FINAL DRAFT

AVOIDING THE "ANTICOMMONS": A Mixed Liability and Property Rule Approach to Prevent Underuse of Patented Resources in R&D Involving Microbiological Materials

by Dana Beldiman[1]

ABSTRACT

As microbiological materials increasingly provide input into research and development of commercial applications, new IP issues are raised. One such issue is the risk of underuse of inventive resources due to high transaction costs. This risk is particularly strong when, physical biological materials serve as research input and commercialization is imminent. Transaction costs may be caused by dynamics such as patent thickets, obligations associated with the biological materials used as research input and the race among developers for technological exclusivity. If transaction costs are disproportionately high compared to the prospective gain, developers lack incentive to place products on the market.

This paper seeks to develop a conceptual model for mitigating underuse. It proposes a mixed property - liability rule among recipients of physical biological materials. Its specific mechanism is to use the Material Transfer Agreement (MTA) under which the physical materials are released, to require researchers to cross-license their inventions in exchange for release of the materials. This contractual re-allocation of initial entitlements would help eliminate patent thickets and would give all parties access to each others' technologies. The solution is developed in the narrow context of the H5N1 influenza virus. However, its general mechanism could apply to reduce transaction costs and improve chances of commercialization in any setting in which microbiological and plant materials are used for commercial purposes.

KEYWORDS: biotechnology, microorganisms, material transfer agreement, MTA, patents, patent thicket, anticommons, underuse, property rule, liability rule

INTRODUCTION

Advances in biotechnology, shipping and handling of microbiological materials are opening up a broad spectrum of commercial applications. With this, a new and complex IP landscape is emerging. This paper addresses the subset of those issues that deals with potential underuse of inventive resources as a result of transaction costs facing a product developer.

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Biotechnology patents are well-known for being fragmented and overlapping. Development of a product typically requires negotiation of freedom to operate with multiple owners. The resulting transaction costs may be disproportionately high compared to the expected gain and detract from the incentive to commercialize. Use of tangible biological materials adds a further layer of complexity, in that their owners may demand IP rights to derivative inventions. Finally, when research is close to commercialization means that competition among a small number of players will intensify and strategic behaviour can be expected. The combined effect of these conditions risk adversely impacting commercialization, and resulting in underuse of inventive resources. While scholarly literature has dealt with IP topics pertaining to upstream research involving microbiological materials, little attention has been paid to the downstream environment.

This paper proposes to examine the dynamics that lead to underuse and to develop a conceptual approach mitigating the risk of underuse.

Part I is concerned with potential underuse of inventive resources as a result of multiple distributed ownership of patents, where physical materials are used as research input. It starts out by reviewing existing theory on the dynamics that lead to underuse, including anticommons and patent thickets. Two scenarios are considered: first R&D which requires only intangible input, in the form of knowledge and second, R&D which additionally requires input of tangible biological materials, such as plant or microbial resources. A discussion of transaction costs arising in both scenarios concludes that use of tangible biological materials is likely to exacerbate the already existing tendency to underuse in biotechnology inventions.

Part II applies the concepts of dynamics of underuse developed in Part I, to an empirical framework. A suitable setting for examining these issues is provided by development of vaccines and diagnostics based on the H5N1 influenza virus. Under an international agreement, the virus is held by WHO affiliated centers and released to qualifying researchers for R&D purposes without restriction on appropriation of the inventions. The analysis reveals that the dynamics of the patent system in this setting give rise to transaction costs which in turn may reduce the number of players in the market to a single player, giving rise to a monopoly situation, or they may impede commercialization altogether.

Part III will discuss a possible theoretical basis for avoiding the risk of underuse of inventive resources described in Part II. Review of the Calabrese and Melamed and Coase theories on entitlements and transaction costs, indicates that underuse of inventive resources may result from high transaction costs, attributable to the suboptimal functioning of the patent system. As an alternative, to the property rule on which the patent system is based, use of a liability rule is explored. It is, however, found to provide insufficient incentive for investment, due to the fact that it offers no exclusivity. Instead, a mixed property-liability rule is proposed, under which recipients of virus samples would cross license to each other all inventions based on the virus. This cross licensing could take the more formal structure of a patent pool.

The approach proposed could be useful to tailor the structure of IP regimes whenever biological materials are used in R&D with a definite commercial endpoint.

I. UNDERUSE OF PATENTED RESOURCES IN KNOWLEDGE INPUT AND PHYSICAL INPUT RESEARCH

This part is concerned with potential underuse of inventive resources, as a result of multiple distributed ownership of patents. We will start out by reviewing existing theory relating to the dynamics that lead to underuse, including anticommons, patent thickets and hold-outs. Initially, the discussion will focus on R&D that requires intangible input, in the form of knowledge only, such as patented inventions. Next we will discuss how the need for input of tangible biological materials, such as plant or microbial resources, into the R&D process impacts these dynamics, with a view to determining the source of heightened transaction costs.

