEG LA's current attempt to create a patent pool in the CRISPR arena. This analysis discusses why a CRISPR patent pool would work, as well as arguments suggesting its failure. This Note ultimately concludes that, while there are many barriers which could impede a CRSIPR patent pool's success, MPEG LA's patent pool is a promising approach to a complex licensing problem in a budding technological area.

I. INTRODUCTION

In June of 2012, scientists at the University of California Berkeley ("UC Berkeley") created a new method for genome editing called "CRISPR."[1] CRISPR, or Clustered Regularly Interspaced Short Palindromic Repeats, loosely refers to various systems that can be "programmed to target specific stretches of genetic code and to edit DNA at precise locations."[2] The simplest ways to think about this innovation are a pair of scissors that can cut DNA at a precise location, or a word-

* © 2020 Patrick Neville. J.D. Candidate, 2020, University of Utah, S.J. Quinney College of Law. The author thanks Kristin Neuman for her helpful comments and discussion.

[1] Knut J. Egelie et al., *The Emerging Patent Landscape of CRISPR–Cas Gene Editing Technology*, 34 NATURE 1025, 1026 (2016). This paper discusses the licensing issues surrounding the CRISPR-Cas9 patents, hereinafter referred to as "CRISPR."

[2] *Questions and Answers About CRISPR*, BROAD INST., https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/questions-and-answers-about-crispr [https://perma.cc/U7ES-8MQW] (last visited Sept. 11, 2019).

processor that allows scientists to precisely change DNA, similar to how a word-processor fixes a typo.[3] This technology has the potential to permanently modify genes in living organisms and possibly, in the future, may be used to correct mutations at precise locations in the human genome to treat genetic diseases.[4] The rapid advancements and potential uses of CRISPR-related technology have created many ethical,[5] intellectual property, and licensing concerns in the biotechnology sphere.

Biotechnology[6] is the "manipulation (as through genetic engineering) of living organisms or their components to produce useful, and usually, commercial products."[7] This industry covers products and processes involving human therapeutics, bio-pharmacy, bio-agriculture, bio-services, and bio-industrial

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[3] *Id.*

[4] *See id.*; Jennifer Doudna, *How CRISPR Lets Us Edit Our DNA,* TED (Sept. 2015), https://www.ted.com/talks/jennifer_doudna_we_can_now_edit_our_dna_but_let_s_do_it_wisely [https://perma.cc/PWY3-55V3] (explaining how scientists in Philadelphia have showed that they can remove the DNA of an "integrated HIV virus from infected human cells."); Paul Knoepfler, *The Ethical Dilemma of Designer Babies*, TED (Oct. 2015), https://www.ted.com/talks/paul_knoepfler_the_ethical_dilemma_of_designer_babies/details [https://perma.cc/G373-Y3MY] (discussing how parents soon could choose "advantageous traits" for their in vitro child); Emily Mullin, *Arming Bodies with CRISPR to Fight Huntington's Disease and ALS*, MIT TECH. REV. (Oct. 5, 2017), https://www.technologyreview.com/s/608967/arming-bodies-with-crispr-to-fight-huntingtons-disease-and-als/ [https://perma.cc/56H8-P36H] (explaining the potential for genetic diseases to be eliminated); Kelly Servick, *CRISPR Slices Virus Genes Out of Pigs, but Will It Make Organ Transplants to Humans Safer?*, SCI. MAG. (Aug. 10, 2017, 2:00 PM), https://www.sciencemag.org/news/2017/08/crispr-slices-virus-genes-out-pigs-will-it-make-organ-transplants-humans-safer [https://perma.cc/78ET-Y7Q2] (discussing how patients on organ transplant lists could receive surgery without having to wait years); Simon Worrall, *We Could Resurrect the Woolly Mammoth. Here's How.*, NAT'L GEOGRAPHIC (July 8, 2017), https://news.nationalgeographic.com/2017/07/woolly-mammoths-extinction-cloning-genetics/ [https://perma.cc/HN66-DZH3] (noting how extinct animals could be brought back to existence, specifically, the possible resurrection of the woolly mammoth).

[5] The many ethical concerns surrounding genome editing and CRISPR technology can and have filled their own paper(s). *See, e.g.*, Niklaus H. Evitt et al., *Human Germline CRISPR-Cas Modification: Toward a Regulatory Framework*, 15 AM. J. BIOETHICS 25 (2015), (discussing the ethical implications of CRISPR technologies and the need for a regulatory framework); Alvaro P. Reyes & Fredrik Lanner, *Towards a CRISPR View of Early Human Development: Applications, Limitations and Ethical Concerns of Genome Editing in Human Embryos*, 144 THE COMPANY OF BIOLOGISTS 3 (2017), http://dev.biologists.org/content/develop/144/1/3.full.pdf [https://perma.cc/X7JD-L4AU] (discussing the ethical considerations of editing human pre-implantation embryos using CRISPR Cas9 technology). However, such ethical concerns are largely outside the scope of this paper.

[6] Hereinafter referred to as "biotech."

[7] *Biotechnology*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/biotechnology [https://perma.cc/7ZCV-F78Q] (last visited Sept. 11, 2019).

applications.[8] It is a lucrative industry that was valued in 2015 at over $330.3 billion and, in all likelihood, is only going to continue to grow.[9]

The biotech industry, and specifically the CRISPR field, presents a foray of licensing issues that could impact future research, innovation, and profits.[10] However, in 2000, a report conducted by the United States Patent and Trademark Office suggested that a patent pool could be a useful licensing tool for biotech, "serv[ing] the interests of both the public and private industry, a win-win situation."[11] A patent pool forms when multiple patentees combine their patents and use a single independent entity to license all of the combined patents to third-parties as a single package.[12] This package of intellectual property rights ("IPR") is then licensed on a non-exclusive basis, providing licensees with affordability and freedom to operate, while giving licensors adequate royalty returns.[13] MPEG LA, for example, is an independent licensing agent attempting to create a patent pool for licensing in the CRISPR sphere.[14]

A patent pool could alleviate the licensing burdens in the CRISPR sphere, but the biotech industry introduces business and scientific factors that can cause licensing roadblocks for a patent pool.[15] Because CRISPR technology has many applications,[16] it is essential that there be a licensing scheme available which allows information sharing while providing compensation for patent holders.[17] This Note

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[8] *The Biotechnology Market Is Projected to Grow*, PR NEWSWIRE (Jan. 26, 2018), https://www.prnewswire.com/news-releases/the-biotechnology-market-is-projected-to-grow-671271954.html [https://perma.cc/3ENJ-VEPB].

[9] *Id.*

[10] *See infra* Section III.A for discussion on the "Tragedy of the Anticommons" and the licensing issues that could be solved using a patent pool.

[11] Jeanne Clark et al., *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?*, U.S. PAT. & TRADEMARK OFFICE 11 (Dec. 5, 2000), http://www.consultstanton.com/wp-content/uploads/2015/02/PATENT-POOL-WHITE-PAPER.pdf [https://perma.cc/ZV6Z-2TXH]; *see also* Jorge L. Contreras, Policy Forum, *The Anticommons at 20: Concerns for Research Continue*, 361 SCIENCE 335, 337 (2018) (showing that a patent pool is a potential solution to the licensing problems in the CRISPR sphere specifically).

[12] Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting,* 1 INNOVATION POL'Y & ECON. 119, 134 (2000).

[13] *See id.* at 135; Richard J. Gilbert, *Ties that Bind: Policies to Promote (Good) Patent Pools*, 77 ANTITRUST L.J. 1, 26 (2010).

[14] MPEG LA, *CRISPR, The Initiative*, http://www.mpegla.com/main/pid/CRISPR/Initiative.aspx [https://perma.cc/QZ87-9WBM] (last visited Sept. 11, 2019) [hereinafter MPEG LA, *CRISPR*] .

[15] *See* E-mail from Kristin Neuman, Executive Director, Biotechnology Licensing, MPEG LA, to Patrick Neville, Student at the S.J. Quinney College of Law (Oct. 11, 2018, 02:35 MST) (on file with author).

[16] *See supra* note 4 and accompanying text for a discussion on the potential life-saving and world-changing uses of CRISPR technology.

[17] *See* E-mail from Kristin Neuman, *supra* note 15.

will discuss (II) the requisite background information on patent pools in general, the MPEG LA licensing administration, and the current state of the CRISPR patent landscape, (III) the licensing issues facing patent pools in biotech, and (IV) an analysis of MPEG LA's potential pool. This Note ultimately concludes that, although there are many barriers which could impede its success, MPEG LA's CRISPR patent pool is a promising approach to solving a complex licensing problem in a budding technological area.

II. BACKGROUND

A. What Is a Patent Pool?

1. Patent Pool Background

A patent pool forms when multiple patentees combine their patents and use a single entity to license all the combined patents to third-parties as a single, non-exclusive licensing package.[18] These pools can be useful for licensees because they provide affordability and the convenience of "one-stop shopping."[19] This convenient package of intellectual property rights ("IPR") allows licensees to avoid the danger of paying and negotiating for rights that might be useless on its own.[20] The advantages of a patent pool include the ability to overcome patent licensing roadblocks,[21] reduce transaction costs, prevent potential downstream litigation, promote information exchange,[22] and in a sense, "compress[] [the licensing] process into a single event."[23] This results in a secondary benefit—reducing the odds that a patent holder will strategically hold out for higher fees.[24] Ideally, patent pools serve to regularize and stabilize technology transfer and licensing in a certain field of use.[25]

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[18] Shapiro, *supra* note 12, at 134.

[19] *Id.*

[20] *Id.*

[21] For example, patent pools allow coordination of the licensing of complementary patent rights in a single transaction and they can eliminate a potential licensee's burden of conducting extensive patent searching in particular technological areas. Michael Mattioli & Robert P. Merges, *Measuring the Costs and Benefits of Patent Pools*, 78 OHIO STATE L.J. 281, 295–96 (2017).

[22] *See* Richard J. Gilbert, *Collective Rights Organizations: A Guide to Benefits, Costs and Antitrust Safeguards*, *in* THE CAMBRIDGE HANDBOOK OF TECHNICAL STANDARDIZATION LAW: COMPETITION, ANTITRUST, AND PATENTS 125, 125–26 (Jorge L. Contreras ed., 2017) [hereinafter Gilbert, *Collective Rights Organizations*]; Michael Mattioli, *Communities of Innovation*, 106 IND. UNIV. L. REV. 103, 117 (2012).

[23] Mattioli & Merges, *supra* note 21, at 285.

[24] *Id.* at 285–86.

[25] ROBERT P. MERGES, INSTITUTIONS FOR INTELLECTUAL PROPERTY TRANSACTIONS: THE CASE OF PATENT POOLS 6, 16 (Aug. 1999), https://www.law.berkeley.edu/files/pools.pdf [https://perma.cc/VF6H-W3Z9].

For a pool to be stable, it should include "essential" and "complementary" IPR.[26] "Essential" patents are ones that are valid and, "absent a license, necessarily infringed by products covered by the pool's licensing program."[27] Similarly, patents can be "complements" to one another when they are essential to make, use, or sell a product.[28]

Classically, the creation of a patent pool involves four major characteristics: (1) it is built around the voluntary inclusion of essential and complementary IPR holders;[29] (2) it relies on a standard;[30] (3) it requires pool administrators to conduct an in-depth and continual search of the patent landscape;[31] and (4) it can be subject to anticompetition laws.[32] Thus, a patent pool must be open to all IPR holders, but

[26] *See* Shapiro, *supra* note 12, at 134–35 (discussing how the standard must include all patents, essential and complementary, to utilize the technology); *see also* Gilbert, *supra* note 13, at 7 (discussing how "essential" patents are ones that have no economically viable substitutes, a party needs a license to utilize the IPR. "Complementary" patents are ones where if the price of one patented product should increase, the demand for the other product would decrease. Essential patents, by their nature, are complementary when one patent is not useful without access to the other); Timo Minssen et al., *Clearing a Way Through the CRISPR Patent Jungle*, LSIPR (May 8, 2018), https://www.mpegla.com/wp-content/uploads/2019/02/Clearing-a-way-through-the-CRISPR-patent-jungle.pdf [https://perma.cc/29T5-GD9V] (noting how for CRISPR patents, where the landscape is fragmented, essential patents will almost always be complementary to other IPR).

[27] Gilbert, *Collective Rights Organizations*, *supra* note 22, at 135.

[28] *Id.* at 133.

[29] *See* Shapiro, *supra* note 12, at 134; Sophie Lawrance et al., *The Competition Law Issues of the CRISPR Patent Pool*, LEXOLOGY (Feb. 26, 2018), https://www.lexology.com/library/detail.aspx?g=62ef2525-a34c-4e5e-b401-ea0c90082374 [https://perma.cc/ZS2F-H6WQ].

[30] A standard is an attempt to encapsulate the details and patents necessary to enable "uniformity of practice across a diverse range of implementations." CHARLES M. SCHMIDT, BEST PRACTICES FOR TECHNICAL STANDARD CREATION: GUIDELINES FOR THE DESIGN, SOCIALIZATION, FORMALIZATION, AND ADOPTION OF NEW TECHNICAL STANDARDS v (MITRE 2017). Note that the CRISPR-related patents and the research itself does not involve the use of a standard and this is one major licensing roadblock for the potential pool. *See* Email from Kristin Neuman, *supra* note 15.

[31] *See* Shapiro, *supra* note 12, at 134–35; Lawrance et al., *supra* note 29.

[32] *See* MERGES, *supra* note 25, at 28; Lawrance et al., *supra* note 29. (discussing how the fear of competition laws can be greatly reduced by reviewing pooled patents regularly and by considering the licensing aspect of the pool separately); Shapiro, *supra* note 12, at 132–33, 136. Anticompetition laws are largely outside the scope of this paper because any issues regarding anticompetition laws and patent pools has largely been resolved since 1997 when the Department of Justice granted MPEG LA procompetitive clearance. Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 YALE J. ON REG. 359, 371 (1999).

each patent must be individually examined and analyzed to determine if it is necessary before possible inclusion.[33]

Similarly, something patent pools should do is allow members to license their patents independently outside the pool.[34] If the pool lacks this quality, the integrity of the single licensed package may be called into question and fracturing can occur, because licensees may think the pool contains substitute patents—patents which could be licensed independently as a substitute for the patents included in the pool—which could force lower prices in the market.[35]

2. Economics

From an economic standpoint, patent pools are designed to conserve transaction costs.[36] For licensees, a pool can reduce the number of negotiations when there is a patent thicket,[37] or diffusion of IPR, and it can simultaneously coordinate the licensing of complementary rights.[38] Since there has been a rise in patent litigation, licensees have begun conducting "freedom-to-operate" analyses,[39] but a pool can reduce this cost as its administrators must conduct these analyses to determine the essential and complementary nature of the included patents.[40]

The simplest incentive for patentees to join a pool would be a royalty that would exceed what the patentee could earn if it defected and licensed independently.[41] However, there are at least three other financial reasons to join a pool outside of royalties. First, each patentee in the pool generally gets "grantback" licenses (non-exclusive licenses) to all IPR included in the pool and improvements made from said IPR.[42] These grantback licenses are usually given at a standard rate or a royalty-free rate.[43] For patentees, grantback licenses provide IPR that they otherwise wouldn't

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[33] *See* Lawrance et al., *supra* note 29 (discussing how pool administrators, like MPEG LA, utilize independent experts who analyze both the patent landscape and potential patents themselves before inclusion).

[34] Gilbert, *Collective Rights Organizations*, *supra* note 22, at 130–38.

[35] *Id.* at 139–40.

[36] Mattioli & Merges, *supra* note 21, at 287.

[37] A patent thicket is "[a]n overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees." Shapiro, *supra* note 12, at 119.

[38] Mattioli & Merges, *supra* note 21, at 293, 296.

[39] A "freedom-to-operate" analysis is an expensive endeavor. *Id.* at 293. A freedom-to-operate analysis "yields a list of potential patent holders, the prospective licensee must then contact and successfully negotiate a license with each one." *Id.* The negotiation process then places costs upon both the licensee and patent holders, including, "salaries paid to business personnel who conduct the deals and fees or salaries paid to lawyers who draft the agreements." *Id.*

[40] *Id.* at 294.

[41] Gilbert, *supra* note 13, at 26.

[42] Mattioli & Merges, *supra* note 21, at 296–97, 343.

[43] *Id.* 296–97.

have had rights to in the form of improvements.[44] For the pool and potential licensees, grant-back licenses prevent patent holders from charging royalties that interfere with the adoption or utilization of products covered by the pool.[45] Second, patent pools can act as a mechanism to reduce litigation, and the costs associated therewith, between patentees.[46]

Third, all parties involved will reduce their licensing costs as they will not have to pay large-salary employees, such as lawyers, to negotiate multiple, lengthy licenses.[47] In 2017, Robert Merges and Michael Mattioli conducted one of the first empirical studies showing how much money patent pools save its participants.[48] This study used two successful pools (including one administered by MPEG LA) and determined that, "even at a moderate cost per license, the availability of a standard form 'rate schedule' type license lowers the costs of transferring patent rights to licensees by a huge amount."[49] They estimate that a successful patent pool conserved transaction costs for all parties involved on a scale of hundreds of millions of dollars.[50]

3. Non-Financial Incentives

In addition to the financial reasons discussed in the previous section, there are other, non-financial reasons patentees may favor patent pool over traditional licensing techniques. For platform-based technologies, the patentees may join a pool in an attempt to spread the adoption of the platform.[51] Other reasons for patentees to join a patent pool include: ease of administration,[52] as a reaction to government threats of compulsory licensing,[53] as a means of breaking through patent thickets based on the belief that broadening the base of licensees is the best way to maximize

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[44] *Id.* at 343.

[45] Gilbert, *Collective Rights Organizations*, *supra* note 22, at 145 (noting that grantback licenses can harm competition if it enables a patentee to prevent the development of rival technology).

[46] Mattioli & Merges, *supra* note 21, at 297.

[47] *Id.* at 304–05.

[48] *See id.* at 281.

[49] *Id.* at 324.

[50] *See id.* ("The patent pools we studied saved, we estimate, $600 million and almost $400 million, respectively.").

[51] *Id.* at 333–34. It should be noted that the CRISPR pool is a platform-based pool, where the patentees are pooling patents related to the underlying CRISPR platform. Email from Kristin Neuman, *supra* note 15.

[52] Mattioli & Merges, *supra* note 21, at 334.

[53] Ed Levy et al., *Patent Pools and Genomics: Navigating A Course to Open Science?*, 16 B.U. J. SCI. & TECH. L. 75, 80–81 (2010) ("This is, in large part, what occurred with respect to airplanes when the U.S. government determined that a group of patent holders was blocking its efforts to [scale up] aircraft manufacturing for the conduct of WWI.") (internal citations omitted).

profits,[54] to create an arrangement more "commensurate with the norms of open science. . . ,"[55] or based on the short-term goal of avoiding litigation.[56] Along similar lines, in biosciences, a patent pool could be a philanthropic instrument, used to increase access to medicines and improve global health.[57]

For example, in 2009, the Medicines Patent Pool ("MPP") gained IPR due to government pressure.[58] The pool was formed to develop treatments for HIV in developing nations, which the World Health Organization deemed a "global health emergency."[59] HIV drugs were not reaching developing nations largely because of high transaction costs on the necessary patents.[60] The pool was structured to offer royalties on future product sales in exchange for licenses for drug developers to facilitate research and development of pediatric HIV pills.[61] The integral pressures which led to its formation came in the form of political, governmental, and media pressures.[62] One hundred and fifty members of the British parliament signed a petition calling on private companies to join, and British politicians went on national media outlets to market the pool.[63] The pool struggled to gather members until July of 2011, when Gilead Sciences joined.[64] In the following year, after Gilead joined, MPP's license allowed for the production and distribution of four drugs in over one hundred low-income nations.[65]

Similarly, in 2009 the U.S. government induced the creation of the Neglected Tropical Disease ("NTD") pool as a way to generate innovation for the treatment of neglected tropical diseases.[66] Neglected tropical diseases are not a large money-making area, and interest in the sphere was lacking until the government offered Food and Drug Administration ("FDA") priority review vouchers for future drugs and patents in exchange for patent inclusion.[67] Commentators have stated that the NTD pool's success came from the FDA vouchers, as well as the fact that the pool

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[54] *Id.* at 81 (noting that this was the motivation for MPEG LA to create the MPEG 2 patent pool).

[55] *Id.* (arguing that patent pools make affordable licenses more available thus, more licensees will create more upstream research and downstream commercialization).

[56] Mattioli, *supra* note 22, at 120.

[57] Levy et al., *supra* note 53, at 81.

[58] Mattioli, *supra* note 22, at 133.

[59] *Id.* at 121.

[60] *Id.*

[61] *Id.* at 122.

[62] *Id.* at 122–23.

[63] *Id.*

[64] *Id.* at 125.