1. Underuse of patented inventions in R&D that requires intangible input

Patent law is intended to incentivize commercialization. Yet, under certain circumstances, it is not able to perform that task. Patented inventions may remain unused as a result. In that case we speak of underuse.

Underuse of inventive resources is to a large extent attributable to the nature of innovation in the particular field. Innovation in most areas of biology is both cumulative and complementary, in the sense that each invention builds on previous inventions, and that inventions contain elements derived from more than one source. Patents are therefore often issued for narrow, fragmented and overlapping, inventions.[2] Because technologies are complex, a single product is often based on multiple patents under divided ownership. To develop a drug, a developer must acquire rights to the different discrete technological components of the product it proposes to develop and place on the market, by negotiating licenses with each individual patent owner.[3]

If the perceived burden of negotiating these multiple licenses results in transaction costs disproportionate to the expected gain,[4] potential developers may be deterred from

[2] Innovation in many areas of biology is "cumulative, in the sense that each invention builds on previous inventions, and complementary, in the sense that each invention contains elements derived from more than one source. Keith Aoki, Free Seeds, Not Free Beer: Participatory Plant Breeding, OpenSource Seeds, and Acknowledging User Innovation in Agriculture, 77 Fordham Law Review 2275, 2297 (2009).

[3] See Dan L. Burk & Mark A. Lemley, Biotechnology's Uncertainty Principle, 54 Case W. Res. L. Rev. 691, 738 (2004).

[4] Garrett Hardin, The Tragedy of the Commons, 162 SCIENCE 1243 (Dec. 13, 1968); Rebecca Eisenberg, Noncompliance, Nonenforcement, Nonproblem? Rethinking the AntiCommons in Biomedical Research, 45 Houston Law Review 1959, 1060, note 62 (2008) (Eisenberg, Noncompliance); Transaction costs include all costs necessary to contractually facilitate innovation and commercialization. See notes 11-12 infra.

attempting to commercialize. They may elect not to enter negotiations at all, or alternatively, transactions may break down due to obstacles such as costs, uncertainty or holdouts by a single party. The resulting failure to commercialize constitutes an inefficient underuse in that the inventive effort is wasted and the invention is prevented from performing its useful social function.[5] Such underuse is attributed to the suboptimal functioning of the patent system in connection with conditions that prevail in the biotechnology field, and, most acutely, its subset involving gene sequences.[6]

Underuse occurs primarily in the form of two distinct patent-related dynamics, anticommons and patent thickets.

(a) Anticommons

Anticommons, a dynamic well documented in the literature,[7] are described as accumulations of "too many IP rights in "upstream" research results that could … restrict "downstream" research and product development by making it costly and burdensome to collect all the necessary licenses."[8] Negotiations to clear rights to all product components can be onerous.[9] Owners may block each other for strategic reasons.[10] Complex

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[5] See generally, Hardin, supra note 4; resources may be underutilized because of too many bottlenecks along the path towards commercialization. Keith Aoki, supra note 1, at 2297.

[6] This is particularly true in with respect to genetic patents. "Patentees have acquired thousands of patents on DNA sequences that cover specific genes of in some cases fragments of genes. Further biotechnology companies have patented probes, sequencing methods and other research tools. Any particular gene therapy requires the simultaneous use of many of these patents, leading to anticommons problems." Burk and Lemley, supra note 3, at 731.

[7] The terms was coined by Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 SCIENCE 698 (May 1, 1998)], available at http://www.justice.gov/atr/public/hearings/ip/222655.pdf. Also termed "tragedy of the anticommons, the concept is in contrast with the classic example of the "tragedy of the commons" which describes the wasteful overuse of economic resources in the absence of property rights. Hardin, supra note 3; "… an "anticommons" entails a situation in which a particular resource is underutilized because of too many bottlenecks where several permissions must be obtained due to overlapping property/ownership claims." Aoki, supra note 1, at 2297; Hillary Greene, Patent Pooling Behind the Veil of Uncertainty: Antitrust, Competition Policy, 90 Boston University Law Review 1397, note 18 (2010). www.healthcarepackaging.com/archives/2009/09/global_influenza_market_to_be.php.at note 18.

[8] See generally, Heller and Eisenberg, supra note 6; Eisenberg, Noncompliance, supra, note 4, at 1060. Parties wishing to commercialize must find their way through the "tangled, twisted mass of IPRs, which criss-cross the established walkways of commerce, rather, it requires numerous contracts with multiple, independent right holders." Robert Merges, Contracting into Liability Rules: Intellectual Property Rights and Collective Rights, 84 Calif. L. Rev 1293, 1296 (1996). The distinction upstream – downstream research is usually defined in terms of proximity to commercialization, whereby upstream is relatively far removed, while downstream refers to research tht is closely related to a specific end product. Downstream research necessarily utilizes upstream research. See Eisenberg, Noncompliance, supra note 4, at 1075.