[65] *Id.*

[66] *Id.*

[67] *Id.* at 126–27 (noting that these "vouchers" can be used "to obtain expedited FDA review on future products of the holder's choosing, or alternatively, they could be transferred.").

was designed around researching new drugs rather than lowering transactional costs for existing ones.[68]

Other biotech pools have formed based on philanthropic and social reasons. For example, in 2000, the Golden Rice Pool was organized as a non-profit that granted a package free of charge to developing nations.[69] Although patentees got nothing in return, they may have been motivated by the public good or an attempt to achieve widespread use of their platform.[70] Similarly, in 2004, another non-profit pool formed in an attempt to quell the severe acute respiratory syndrome ("SARS") outbreak, in the hope that the pool would get a cost-effective SARS vaccine to market.[71] However, this pool never caught on. This failure could be due to the fact that the pool was formed around patents still in the application phase (i.e. still being prosecuted in front of the United States Patent and Trademark Office), before any patent rights have been granted, making their future value uncertain.[72] Another theory is that the relationship between the potential commercial product and the patents' underlying technology is complex and undetermined, requiring a lengthy research and development process that made "patent essentiality" hard to determine.[73]

It should also be noted that there have been for-profit patent pools in the biotech sphere. In 2012, the Librassay® pool was launched by MPEG LA based on genetic diagnostic testing patents.[74] Librassay® started with about 400 patents and operated as a "supermarket," making essential patents available on nonexclusive, nondiscriminatory terms.[75] Diagnostic patents were chosen because they are more of a "component based" technology (which are more classically susceptible to patent pooling) and it is a commercially focused area where players in the market have the common goal of providing accurate testing.[76] The pool's success, however, was limited. At its inception, nine well-respected U.S. institutions decided to participate and MPEG LA licensed to several firms for diagnostic testing, life science research, and medical devices.[77] Then, in 2012, in Librassay's second year of existence, the pool suffered the effects of two recent U.S. Supreme Court decisions, *Mayo*

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[68] *Id.* at 126 (stating that members of the group include large research institutions such as MIT and University of California, Berkeley).

[69] Thomas D. Jeitschko & Nanyun Zhang, *On the Challenges Facing Patent Pooling in Biotechnology*, 19 J. INTELL. PROP. RTS. 113, 116 (2014).

[70] Mattioli, *supra* note 22, at 144–45.

[71] Jeitschko & Zhang, *supra* note 69, at 116.

[72] Levy et al., *supra* note 53, at 91.

[73] *Id.*

[74] Jeitschko & Zhang, *supra* note 69, at 116.

[75] *Id.* at 117.

[76] *Id.*

[77] Ester Van Zimmerman, *IP Coordination Models: Revealing Some of the 'Magic' Behind Patent Pools and Clearinghouses?*, *in* USER GENERATED LAW: RE-CONSTRUCTING INTELLECTUAL PROPERTY LAW IN A KNOWLEDGE SOCIETY 115, 140 (Thomas Riis ed., 2016).

Collaborative Services. v. Prometheus Laboratories, Inc.,[78] and *Association for Molecular Pathology v. Myriad Genetics, Inc.*[79, 80] These cases "considerably limited the patent eligibility of diagnostics methods" resulting in less of a patent thicket and a diminished need for a patent pool.[81] Recently, Kristin Neuman, MPEG LA's Executive Director of Biotechnology Licensing, stated, "Due to the adverse effects of the *Mayo* and *Myriad* Supreme Court decisions, the [Librassay] program is no longer operating."[82]

B. MPEG LA

The third-party entity who is attempting to form the CRISPR patent pool is "MPEG LA,"[83] a private company based in Denver, Colorado.[84] MPEG LA is an independent licensing administrator, the "world's leading packager" of patent pools, which facilitates the market by "creating reasonable access and profitable opportunities for everyone."[85]

For example, MPEG LA rolled out the MPEG-2 pool in 1995 for digital media and compression technology.[86] The pool licensed the MPEG-2 standard in a single package consisting of essential patents and the basic complementary technology.[87] Thus, to create a one-stop licensing package, the first thing a patent pool must do is gather IPR. To gather the necessary patents, MPEG LA uses independent patent experts to determine whether a patent seeking inclusion into the pool is essential or complementary.[88] For MPEG-2, MPEG LA also included what it called "Related

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[78] 566 U.S. 66 (2012).

[79] 569 U.S. 576 (2013).

[80] Zimmerman, *supra* note 77, at 140–41.

[81] *Id.*

[82] E-mail from Kristin Neuman, Executive Director, Biotechnology Licensing, MPEG LA, to Patrick Neville, Student at the S.J. Quinney College of Law (Jan. 18, 2019 07:20 MST) (on file with author).

[83] MPEG LA, *CRISPR, supra* note 14.

[84] *Company Overview of MPEG LA, LLC*, BLOOMBERG, https://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=4458054 [https://perma.cc/672D-ZVVU] (last visited Sept. 11, 2019); *MPEG LA*, NY-BEST, https://www.ny-best.org/page/mpeg-la [https://perma.cc/GHC9-9HBL] (last visited Oct. 8, 2019).

[85] MPEG LA, https://www.mpegla.com/ [https://perma.cc/L5EQ-L893] (last visited Oct. 8, 2019).

[86] *See* MERGES, *supra* note 25, at 28.

[87] *Id.* at 30.

[88] To determine whether a patent is critical to the pool, MPEG LA had its lawyers study over 8,000 abstracts owned by over 100 companies, narrowing the field down to 27 essential patents. MERGES, *supra* note 25, at 30. The Department of Justice stated that this "independent-expert mechanism . . . help[s] ensure that the portfolio will contain only patents that are truly essential to the MPEG-2 standard, weeding out patents that are competitive alternates to each other." Shapiro, *supra* note 12, at 135.

Patents" or classic improvement patents which add value to the standard by implementing, building upon, or employing said standard.[89]

However, unlike MPEG-2, no technological standard exists in the CRISPR sphere.[90] This lack of a technical standard drove MPEG LA to develop its "CRISPR-Cas9 Reference Model," which describes how patent essentiality will be determined with respect to the CRISPR platform.[91] If a patent meets the established criteria, it will be eligible for inclusion into the pool.[92] The Reference Model is purposefully broad, seeking patents intended to encompass the entire CRISPR platform.[93] Because this platform could change due to advancements in technology, MPEG LA created the Reference Model so that the pool's scope can be expanded or altered.[94] Inclusion requires that at least one claim[95] is directed to:

> [T]he CRISPR-Cas9 System (as defined below) or any of its elements; a composition of matter containing the CRISPR-Cas9 System or any of its elements; a composition of matter derived from use of the CRISPR-Cas9 System or any of its elements; or a method of use, or a method of manufacture, pertaining to any of the foregoing.[96]

Specifically, the CRISPR-Cas9 System is defined as:

> (1) DNA-targeting RNA comprising: (a) a CRISPR targeting RNA ("crRNA") that hybridizes or is capable of hybridizing with a target DNA sequence in the operative environment, and (b) a trans-activating crRNA ("tracrRNA") that is associated, associates or is capable of associating with the crRNA to facilitate the formation of a complex, in the operative environment, with the Cas9 protein of element (2) below; and

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[89] MERGES, *supra* note 25, at 30.

[90] Due to the lack of interoperability and compatibility in biotech research, there is not one standard that is used for all applications. *See* Minssen et al., *supra* note 26.

[91] *See* MPEG LA, CRISPR-CAS9 REFERENCE MODEL FOR MPEG LA'S CRISPR-CAS9 JOINT LICENSING PLATFORM VERSION 1.0, at 2 (2017), https://www.mpegla.com/wp-content/uploads/CRISPR-Cas9-Reference-Model-24-Apr-2017.pdf [hereinafter REFERENCE MODEL].

[92] *Id.*

[93] *Id.* at 4.

[94] E-mail from Kristin Neuman, *supra* note 15.

[95] "[T]he patent claim is the basic source from which the subject matter of the patent right is determined." R. CARL MOY, MOY'S WALKER ON PATENTS 4–10 (4th ed. 2012); *see also* Markman v. Westview Instruments, Inc., 517 U.S. 370, 373–74 (1996) ("The claim define[s] the scope of a patent grant, and functions to forbid not only exact copies of an invention, but products that go to the heart of an invention but avoids the literal language of the claim by making a noncritical change.") (internal citations omitted).

[96] REFERENCE MODEL, *supra* note 91, at 2.

> (2) a Cas9 protein, which may be modified from wild-type provided that the Cas9 retains the ability to form a complex with the DNA-targeting RNA, thereby targeting the Cas9 protein to a target DNA sequence in the operative environment.[97]

This outline of essentiality in MPEG LA's Reference Model is meant to encompass all patents essential and complementary to the underlying CRISPR platform.[98] To collect these platform patents, MPEG LA is seeking "target-agnostic" patents that do not require a specific genome.[99]

The Reference Model discloses the criteria for pool inclusion, but it does not include the terms and conditions that MPEG LA will offer to each potential licensee, as that information is still confidential.[100] However, evidence of the proposed terms can be seen in statements from MPEG LA executives and MPEG LA's past patent pools.[101] In a 2017 publication of *Science*, Lawrence Horn, Chief Executive Officer of MPEG LA, stated that "licensing to industry on nonexclusive, cost-effective, transparent, and nondiscriminatory terms, including royalty-free research by universities" would benefit patent holders and licensees alike.[102] Similarly, Kristin Neuman stated that MPEG LA's "initiative" was to provide a "worldwide nonexclusive license to multiple patents held by multiple entities in a single transaction on nondiscriminatory, transparent, and cost-effective terms."[103] While these statements are not official disclosures of the licensing terms MPEG LA will use for the CRISPR pool, they are consistent with its prior pools. One can hypothesize about the CRISPR pool's licensing terms by analyzing MPEG LA's past pools and the statements made by Neuman and Horn.

The licenses issued for the Librassay® pool only included non-exclusive licenses covering: "Royalty-Bearing Products" (with the right of use for downstream recipients), "Royalty-Bearing Uses," and "Royalty-Free Research and Education."[104] Some of the important terms included: a "Basic Annual Fee" consisting of a flat fee per year, per patent (with a maximum fee of $12,500);

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[97] *Id.* at 3–4.

[98] *See id.* at 4 (noting that the Reference Model is meant to include all applications of CRISPR-Cas9 technologies).

[99] E-mail from Kristin Neuman, *supra* note 15.

[100] *See* REFERENCE MODEL, *supra* note 91.

[101] The past patent pools that I will discuss are the MPEG 2 pool and the Librassay® pool. The Librassay® pool is significant for this discussion because it was a for-profit pool in the biotechnology arena.

[102] Lawrence Horn, *Patent Pools for CRISPR Technology*, 355 SCIENCE 1274, 1274 (2017), http://science.sciencemag.org/content/355/6331/1274.2 [https://perma.cc/W256-TSQC] (responding to Jorge L. Contreras & Jacob S. Sherkow, *CRISPR, Surrogate Licensing, and Scientific Discovery*, 355 SCIENCE 698 (2017)).

[103] E-mail from Kristin Neuman, *supra* note 15.

[104] *Librassay® Patent Portfolio License Summary*, MPEG LA, LLC 2 (Sept. 12, 2013) (on file with author).

penalties should the licensee fail to pay the Basic Annual Fee; and a standard royalty fee calculated using a set equation.[105] In light of the terms of Librassay's licensing agreements and the above-mentioned statements of MPEG LA staff, it seems likely that the CRISPR pool will follow a similar structure: a set royalty based on the number of patents licensed and the field of use those patents are intended. Like Librassay®, and consistent with Horn's statements, MPEG LA will likely also grant royalty-free licenses to research institutions.