[9] Anticommons primarily relate to the number of patent s required to assemble a product. Mark Lemley, Contracting Around Liability Rules note 27, February 2012, Stanford Law and

negotiations to secure requisite licenses are often necessary. Whether they succeed or not, transaction costs are involved,[11] in order to reach a contractual solution that facilitates innovation and commercialization.[12] Of primary relevance here are information and negotiation costs, that include identifying potential users of the invention, signaling the inventive capacity of the inventor, valuing the invention, pricing the invention; clearing rights to overlapping technologies, legal costs and opportunity costs; and obtaining financing. When transaction costs are high, they may prevent parties from reaching agreements. In that case the product is not commercialized and the inventive resources invested are wasted.[13]

Scholars have argued both in support and against[14] the existence of anticommons. Critics of the doctrine argue that the occurrence of anticommons has not actually been demonstrated,[15] and that they would rarely affect upstream use, where a substantial sharing ethos among researchers still is in effect.[16] Professor Eisenberg, one of the initial

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Economics Olin Working Paper No. 415, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1910284 (Lemley, Contracting).

[10] Rebecca Goulding, Emily Marden, Rachael Manion, Ed Levy, Alternative Intellectual Property for Genomics and the Activity of Technology Transfer Offices: Emerging Directions in Research, 16 B.U.J. Sci. & Tech. L. 194, 196 (2010).

[11] A party must "discover who it is that [it] wishes to deal with, to inform people that [it] wishes to deal and on what terms, to conduct negotiations leading up to a bargain, to draw up the contract, to undertake the inspection needed to make sure that the terms of the contract are being observed, and so on." Ronald Coase, The Problem of Social Cost, 3 J.L. & ECON. 1, 15 (1960). Transaction costs include 'Information costs (identifying potential users of the invention; signaling the inventive capacity of the inventor; and valuing the invention), Negotiation Costs (pricing the invention; legal costs and opportunity costs; and obtaining financing), and Enforcement Costs (monitoring the parties to the contract; and preventing intra-firm opportunism)." Paul Heald, Transaction costs and Patent Reform, 23 Santa Clara Computer & High Tech L.J. 448, 453 http://www.chtlj.org/sites/default/files/media/articles/v023/v023.i3.pdf

[12] Heald, supra note 11, at 453.

[13] Patent entitlements are often divided, resulting in the need for bargaining with multiple patent holders in order to assemble the technologies necessary for any given product. Burk and Lemley, supra note 3, at 732.

[14] See generally, Heller and Eisenberg, supra note 6; Michael Heller , THE GRIDLOCK ECONOMY, Basic Books (2008), at 3-5.

[15] Ted Buckley, The Myth of the Anticommons, May 31, 2007, http://test.bio.org/ip/domestic/TheMythoftheAnticommons.pdf; John P Walsh et al, Effects of Research Tool Patents and Licensing on Biomedical Innovation, in PATENTS IN THE KNOWLEDGE BASED ECONOMY 285, (Wesley M Cohen & Stephen A Merril, eds, 2003); John Walsh and W. M. Cohen, View from the Bench: Patents and Material Transfers." Science Vol 309, 23 September 2005; Ronald Bailey, The Tragedy of the Anticommons: Do Patents Actually Impede Innovation?, Reason, Oct. 2, 2007, http://reason.com/archives/2007/10/02/the-tragedy-of-the-anticommons; see also Burk and Lemley, supra note 3, at 729, 732.

[16] Nagaoka, "An Empirical Analysis of Patenting and Licensing Practice of Research Tools from Three Perspectives," presented in OECD Conference in Research Use of Patented Inventions, Madrid, 2006, finding that "patent thickets" rarely affect the research of academic scientists.

proponents of the anticommons theory, also points out that high transaction costs do not necessarily lead to inefficient underuse.[17]

Supporters, on the other hand, argue that increasingly many rights are required to assemble products. In biotechnology, particularly as it relates to DNA, patents are characterized by long and costly product development and the resulting patents are numerous and narrow. Products involve the simultaneous use of patents on genes, fragments of genes, sequencing methods and other research tools. This context is likely to run high anticommons risks.[18]

(b) Patent Thickets

A related dynamic, the patent thicket, is attributable to the overlap in scope of multiple patents (unlike anticommons which are attributed to the number of patents to be aggregated into a product).[19] Patent thickets occur when, as a result of cumulative and complementary innovation, patents that cover nominally different ideas overlap,[20] so that a downstream product developer must clear rights to multiple patents in order to gain freedom to operate.[21]

The subset of biotechnology that deals with DNA sequence patents is particularly prone to patent thickets. Patents are routinely being issued on DNA sequences that cover specific genes or fragments of genes, as well as on research tools.[22] Patentees are likely to seek broad patents in order to effectively exclude design-arounds based on possible

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[17] "Not every property right is like a padlock on a door that cannot be opened without first tracking down the owner and negotiating to use the key." Eisenberg, Noncompliance, supra note 4, at 1088.