Finally, to ensure that no single party has control over the licensing of the package, MPEG LA works with all the included patent holders to create a single set of licensing terms and conditions, upon which all of the patent holders must agree.[106] The patent holders also hold most of the enforcement powers. While MPEG LA can enforce contractual provisions,[107] it does not file patent enforcement lawsuits on its own; instead, it must notify the patentees that they *may* want to file an enforcement suit.[108]

C. CRISPR Landscape[109]

1. The Patent Landscape

To create a sustainable and rewarding patent pool, MPEG LA will have to analyze the CRISPR patent landscape to find essential and complementary patents for inclusion.[110] This is no easy task because, as of May 2018, there were more than 1,700 applications for "CRISPR patent families,"[111] with around 100 new families

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[105] *Id.* at 2–3 (noting that the equation used to determine the royalty payment was: Royalties = "Royalty Rate" x "Collectibles" for a given Royalty-Bearing Product or Use. Where "Royalty Rate" is a predetermined, set value based on the number of patents licensed on a royalty bearing product or use in a country. And "Collectibles" is defined as the "commercial list price of a Royalty-Bearing Product or Use to the extent paid to Licensee directly or indirectly by any party (subject to fair market value determination)").

[106] *See* E-mail from Kristin Neuman, *supra* note 15.

[107] Peter Bright, *MPEG LA: 12 Companies Own Patents Essential to Google's VP8 Codec*, WIRED (Aug. 1, 2011, 10:50 AM), https://www.wired.com/2011/08/mpeg-la-12-companies-own-patents-essential-to-googles-vp8-codec/ [https://perma.cc/G43E-L9V8].

[108] Joe Mullin, *Patent Litigation Weekly: MobileMedia's Unusual Patent Infringement Campaign*, THE PRIOR ART (Apr. 23, 2010), https://thepriorart.typepad.com/the_prior_art/2010/04/mobilemedia-ideas-v-apple.html [https://perma.cc/CYG3-QB2L].

[109] *See* Corinne Buhan & Fabian Palazzoli, CRISPR PATENT LANDSCAPE, IPSTUDIES (Jan. 2018), https://www.ipstudies.ch/wordpress/wp-content/uploads/2016/05/201801-CRISPR-Patent-Landscape_Sample.pdf [https://perma.cc/RKJ5-M3JK]. But note that this source is only a partial representation of the CRISPR patent landscape as of January 2018 covering 2,230 patent families worldwide.

[110] *See* Gilbert, *supra* note 13, at 25–26; Lawrance et al., *supra* note 29.

[111] A patent "family" is a set of patent applications which cover similar technical material that have been filed in different jurisdictions. Minssen et al., *supra* note 26.

published every month.[112] The bulk of these applications have been filed by institutional applicants/assignees[113] and industrial applicants.[114] There are at least 31 institutional and industrial applicants who have filed at least 14 patent family applications as of January 2018.[115] The patent claims are equally diverse, covering various cells and organisms,[116] molecular tools,[117] and at least 9 different CRISPR applications.[118] Even when the scope is narrowed from all CRISPR patent families to only CRISPR-Cas9 inventions, there are at least 591 inventions.[119]

As noted, the CRISPR landscape is somewhat fragmented with essential and complementary patents held by a variety of parties.[120] UC Berkeley and the Broad Institute of MIT and Harvard ("Broad") are considered two major players because they were some of the first applicants, and their patents claimed broad IPR.[121] The Berkeley Group (collectively including Inventors Doudna and Charpentier, UC Berkeley, and the University of Vienna) and its surrogate, Caribou licensing, has rights to at least 80 patent family applications.[122] The Berkeley Group's IPR includes one of the first major filings in May 2012, claiming CRISPR-Cas9 system prokaryotes, featuring single guide RNA for use in the environment, with the idea to use the system as a genetic engineering tool.[123] Broad and its surrogate, Editas, have IPR to at least 150 patent family applications.[124] Broad was another original filer, with a priority date of December 2012, claiming IPR to CRISPR-Cas9

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[112] Lawrance et al., *supra* note 29.

[113] Buhan & Palazzoli, *supra* note 109, at 5. Institutional applicants make up 60.3% of the landscape consisting of 1,345 patent applications. *Id.*

[114] *Id.* Industrial applicants make up 31.8% of CRISPR patent applications, consisting of 709 filings. Note that the remaining 7.9% of filings in the landscape are done by either individual inventors or co-filings between an individual inventor and institutional/industrial assignees.

[115] Buhan & Palazzoli, *supra* note 109, at 7.

[116] *Id.* at 9. The claims cover cells and organisms including, but not limited to "Human cell-subject," "Mammalian cell-organism," "Plant cell-organism," "Eukaryotic cell-organism," and "Undefined cell-organism." *Id.*

[117] *Id.* The claims cover a wide variety of "Molecular tools," including but not limited to, "Nuclease," "Cas-CRISPR enzyme," and "gRNA-guide sequence." *Id.*

[118] *Id.* These patent applications cover at least 9 different CRISPR applications ranging from "Genome editing" to "Therapeutics-Diagnostics" to "Drug screening." *Id.*

[119] Egelie et al., *supra* note 1, at 1028.

[120] Buhan & Palazzoli, *supra* note 109, at 7. MIT has filed the most with over 150 patent family filings. Other parties who have filed at least 50 patent families include: Broad – an institution of MIT and Harvard – at over 110, Harvard around 110, the Chinese Academy of Sciences (CAS) over 80, Berkeley over 80, The Chinese Academy of Agricultural Sciences (CAAS) around 70, and Du Pont around 60.

[121] *See* Egelie et al., *supra* note 1, at 1026–27.

[122] Buhan & Palazzoli, *supra* note 109, at 7.

[123] *See* Egelie et al., *supra* note 1, at 1026; *see also* U.S. Patent No. 10266850 (filed Mar. 15, 2013).

[124] Buhan & Palazzoli, *supra* note 109, at 7.

application in eukaryotic cells.[125] MPEG LA claims that Broad holds at least 22 essential patents.[126]

However, a successful patent pool will likely not depend on the consent of Broad and the Berkeley Group alone.[127] There are many parties who hold important IPR, including but not limited to Vilnius University, ToolGen, Rockefeller University, Cellectis, and MilliporeSigma.[128] MilliporeSigma, formerly known as Sigma Aldrich, deserves attention because its patent portfolio discloses CRISPR-Cas9 applications in eukaryotes, which are very similar to what Broad has always claimed to be "its pioneering feature over the Berkeley portfolio. . ." potentially making a complicated IP situation worse.[129]

2. The Licensing Landscape

Large research institutions, like Broad and UC Berkeley, have created surrogate companies to help facilitate licensing.[130] A surrogate is a "spinoff" institution—created by the patent holder and/or one of the principal researchers—

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[125] *See* Egelie et al., *supra* note 1, at 1026; U.S. Patent No. 8,697,359 (filed Dec. 12, 2012).

[126] Press Release, Broad Institute, Broad Institute of MIT and Harvard Joins Discussions to Create Worldwide Crispr-Cas9 Licensing pool (July 10, 2017), https://www.broadinstitute.org/news/broad-institute-mit-and-harvard-joins-discussions-create-worldwide-crispr-cas9-licensing-pool [https://perma.cc/5KY2-K9GE].

[127] Ulrich Storz, *Crispr Cas9-Licensing What Can't be Licensed*, 53 LES NOUVELLES 123, 126 (2018).

[128] *See id.* at 126–28, fig.1 (noting that The University of Vilnius has an earlier priority date than Berkeley and Broad, claiming CRISPR methods for *in vitro* applications with disclosures that could be considered the foundation of Berkeley's patents. ToolGen is a Korean company whose patent family disclosed CRISPR applications in eukaryotes by means of nuclear localization sequences. ToolGen's patents have been granted in Korea but are still pending in the USA. Rockefeller is a co-inventor with Broad on multiple patents involving CRISPR-related technologies); Matthias Blamont, *France's Cellectis Wins U.S. Patents For Gene Editing Technology*, REUTERS (Feb. 12, 2018, 10:02 PM) https://www.reuters.com/article/us-cellectis-gene/frances-cellectis-wins-u-s-patents-for-gene-editing-technology-idUSKBN1FX0EO [https://perma.cc/3BS3-RLV4] (discussing how Cellectis has patents in both the EU and the U.S. regarding CRISPR tech and T cells, "which play a key role in the immune response to cancer . . ."); Corinne Le Buhan, *Recent Developments in the CRISPR Patent Landscape*, IPSTUDIES (Mar. 6, 2017), https://www.ipstudies.ch/2017/03/recent-developments-in-the-crispr-patent-landscape/ [https://perma.cc/T94Z-JNGK] (stating that Cellectis may be the only patentee in the EU who has a significant position in the CRISPR patent landscape).

[129] Storz, *supra* note 127, at 126–27.

[130] *See* Jorge L. Contreras & Jacob S. Sherkow, *CRISPR, Surrogate Licensing, And Scientific Discovery*, 355 SCIENCE 698, 698–99 (2017) [hereinafter Contreras & Sherkow, *CRISPR*].

which is given exclusive rights including the right to sublicense.[131] Essentially, the surrogate is created by the patent holder who "effectively outsources the licensing and commercialization of a valuable patent portfolio to a private company."[132] This model of licensing is common for research institutions "because it gives them a substantial share of the profits with minimal" risk and allows them to focus on research and innovation.[133]

In the CRISPR sphere, surrogates have been granted the exclusive license to target or develop "any of the 20,000+ genes" that are included in the human genome.[134] Due to the broad nature of such a task, the surrogates are expected to sublicense, in order to enable other companies to target and develop particular genes.[135] To date, most of the licensing by these surrogates has been on a non-exclusive basis in three general fields of use: "(i) basic noncommercial research; (ii) development and sale of tools . . . ; and (iii) development, sale, and use of therapeutics and treatments . . ."[136] While most research users have been granted non-exclusive licenses, all human therapeutic applications have been licensed on an exclusive basis.[137]

III. LICENSING ISSUES FOR A BIOTECH PATENT POOL

While patent pools provide an interesting solution for the licensing of IPR in fragmented fields such as CRISPR, there are multiple challenges which could impede the pool's formation. These challenges include: (A) the "Tragedy of the Anticommons," (B) high transaction costs, (C) the nature of biotech and its patents, and (D) social and business reasons.

A. Biotech and the Tragedy of the Anticommons

A cause of growing concern in the CRISPR sphere is what is known as the "Tragedy of the Anticommons."[138] The "Anticommons" is the "unfettered exercise of individual property rights" that could lead to the "tragic underutilization" of knowledge and other resources.[139] This underutilization can occur when one party

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[131] *Id.*
[132] *Id.*
[133] *Id.*
[134] *Id.*
[135] *Id.*
[136] *Id.*
[137] Jorge L. Contreras & Jacob S. Sherkow, *Response to Patent Pools for CRISPR Technology*, 355 SCIENCE 1274, 1274 (2017), http://science.sciencemag.org/content/355/6331/1274.2 [https://perma.cc/E5RP-CEFP] [hereinafter Contreras & Sherkow, *Response*].
[138] *See* Contreras, *supra* note 11, at 335 (noting that M.A. Heller and R.S. Eisenberg introduced the term, "Anticommons" and applied it to the phrase "Tragedy of the Commons").
[139] *Id.*

refuses to license, or only grants exclusive licenses, thus preventing potential research and the spread of information.[140] The Anticommons could be problematic in biotech areas like CRISPR, where research has the potential to save lives, but its lucrative nature could prevent broad dissemination.[141] There are two reasons the Anticommons could affect the CRISPR patent pool: there is a patent thicket, and the current licensing model being implemented.

First, the potential for an Anticommons goes hand-in-hand with a "patent thicket."[142] A patent thicket forms when there are overlapping rights in many patents belonging to separate patentees, and all of said overlapping rights are required to make, use, or sell a product lawfully.[143] This patent thicket creates the underutilization of IPR because it creates high transaction costs, litigation risks, and high royalty rates.[144] Basically, in the Anticommons, a potential licensee would need to obtain multiple licenses from a large number of licensors who own overlapping IPR, creating a system where all IPR is underutilized.[145] If all the CRISPR patent holders were to license their IPR independently, they could potentially "block others from use of the whole."[146] As Professor Jorge Contreras from the University of Utah, S.J. Quinney College of Law explains, "if multiple holders of [IPR], particularly patents, covering a biomedical technology can individually block others from conducting research on that technology, then overall research progress could be stifled."[147] As noted above, there is a patent thicket in the CRISPR sphere with some fragmentation of IPR.[148] CRISPR IPR is fragmented because the technology tends to be patented and licensed on a gene-by-gene basis.[149]

Second, the worry with the surrogate licensing model currently being used is that there may be bottlenecks in research.[150] A research bottleneck could occur because the exclusive licensing to surrogates has limited the availability of the CRISPR technology as an overall platform, and traditional safeguards against the

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[140] *Id.* at 335–37.

[141] *See* Contreras, *supra* note 11, at 337.

[142] Gilbert, *supra* note 13, at 2.

[143] These rights are "required," as patent law makes it unlawful for any person to make, use or sell a product that is covered by a patent. *See* 35 U.S.C. § 271(a) (2012). With a patent thicket and overlapping IPR, a licensee needs to reach agreements with all parties who have rights in the overlapping rights to make, use or sell the product. Gilbert, *supra* note 13, at 2.

[144] Gilbert, *supra* note 13.

[145] *See* Contreras, *supra* note 11, at 335.

[146] *See id.*

[147] *Id.*

[148] *Id.* at 337; *see also* discussion, *supra* Section II.C for a more specific discussion about the CRISPR patent landscape.

[149] Contreras, *supra* note 11, at 337.

[150] Contreras & Sherkow, *CRISPR*, *supra* note 130, at 700.

overbroad surrogate licenses will not work.[151] Patent pools, arguably, could be the solution to the potential Anticommons issue.

B. High Transaction Costs

There are at least two problems for patent pools in biotech which cause high transaction costs: (1) the need for market exclusivity, and (2) the interests of the patent holders.[152]

First, transaction costs tend to be high in biotech for a variety of reasons. Usually, there are high costs for product development, required clinical trials, and the uncertainty that takes place in biotech research.[153] Similarly, regulatory approval is necessary for new drugs, treatments, or products before they can hit the market.[154] Due to these high development and regulatory costs, licensees generally require some market exclusivity in order to return a profit.[155]

Second, high licensing fees can arise in biotech due to the overvaluing of IPR.[156] Researchers have suggested that the large overestimation of patent value in biotech is due to cognitive bias.[157] This bias is problematic because essential patent owners who overvalue their discoveries force downstream licensees to pay more in licensing fees on a product, technique, or discovery that is not guaranteed to be commercially successful.[158] Similarly, some patentee's (especially start-ups) only

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[151] *See, e.g.*, *id.* at 699 (noting how diligence milestones, which "require an exclusive licensee to demonstrate progress toward commercialization of a licensed technology," will not work as a safeguard because the surrogates can easily show some progress in the incredibly broad field that covers over 20,000 genomes).

[152] *See* Conteras, *supra* note 11, at 335–36; Lawrance et al., *supra* note 29; Minssen et al., *supra* note 26.

[153] Contreras, *supra* note 11, at 336; *see also e.g.*, Bill Edelman, *Explaining the Cost of Biotech Therapies*, 1 BIOTECHNOLOGY HEALTHCARE 37–41 (May 2004), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3555164/ [https://perma.cc/MU86-LJZW] ("[I]t costs, on average, $897 million to develop a new drug and bring it to market."); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 700 (1998) (discussing how transaction costs likely arise early in the course of research and development, where the outcome is uncertain, potential economic gains are uncertain, and the potential value of any downstream products is equally uncertain).

[154] Contreras, *supra* note 11, at 336.

[155] *Id.* (noting that market exclusivity is needed based on the very high costs licensees must pay in order to get a product to market); Contreras & Sherkow, *Response*, *supra* note 137, at 1274 (discussing how in pharmaceutical and other biotech industries, the licensee is only profitable because they can leverage the market using their exclusive rights).

[156] *See* Heller & Eisenberg, *supra* note 153, at 701.

[157] *Id*.

[158] *Id*. ("[I]f each owner overestimates the likelihood that her patent will be the key [to a new drug for example], then each will demand more than the probabilistic value, the upstream owners collectively will demand more than the aggregate market value of their

tangible asset is their IP portfolio.[159] Thus, sometimes the optimal use of their IPR is to "establish a favorable context for their own products that require other companies either to work around them or to seek to license . . . . [T]he prospect of putting IP into a pool, and thereby ceding a degree of control and possibly realizing less revenue, could make this option less than attractive."[160]

The high licensing costs mentioned above might require a pool to increase its royalty rate to financially incentivize potential members to join based on a return value that would be higher than said member's ability to license on their own.[161] If the pool rate gets too high, potential licensees will seek rates from an independent licensor.[162] Because exclusive licensing and high transaction costs are contrary to an effective patent pool, biotech has not often utilized patent pools.[163] Despite all this, MPEG-LA believes that they can create a sustainable patent pool that would create a one-stop-shop for CRISPR related patents.[164]

C. The Nature of Biotech and Biotech Patents

The nature of biotech could be a potential problem for pool formation. First, the end products in this field (drugs, human therapeutics, etc.) "are often only loosely defined in upstream research."[165] Loosely defined upstream research can create problems for defining what is essential.[166] Traditionally, patent pools are "product-based," meaning essential patents are determined with respect to particular products or whether a patent is required for a specific standard.[167] However, when the product is only loosely defined, and essentiality is difficult to determine, this could result in the diminished utility of the pool, as it may be too narrow to be useful for product development.[168] For example, in the field of genomics, "patents can be so far upstream that they do not relate to particular, identifiable products in the same concrete ways that we see in traditional cases."[169] Similarly, in the case of the SARS patent pool, the strategy was to include only "patents that covered the SARS

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inputs, the downstream user will decline the offers, and the new drug will not be developed."); *see also* Zimmerman, *supra* note 77 for more on the uncertainty of commercial success and the interplay with transaction costs.

[159] Levy et al., *supra* note 53, at 94.

[160] *Id.*

[161] *See* Gilbert, *supra* note 13, at 26–27.

[162] *Id.*

[163] *See* Contreras & Sherkow, *Response*, *supra* note 137, at 1274 (noting that, due to the many licensing problems, it is a question whether patent pooling for CRISPR would ultimately be successful).

[164] MPEG LA, *CRISPR*, *supra* note 14.

[165] Levy et al., *supra* note 53, at 93.

[166] *Id.*

[167] *Id.* at 84.

[168] *Id.* at 96.

[169] *Id.*

sequence and the proteins expressed. Thus, much of the development work relating to SARS—vaccines, diagnostics and therapeutics—would likely have recourse to the SARS sequence."[170] However, had the pool included sequence IPR, that would have "at least eliminate[d] the growth of thickets in this crucial area."[171]

Secondly, loosely defined upstream research can cause long periods of development.[172] Biotech patents tend to have "incompleteness," where further innovation must be completed before the final product is embodied and taken to the market.[173] The incompleteness and long development cycles can make it difficult to define what patents are complementary.[174] This can be a problem because, if a pool does not contain complementary rights, the pool may no longer be a one-stop-shop for potential licensees.

Third, the very nature of the biotech industry can cause licensing problems that oppose the formation of a patent pool.[175] Biotech does not require the same level of "interoperability and compatibility" of IPR that was required in previously successful patent pools such as MPEG-2.[176] Some researchers have suggested that patent pools on non-diagnostic products may not work, due to the lack of alignment of industry interests:

> When considered from the perspective of the overall biotechnology industry, while patent pools may be useful for assembling IP related to platform technologies that need to establish industry-wide standards (for example, DVD, MP3), the value of patent pooling is much less when industry interests are not aligned (still maturing industries), which, indeed, is the general case with biotechnology. Hence, in the context of R&D in many biotechnological applications . . . industry interests can hardly be considered aligned. Indeed, if a technology has not matured to the stage where industry standards can even be contemplated, then a patent pool would likely not be the favored option.[177]

D. Business and Social Reasons for Failure

As noted above, the reasons to join a patent pool are not always financial.[178] That being said, patent pools can fail for a variety of social and business reasons not discussed above. In 2008, the Intellectual Property Exchange International, Inc. ("IPXI"), was created as a market-based trading platform where licensees could get

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[170] *Id.*
[171] *Id.*
[172] *Id.* at 93.
[173] Jeitschko & Zhang, *supra* note 69, at 118.
[174] Levy et al., *supra* note 53, at 93.
[175] *See* Minssen et al., *supra* note 26.
[176] *Id.*
[177] Jeitschko & Zhang, *supra* note 69, at 118.
[178] *See* discussion *supra* Section II.A.3.

a single package of fixed rights under a specified portfolio of patents.[179] IPXI was created around IEEE's[180] 802.11n "Wi-Fi" standard,[181] but despite backing from several significant patent holders, IPXI ceased operating in March of 2015.[182] There are several possible reasons for this failure.

First, some licensees may be unwilling to obtain a license unless they are threatened with litigation.[183] For IPXI, this may have been a crucial problem because IPXI had no history of patent litigation or enforcement, and it makes financial sense for a potential licensee to take a "wait-and-see" approach.[184] Secondly, the structure of IPXI itself was not a true one-stop-shop for manufacturers.[185] It did not alleviate the burdens of bilateral negotiations because it only prevented licensees from having to negotiate with the patentees who joined the group, it was not clear if the patentees were the key players in the relevant market, and the packages of IPR did not include complementary patents (creating a potential need for more licensing negotiations).[186] Third, IPXI was not attempting to package a new standard; thus, manufacturers likely already had years to solidify licensing relationships with key patent holders, thereby diminishing any need for IPXI.[187] Fourth, the inability of cross-licensing prevents parties from using their own patents as an exchange, and "[t]he practice of cross-licensing is key to many technology markets, and often results in royalty-free

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[179] Jorge L. Contreras, *Frand Market Failure: IPXI's Standards-Essential Patent License Exchange*, 15 CHI.-KENT J. INTELL. PROP. 419, 421–424 (2016) [hereinafter Contreras, *IPXI*]. It should be made clear that IPXI is not a patent pool per se, but it is similar in a number of ways and provides useful insight into social and business reasons as to why collaborations of IPR may fail. The differences between IPXI and an ordinary patent pool that should be noted include: IPXI's package licenses could be freely traded or transferred by the purchaser, and the pricing was not fixed as it is in a patent pool. *Id.* at 426.

[180] IEEE is the world's largest technical professional society, an international standards organization "dedicated to advancing innovation and technological excellence for the benefit of humanity. . . . It is designed to serve professionals involved in all aspects of the electrical, electronic, and computing fields and related areas of science and technology that underlie modern civilization." *History of IEEE*, IEEE https://www.ieee.org/about/ieee_history.html [https://perma.cc/K357-2TAY] (last visited Sept. 11, 2019).

[181] 802.11n was a standard rolled out by IEEE seeking "to increase the achievable speeds of Wi-Fi networks beyond that achievable using" previous IEEE standards 802.11a, 802.11b, and 802.11g. *IEEE 802.11n Standard*, ELECTRONICSNOTES, https://www.electronics-notes.com/articles/connectivity/wifi-ieee-802-11/802-11n.php [https://perma.cc/88YE-SVV4] (last visited Oct. 10, 2019).

[182] *See* Contreras, *IPXI, supra* note 179, at 419.

[183] *Id.* at 433.

[184] *Id.* It should be noted that most licenses are not negotiated or executed only after threats of litigation, but IPXI's executives did state that although they retained the right to enforce the patents, "there was no incentive [for potential licensees] to talk without the threat of litigation." *Id.*

[185] *Id.* at 434.

[186] *Id.* at 434–36.

[187] *Id.* at 435.

exchanges of patent licenses by market participants."[188] Fifth, there were social reasons that may have contributed to IPXI's 2015 failure, including a general unease regarding the value and strength of the patents following the U.S. Supreme Court's 2014 landmark decision in *Alice Corp. v. CLS Bank International*,[189] as well as the uncertainty of joining a complex platform with which lawyers and firms were unfamiliar.[190]

IV. ANALYSIS

A. Will the Pool Work

MPEG LA gained a large swing of momentum in July 2017 when the Broad Institute announced that it would join the patent pool.[191] Issi Rozen, Broad's Chief Business Officer, has stated Broad's position on licensing: "The Broad Institute already licenses CRISPR-Cas9 non-exclusively for all applications, with the exception of human therapeutics, where we have significantly limited the exclusivity. We look forward to working with others to ensure the widest possible access to all key CRISPR intellectual property."[192]

After Broad's decision to join the pool, MPEG LA made an "open-call" for all patents.[193] While Broad's commitment is a major and necessary step, others have stated that UC Berkeley, and possibly all of the Berkeley Group, "must also join in order for the pool to be commercially successful,"[194] because those parties hold patents to some of the underlying technology.[195] However, it is unclear if UC Berkeley and the Berkeley Group will want to engage in a joint licensing scheme

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[188] *Id.* at 435–36.

[189] 573 U.S. 208 (2014). *Alice* was a landmark patent case which resulted in more software patents being invalidated, "In 2015, over 60 percent of the software patents challenged under *Alice* were found to have at least one claim unpatentable." Joseph Saltiel, *In the Courts: Five Years After* Alice - *Five Lessons Learned from the Treatment of Software Patents in Litigation*, WIPO Magazine (Aug. 2019), https://www.wipo.int/wipo_magazine/en/2019/04/article_0006.html [https://perma.cc/4YDS-5R6Z]

[190] *See* Contreras, *IPXI, supra* note 179, at 438–39.

[191] Broad Institute, *supra* note 126.

[192] *Id.*

[193] Lawrance et al., *supra* note 29.

[194] *See* Minssen et al., *supra* note 26.

[195] Berkeley scientist Jennifer Doudna described the relationship between UC Berkeley's and Broad's IPR as UC Berkeley's rights "will be for all tennis balls and Broad's will be for green tennis balls." Susan Decker & Michelle Cortez, *This Court Battle Will Decide Who Will Make a Fortune from Gene-Editing Tech*, BLOOMBERG (Apr. 29, 2018), https://www.bloomberg.com/news/articles/2018-04-29/berkeley-fights-harvard-mit-over-profits-from-gene-editing-tech [https://perma.cc/W5SW-WGH9].

with Broad because the two institutions only recently ended a long, ongoing patent interference dispute, where Broad's rights were affirmed over UC Berkeley's.[196]

In September 2018, it became public knowledge that Broad, MIT, Harvard, and Rockefeller University will participate in MPEG LA's pool.[197] More recently, in July of 2019, Broad announced a joint CRISPR licensing framework with MilliporeSigma to "encourage innovation."[198] With the intention of streamlining access for scientists, this licensing agreement includes IPR from multiple key parties including: Broad, Millipore Sigma (under the Sigma-Aldrich portfolio), Harvard University, MIT, New York Genome Center, The Rockefeller Center, and more.[199] It is unclear how this new licensing venture will affect Broad's participation in MPEG LA. The press release states that Broad's intention is to "allow other key patent holders to participate in the future – either through this framework or *via a third-party patent pool collaboration*. . . ."[200] Lee McGuire, Broad's Chief Communications Officer, reiterated that Broad is "still actively participating in patent pool discussions with MPEG LA."[201] While Broad still appears to be a member of MPEG LA's potential pool, if nothing else, this new licensing venture raises doubts that key patent holders do not, or have not, come to the table.[202]

MPEG LA, however, has stated that they are "in communication" with all patent holders that they have determined are critical for the success of the pool.[203] One can infer that Broad's decision to join MPEG LA was influential in the sphere, considering the recent interference determination over Berkeley.[204] Kristin Neuman said MPEG LA is not waiting on a specific critical mass that must be met before the patent pool can go public:

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[196] *See* Regents of Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286, 1296–97 (Fed. Cir. 2018) (holding that Broad's patent claims did not interfere with those of Berkeley); Decker & Cortez, *supra* note 195 (noting that the reason the dispute took place is because Broad's "green tennis balls," which cover most of human therapeutics, could be where the money is).

[197] E-mail from Kristin Neuman, *supra* note 15.

[198] Broad Communications, *Broad Institute and MilliporeSigma Announce CRISPR License Framework to Encourage Innovation*, BROAD INST. (July 18, 2019), https://www.broadinstitute.org/news/broad-institute-and-milliporesigma-announce-crispr-license-framework-encourage-innovation [https://perma.cc/M73V-XUTQ].

[199] *Id.*

[200] *Id.* (emphasis added).

[201] E-mail from Lee McGuire, Chief Commc'n Officer, The Broad Inst., to Patrick Neville, Student at the S.J. Quinney College of Law (Sept. 6, 2019, 04:02 AM MST) (on file with author).

[202] MPEG LA released its own statement after Broad's decision to create a licensing scheme with Millipore Sigma. It is MPEG LA's opinion that it is still the best option moving forward for "maximiz[ing] the benefits of CRISPR" because of its "independence and neutrality." *Media/Licensing Programs*, MPEG LA (July 25, 2019), https://www.mpegla.com/media/ [https://perma.cc/XSM9-RWTL].

[203] *See id.*; E-mail from Kristin Neuman, *supra* note 15.

[204] *See generally* Regents of Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286, 1296–97 (Fed. Cir. 2018) (holding that Broad's patent claims did not interfere with those of Berkeley).

> There are no firm numbers defining critical mass. Before taking the pool public, [MPEG LA] require[s] a package of patent assets that the market will deem sufficiently valuable to license on reasonable, nonexclusive terms and a set of terms and conditions for the licensing of the package upon which all of the patent holders agree . . . . [W]e have the former, and are working on the latter.[205]

Based on Neuman's statements, one can conclude that MPEG LA is close to reaching the pool's critical mass for going public.[206] This means that MPEG LA is close to having the essential "patent assets" needed to create a single licensing package where licensees will not have to worry about downstream litigation.[207] This is all well and good, but if the pool does not contain all essential and complementary rights, it will not work as intended.

MPEG LA plans on including those IPR essential and complementary to the underlying CRISPR platform.[208] Based on the Reference Model, the CRISPR pool is constructed to contain only broad, "target-agnostic" patents.[209] By including foundational, target-agnostic patents, MPEG LA will create a single licensing package such that any potential licensee will have the ability to use the technological platform.[210] However, the Reference Model also preserves the biotech industry's need for exclusivity via "target-specific" patents that will not be included in the scope of the pool.[211] This sub-category of exclusive licenses gives drug/product developers the market leverage required to incentivize the funding and development of new products, while still participating in the foundational CRISPR patent pool, using the pool license as a research tool.[212] These developers could get a license from a pool member on an independent basis for specific-target genes or applications as necessary.[213] This system could create the appropriate balance to effectuate a patent pool in the biotech market.[214] However, this potential balance could be negated by existing exclusive licenses in human therapeutics.[215] This would become a problem if the exclusive licenses were to create overlapping IPR.[216] Neuman does not see

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[205] E-mail from Kristin Neuman, *supra* note 15.

[206] *Id.* Note: MPEG LA was specifically asked for a list of participating patent holders but was informed that those not already listed in this paper requested to remain confidential.

[207] *See id.*

[208] *See* REFERENCE MODEL, *supra* note 91, at 1–3.

[209] E-mail from Kristin Neuman, *supra* note 15.

[210] *See id.*; REFERENCE MODEL, *supra* note 91, at 2–3.

[211] *See* E-mail from Kristin Neuman, *supra* note 15; REFERENCE MODEL, *supra* note 91, at 2–3.

[212] E-mail from Kristin Neuman, *supra* note 15.

[213] *See id.*

[214] *Id.*

[215] *See supra* note 137 and accompanying text.

[216] *Id.*

these existing licenses as an issue: "[C]ompanies would benefit from a CRISPR patent pool that would provide a nonexclusive license to CRISPR as a research tool, and it would appear that many of the exclusive licenses already granted in the CRISPR field would permit this field of use to be included in a pool license."[217]

Ideally, the pool's broad coverage would create a diverse market because it is broad enough to facilitate parallel development.[218] Parallel development allows multiple licensees to develop multiple applications at the same time, while the patent holder can spread their risk through constant royalty streams from the multiple parallel licensees.[219] But considering how rapidly the patent landscape is growing,[220] there are other licensing issues that could be problematic in application. Without specifics on who and what IPR is contained in the pool, the ability to generate a one-stop-shop for CRISPR technology will remain in doubt. Similarly, if Broad's new licensing scheme with Millipore Sigma alters its participation, the pool will likely not have the essential IPR necessary to be effective. However, should the pool go public, it could alleviate many licensing concerns including: (1) fragmentation and downstream litigation, (2) the Tragedy of the Anticommons, and (3) licensor issues. Some researchers have suggested that a successful patent pool could do more than solve licensing issues; it could also alleviate ethical concerns[221] and judicial intervention.[222]

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[217] E-mail from Kristin Neuman, *supra* note 15.

[218] *Id.*

[219] *See id.* (noting that this method of licensing also benefits the public by allowing the creation of multiple products at the same time thus bringing new products and services to the market faster at a lower price).

[220] *See* discussion *supra* Section II.E.

[221] While this topic is largely outside the scope of this paper, many scientists and lawmakers ethically criticize the use of CRISPR technologies because of its potential to make germline edits and therapies too simple. *See* David Baltimore et al., *CRISPR Controversy*, THE TRANSLATION SCIENTIST (Jan. 21, 2016), https://thetranslationalscientist.com/issues/0116/crispr-controversy/ [https://perma.cc/Q49M-DM92]. However, MPEG LA and its potential licensors could potentially solve said ethical dilemmas through ethical constraints in their licensing agreement. In fact, Broad has used ethical limitations in their licensing agreements by granting licenses for only very specific applications. *See* Storz, *supra* note 127, at 125 (discussing Broad's non-exclusive licensing with Bayer for specific agricultural applications such as genetic modification of plant varieties, and Broad's licensing agreement with its surrogate, Editas, which states that Editas may "use or outlicense the technology to modify human germ cells or embryos for any purpose."). Similarly, a successful patent pool could provide constraints on "legal grey area[s]" by imposing licensing constraints on ethical concerns where lawmakers are behind the rapidly expanding technology. *See id.* at 1025.

[222] While this topic is largely outside the scope of this paper, licensing bottlenecks in human health and wellbeing research and products has provoked judicial and policy activity. *See* Anja von der Ropp & Tony Taubman, *Bioethics and Patent Law: The Case of Myriad*, WIPO MAGAZINE (Aug. 2006), http://www.wipo.int/wipo_magazine/en/2006/04/article0003.html [https://perma.cc/F3Z5-M78F] (noting that the debate about the validity of Myriad's patents stemmed from their licensing policies, which demanded incredibly high prices and

1. A Patent Pool Could Alleviate Fragmentation and Litigation Concerns

As discussed above, the CRISPR patent landscape is complex,[223] and any use in this field without a proper license could result in litigation; "[the] [f]reedom to operate will not be possible without *multiple* licenses."[224] Even if a company were able to obtain these multiple licenses, royalty stacking, multiple negotiations, and diligence operations would be very burdensome.[225] Generally, exclusive patent licenses in lucrative fields create potential litigation, heightening the likelihood that the patent will be questioned in court by those whom the licensing scheme excludes from the field.[226]

However, inclusion in the market will be emphasized in MPEG LA's patent pool because it issues only non-exclusive licenses.[227] Because this license will contain the IPR needed for the CRISPR platform, downstream users will not have to worry about litigation on general CRISPR technology applications.[228] If Neuman is correct and current exclusive licensees "would permit" research uses "to be included in [the] pool license," the fear of downstream litigation will be non-existent for all research applications of the platform.[229] Thus, the downstream research and product development could increase as the pool's license opens "alternative paths for the development of new therapies, creating alternative product and royalty revenue streams, and reducing the potential for patent enforcement activity."[230]

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essentially prevented other laboratories across the country from practicing the diagnostic testing); *see also* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 583, 590–94 (2013) (holding that crucial discoveries of specific DNA locations enabling Myriad to develop medical tests that are useful for detecting whether the patient has an increased risk of cancer were not patentable); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 74–75 (2012) (noting how exclusive licensee sued licensor for patent infringement, while licensor claimed that the patents involved in the parties' licensing agreement were invalid). Such judicial activity can result in the "severe curtailment or all-out loss of patent rights" which can greatly impede the economy or innovation. E-mail from Kristin Neuman, *supra* note 15. The licensing balance struck by patent pools allows licensors and licensees to be in "concert with the market" and attain their financial and technological advancements without the need for judicial intervention. *Id.*; *see also* Horn, *supra* note 102.

[223] *See* discussion, *supra* Section II.E.

[224] KRISTIN NEUMAN, WHAT COULD A PATENT POOL DO FOR THE PROMISE OF CRISPR?, MPEG LA 9 (2017), http://www.keionline.org/sites/default/files/CRISPR_Neuman.pdf [perma.cc/X62E-QN33].

[225] *Id.* at 9.

[226] *See* E-mail from Kristin Neuman, *supra* note 15.

[227] *Id.*

[228] *See id.*; REFERENCE MODEL, *supra* note 91, at 2.

[229] *See* E-mail from Kristin Neuman, *supra* note 15.

[230] *Id.*; *see* REFERENCE MODEL, *supra* note 91, at 2–3.

2. A Patent Pool Could Alleviate Anticommons Concerns

A patent pool may resolve the fear that exclusive licensing would lead to the underutilization of the technology and the stifling of innovation and research.[231] While exclusive licenses have generally been utilized in biotech in the past, such a system is a deterrent in the CRISPR field because the technology constitutes such a fundamental platform that only a broad, non-exclusive licensing system could support the "vast potential" of industries, ranging from healthcare to agriculture.[232] In biotech, non-exclusive licensing schemes have been shown to enable numerous companies to enter the market, creating a "commercial ecosystem" that enhanced innovation and the economy.[233]

MPEG LA's non-exclusive patent pool could not only alleviate the Anticommons concerns, but may expand and accelerate the commercialization of CRISPR products and therapies.[234] Potentially, the market will be accelerated by the pool because the terms MPEG LA is purporting to use will result in the broad dissemination of the CRISPR platform.[235] According to statements by Horn and Neuman,[236] the license terms may be non-exclusive, cost-effective, transparent, nondiscriminatory, and include royalty-free research for universities.[237] Such terms could decrease the potential for downstream litigation, allowing more licensees to enter the market and, without the fear of litigation, the relevant market should become more stable.[238] This stability, coupled with easy and cost-effective packaging, would free up resources, allowing firms to focus on research, product

[231] *See* Horn, *supra* note 102, at 700 (noting that even before CRISPR related tech had been developed, the National Institutes of Health has recommended that patents on the research tools, especially those developed through federal funding, be licensed on a non-exclusive basis to allow the promotion of their "greatest utilization, commercialization and public availability."); E-mail from Kristin Neuman, *supra* note 15 (discussing how MPEG LA is attempting to license the CRISPR platform that has many broad applications).

[232] *See* E-mail from Kristin Neuman, *supra* note 15.

[233] Non-exclusive licensing schemes have been effective in the past, specifically, "[the] regime put in place by Stanford University for the Cohen-Boyer patents protecting the recombinant DNA technology platform set the stage for the rise of the modern biotechnology industry in America." *See* E-mail from Kristin Neuman, *supra* note 15.

The scheme generated more than $35 billion in sales and the creation of over 2400 new products. *Id.* It is important to note, however, that the Cohen-Boyer scheme was not a patent pool, rather a system designed around minimizing licensing fees and the use of non-exclusive licensing agreements. Clark et al., *supra* note 11, at 3.

[234] Horn, *supra* note 102.

[235] *See* E-mail from Kristin Neuman, *supra* note 15; NEUMAN, *supra* note 224, at 9.

[236] *See* E-mail from Kristin Neuman, *supra* note 15; Horn, *supra* note 102.

[237] Letter from Horn, *supra* note 102 (noting however that to make these lofty goals a reality, they must be able to pool all the essential patents).

[238] *See* E-mail from Kristin Neuman, *supra* note 15.

development, or product quality.[239] This patent pool scheme would allow companies to innovate more effectively, creating new products and techniques that would not have been discovered or produced under an exclusive licensing system.[240]

3. Incentives for Patentees to Join

A patent pool is the most practical option moving forward for a broad platform like CRISPR because of the licensing balance between future innovation and the financial return for IPR holders.[241] The pool's balance hinges on the financial return to patentees while providing cost-effectiveness and associability to potential licensees.[242]

To alleviate financial concerns held by patentees, MPEG LA will attempt to provide royalty rates higher than what a patent holder could make on their own.[243] As discussed above, MPEG LA believes the pool will create a more diverse market with *more* licensees.[244] More licensees would allow the pool to generate more royalties due to the larger number of participating licensees.[245] Accordingly, if the pool creates a large, steady stream of licensees, the royalties from the pool will be larger and more stable than what a licensor could achieve based on a single or small number of exclusive licensees.[246] Neuman suggests that there will be "a steady stream of predictable pool royalties from hundreds of licensees starting from day 1 of the pool's existence."[247]

CRISPR patentees seek to spread the CRISPR platform. Because the pool will include patents revolving around CRISPR's underlying platform,[248] patentees may join to create an industry platform that only utilizes their IPR. The CRISPR pool is not only being created to lower transaction costs (a happy side-effect), but also to create the widespread use of the CRISPR platform for innovation.[249]

As noted above, the majority of patentees in this sphere are research institutions.[250] These institutions may prefer a third-party agent such as MPEG LA to conduct licensing for ease of administration, as evidenced by the fact that some

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[239] *See id.* (noting that the stable market and reasonable terms created by the patent pool should make the entire licensing, research and development process faster); Horn, *supra* note 102.

[240] *See* E-mail from Kristin Neuman, *supra* note 15.

[241] *Id.*

[242] *See* Gilbert, *supra* note 13, at 26; Horn, *supra* note 102.

[243] Gilbert, *supra* note 13, at 26.

[244] *See* discussion, *supra* Section IV.A.2.

[245] *See* E-mail from Kristin Neuman, *supra* note 15.

[246] *See id.*; Gilbert, *supra* note 13, at 26–27.

[247] E-mail from Kristin Neuman, *supra* note 15.

[248] *See* REFERENCE MODEL, *supra* note 91, at 2–3.

[249] *See* Email from Kristin Neuman, *supra* note 15.

[250] *See* discussion *supra* Section II.C.1 noting how the major players in the CRISPR sphere include the research institutions of MIT, Harvard, and Berkeley to name a few.

patentees, including UC Berkeley and Broad, already created surrogate companies for this very purpose,[251] and Broad has already decided to join MPEG LA.[252] Because CRISPR is a foundational tool,[253] many patentees may join the pool to disseminate information for open science,[254] philanthropic reasons,[255] or to ease all parties' licensing costs.[256]

As shown by the drawn-out legal proceeding between Broad and UC Berkeley,[257] parties in the CRISPR sphere are willing to fight for their IPR in the open market (due to its potentially lucrative nature). Thus, patentees may join the pool based on the short-term goal of avoiding litigation.[258] Joining the pool would help avoid litigation because inclusion in the pool would likely result in grantback licenses.[259] Grantback licenses would give patentees access to the technology without having to conduct licensing negotiations or engage in litigation.

Regardless of the potential philanthropic interests at play, MPEG LA has repeatedly stated they will use "cost-effective" terms,[260] meaning the pool will not be licensed on a royalty-free basis. There may be some philanthropic goal for dissemination, due to CRISPR's potential medical benefits.[261] But, unlike the Golden Rice Pool and the SARS pool, the CRISPR pool is not being formed to solve a single specific need.[262]

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[251] *See* discussion *supra* Section II.E.1 noting how UC Berkeley and Broad already created surrogate companies to handle the licensing involved with their CRISPR patents.

[252] *See* Press Release, *supra* note 126.

[253] *See* Email from Kristin Neuman *supra* note 15; Doudna *supra* note 4 (discussing the possible uses of CRISPR technology).

[254] *See* Levy et al., *supra* note 53, at 81 (discussing how research firms may use patent pools as a way to advance science).

[255] *See* Mattioli, *supra* note 22, 145 (noting how philanthropic reasons can induce patentees to join a pool to provide medical technologies to developing nations).

[256] Mattioli & Merges, *supra* note 21, at 324 (showing how a pool could save hundreds of millions of dollars).

[257] *See* Regents, *supra* note 196.

[258] *See* Mattioli, *supra* note 22, at 120.

[259] *See* Mattioli & Merges, *supra* note 21, at 297 (discussing how grantback licenses and potential litigation are factors considered before joining a pool because it gives the patentee IPR they thought they already had or want).

[260] Horn, *supra* note 102; E-mail from Kristin Neuman, *supra* note 15.

[261] *See supra* note 4 for a discussion on the potential medical uses of CRISPR technology.

[262] *See supra* notes 69–71 and accompanying text (noting that the SARS pool was created in an attempt to get cheap vaccines to developing nations in order to quell a SARS outbreak and the Golden Rice pool was created to provide access to the patents needed to grow Golden Rice to prevent an eating deficiency causing blindness in children in developing nations); Email from Kristin Neuman, *supra* note 15 (noting that the CRISPR patent pool is designed around the foundational CRISPR platform which has countless applications, not a single specific need).

B. Why the Pool May Fail

While there may be potential benefits of a patent pool, there is no guarantee it will work. First, this pool's formation is different than past successful for-profit pools in biotech such as Librassay®. The CRISPR pool is not being formed around a technology whose sole purpose is diagnostics.[263] Unlike Librassay®, there is no "common goal" among market players,[264] nor is the pooled technology component-based.[265] The lack of component-based standardization could be a problem for the CRISPR pool because biotech does not have the same level of interoperability and compatibility of previous successful patent pools like MPEG-2.[266] There is no technological standard here, which Neuman states is "main challenge" for biotech pools because it makes determining essentiality difficult.[267]

Similarly, the CRISPR technology could pose problems determining essentiality and complementarity if the relevant patents define loose, upstream research. If the CRISPR pool does indeed fail to include all essential and complementary patents, then the CRISPR pool, like the SARS pool, would likely fail because it would not eliminate the current patent thicket.[268] Such a result would negate the basic concept of the pool, as parties would no longer have the convenience of one-stop-shopping.[269] However, the Reference Model is designed in an attempt to prevent such an outcome. The pool's inclusion—"intend[ing] to encompass the [CRISPR] system in its entirety as well as the [RNA elements]"—covers the underlying platform that must be utilized regardless of the application.[270]

Second, patentees may not be incentivized to join the pool. While large royalty returns will likely warrant pool inclusion, in practice such royalties will not be guaranteed. The CRISPR sphere, so far, has received little to no government pressure, and no incentive programs (unlike the NTD pool) have been put in place.

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[263] *See* Email from Kristin Neuman, *supra* note 15.

[264] *See* discussion, *supra* Section II.C.1 (discussing the many different applications that CRISPR related patents have been filed to cover).

[265] *See* Email from Kristin Neuman, *supra* note 15 (noting that the CRISPR patent pool is designed around the foundational CRISPR platform which has countless applications).

[266] Timo Minssen, Esther van Zimmeren & Jakob Wested, *Opportunities and Challenges for User-Generated Licensing Models in Gene-Editing*, BILL OF HEALTH (July 14, 2018), http://blog.petrieflom.law.harvard.edu/2018/07/14/could-user-generated-licensing-models-help-us-to-clear-a-path-through-the-crispr-patent-jungle/ [https://perma.cc/QG7Z-23J8]; *see supra* note 76 and accompanying text.

[267] Email from Kristen Neuman, *supra* note 15.

[268] *See* Levy et al., *supra* note 48, at 96 (noting how the SARS pool formation did not correctly determine the necessary essential and complementary patents, resulting in the continued existence of a patent thicket and the pool's failure).

[269] *See* Gilbert, *Collective Rights Organizations*, *supra* note 22, at 125–26 (describing how the single package of rights allows licensees to overcome patent licensing roadblocks, reduce transaction costs and promote information exchange).

[270] REFERENCE MODEL, *supra* note 91, at 4.

Similarly, there does not seem to be much philanthropic pressure. While a royalty-free patent pool in the CRISPR sphere would be advantageous for society, no one is expecting or calling for this result as the technology is too lucrative.

Third, the pool may fail for business and social reasons. The CRISPR pool has some stark similarities to IPXI, which failed, as explained above. Like IPXI, the CRISPR pool has received support from several significant players[271] but, just like IPXI, the CRISPR pool may not have the support of all the key players.[272] As of now, it is unclear whether UC Berkeley will join a joint licensing venture with the likes of the Broad Institute after the two entities' ongoing patent interference recently ended in favor of Broad.[273] Should UC Berkeley opt out of the pool, the packaged license may no longer allow for one-stop-shopping, and parties would still need to negotiate a license with Berkeley and others.[274] This could be devastating for the CRISPR pool's success because UC Berkeley is still considered to have key IPR, even after losing the interference with Broad.[275] Similarly, non-joining parties may own rights complementary to the CRISPR platform, which would result in the same need for multiple negotiations.[276] Similarly, CRISPR technology is only *relatively* new, but possibly not new enough for the purposes of a patent pool's success.[277] Many large corporations, firms, and institutions, like the WIFI sphere for IPXI,[278] have likely already had a few years to solidify relationships with patent holders for licensing purposes.[279] This reduces the need for a patent pool as licensees would already have the channels required to get the necessary licenses from the multiple patentees.[280]

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[271] *See* Broad Institute, *supra* note 126 (disclosing Broad's intention to join MPEG LA's pool).

[272] *See* Email from Neuman, *supra* note 15 (noting that most members or potential members of the pool are still confidential); Minssen et al., *supra* note 26 (claiming that UC Berkeley has currently not agreed to join the pool, and they must join for the pool to be a success).

[273] *See generally* Regents of Univ. of Cal. V. Broad Inst., Inc., 903 F.3d 1286, 1296–97 (upholding Broad's patent rights over Berkeley's).

[274] Minssen et al., *supra* note 26 (claiming that UC Berkeley, regardless of the recent interference determination, still has key patent rights that should be included in the pool).

[275] *Id.*

[276] *See* Shapiro, *supra* note 12, at 134–35 (noting IPR might be useless without complementary rights).

[277] *See* Egelie et al., *supra* note 1, at 1026 (stating that UC Berkeley and Doudna invented CRISPR technologies in June of 2012).

[278] *See* Contreras, *IPXI*, *supra* note 179, at 435.

[279] *See* Egelie et al., *supra* note 1, at 1026 (noting that CRISPR was invented in June of 2012); Contreras & Sherkow, C*RISPR*, *supra* note 130, at 698 (discussing the many licensing uses of Broad and the Berkeley Group since 2012).

[280] *See* Egelie et al., *supra* note 1, at 1026; Contreras & Sherkow, *CRISPR*, *supra* note 130, at 698.

Fourth, like IPXI, MPEG LA has the ability to enforce the pooled patents with the patentees.[281] The question is whether this ability will prevent licensees from continuing to use technology covered by the pool in a wait-and-see approach—in other words, whether potential licensees will just use the technology without a license because they believe litigation is not a likely result.[282] This wait-and-see approach, if similar to IPXI's situation, may allow potential licensees to use the technology without getting a license from the pool. Or, as mentioned above, if the patentees are unwilling to enforce the patents, MPEG LA may be unable to do so. This inability to enforce patents would not generate more licensees, as there would be no need to pay for a license. Similarly, there are still current exclusive licensees in the field who may consider the pool license an infringement.[283] Although Neuman stated that current licensees may be willing to allow the packaged license for certain fields of use (research),[284] that is not a guarantee. Should the current exclusive licensees have a problem, there may still be a threat of downstream litigation, disincentivizing firms from joining the pool.

Finally, and maybe most simply, MPEG LA may not get enough IPR holders to come to the table. Broad's decision to join was a major step forward, but recent information has cast doubt. Broad's decision to launch its own licensing venture with Millipore Sigma[285] raises questions. Even if Broad is still actively participating in MPEG LA's pool,[286] it is unlikely they would need to create the Millipore Sigma scheme if the MPEG LA pool was moving forward or close to going public. To be effective, the pool would require enough essential IPR holders to alleviate licensing burdens and costs.[287] Without enough essential IPR holders, the pool will likely be unable to establish the economic stability required to stay viable.

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[281] For a recent list of legal action taken by MPEG LA, see *Media*, MPEG LA, https://www.mpegla.com/media-legal-action/ [perma.cc/E34C-89KP] (last visited Sept. 11, 2019). For a specific example, see Ed Bott, *Google and MPEG LA Settle Long-running VP8/H.264 Patent Dispute*, ZDNET (Mar. 7, 2013), https://www.zdnet.com/article/google-and-mpeg-la-settle-long-running-vp8h-264-patent-dispute/ [https://perma.cc/M98V-A5VB] (noting that MPEG LA has the power to enforce the patents included in its pool).

[282] *See* Contreras, *IPXI*, *supra* note 179, at 433 (discussing how the threat of litigation is one reason why potential licensees decided not to purchase a license, deciding to use a wait and see approach instead).

[283] *See* Contreras & Sherkow, *CRISPR*, *supra* note 130, at 698 (discussing the many licensing uses of Broad and the Berkeley Group since 2012); Email from Kristin Neuman *supra* note 15 (discussing the potential for current licensees to allow research in their fields of use).

[284] Email from Kristin Neuman, *supra* note 15.

[285] Broad Communications, *supra* note 198.

[286] *See* E-mail from Lee McGuire, Chief Commc'n Officer, The Broad Inst., to Patrick Neville, Student at the S.J. Quinney College of Law (Sept. 6, 2019, 04:02 AM MST) (on file with author).

[287] *See* Gilbert, *Collective Rights Organizations*, *supra* note 22, at 125–26 (noting how it is the single package of rights that allows licensees to overcome patent licensing roadblocks, reduce transaction costs and promote information exchange).

V. CONCLUSION

In sum, MPEG LA's CRISPR patent pool is a promising approach to solving a complex licensing problem in a budding technological area. There are many factors that could lead to the pool's success if it can overcome the many hurdles with pooling patents in the biotech sphere. Should the pool be successful, it could enhance innovation and provide a lucrative research tool at an affordable price. A patent pool's ability to conserve transaction costs and increase innovation make it an appealing licensing scheme for a patent landscape such as CRISPR. However, the nature of the biotech industry, the whims of each essential patentee, and many social and business reasons could impede the pool's success. Regardless, the pool is an interesting approach to solving a complex licensing problem.