[18] Burk and Lemley, supra note 3, at 731-732; Geertrui van Overwalle, Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes, in GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES, Geertrui Van Overwalle, ed., Cambridge University Press (2009), emphasizing the anticommons effects in gene patents.

[19] "While both "anticommons" and "patent thicket" are terms used to describe situations in which a party must license multiple patent rights, I have elsewhere disambiguated the two. An anticommons occurs when a downstream purchaser must obtain rights to many different discrete components. A patent thicket occurs when patents covering nominally different ideas overlap, so that even practicing one invention can require multiple licenses." Lemley, Contracting, supra note 9; see also Richard Gilbert, Ties that Bind: Policies to Promote (Good) Patent Pools, 77 Antitrust Journal 1, 2 (2010).

[20] Lemley, Contracting, supra note 9; Burk and Lemley, supra note 3, at 732.

[21] An anticommons occurs when a downstream purchaser must obtain rights to many different discrete components. A patent thicket occurs when patents covering nominally different ideas overlap, so that even practicing one invention can require multiple licenses." Lemley, Contracting, supra note 9, at note 27; Geertrui Van Overwalle, Individualism, Collectivism and Openness in Patent Law. Promoting Access through Exclusion, Tilburg Law School Legal Studies Research Paper Series, No 08/2011, http://ssrn.com/abstract=1718687 at 16, http://ssrn.com/abstract=1718687.

[22] Burk and Lemley, supra note 3, at 732.

functional equivalents to the invention.[23] The effect is that developers are therefore faced with hard-to-penetrate overlapping thickets of rights to be cleared.[24] The greater the number of patents required to assemble the product, the more daunting the hurdles.[25]

As a practical matter, both patent thickets and anticommons are associated with increased transaction costs resulting from the difficulty and expense of having to negotiate multiple deals. This difficulty is exacerbated by the fact that negotiation occurs in a general context of uncertainty as to whether a product can ultimately be developed. Uncertainty relates to aspects such as which technologies are necessary for development and commercialization of the product,[26] the ability to identify their owner and successfully negotiate numerous separate licensors,[27] the technological relationship among the patents involved,[28] the grant of the own patent applications and the applications for patents licensed in,[29] the scope of patents,[30] etc.

In large measure, the uncertainty is due to the fact that the necessary licenses must often be secured from competitors.[31] This may lead to strategic behaviour by complementary patent holders who seek to maximize their rents.[32] Such behaviour, referred to as holdout, arises when patent holders delay negotiation in an effort to become the last bidding seller,

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[23] See Burk and Lemley, supra note 3, at 730

[24] Burk and Lemley, supra note 3, at 732

[25] "The greater the number of essential licensors, the greater the total risk of bargaining breakdown." Eisenberg, Noncompliance, supra note 4, at 1073. See generally, Greene,supra note 7. Carl Shapiro, Navigating the Patent Thicket: Cross-Licenses, Patent Pools, and Standard Setting, in 1 Innovation Policy & the Economy 118, 120 (Adam B. Jaffe, Josh Lerner & Scott Stern, eds, 2001) http://faculty.haas.berkeley.edu/shapiro/thicket.pdf, expressing the concern that "stronger patent rights can have the perverse effect of stifling, not encouraging, innovation".

[26] Greene, supra note 7, at 1412.

[27] This situation "can raise prices and discourage innovation relative to a situation with fewer patents or with coordinated licensing of the overlapping patent rights." Gilbert, supra note 19, at 2.

[28] Greene, supra note 7, at 1412

[29] In reality the validity of a patent is only determined once an appellate level court has ruled on it.

[30] "[t]he actual scope of a patent right and even whether the right will withstand litigation at all are uncertain and contingent questions. Mark Lemley & Carl Shapiro, Frontiers of Intellectual Property: Patent Holdup and Royalty Stacking, 85 Tex L Rev 1991 (2007).

[31] Empirical evidence indicates that in the field of genetic inventions, commercialization of the final product is jeopardized when the more than 1- 3 licenses are necessary to develop the product. Eisenberg, Noncompliance, supra note 4, at 1064, note 27 (2008); "….the regulatory structure of the modern pharmaceutical industry makes getting a new invention to market far more expensive and uncertain than actually developing that invention." Mark Lemley, The Myth of the Sole Inventor, 110 Michigan Law Review 709, 744 (2012), http://www.michiganlawreview.org/assets/pdfs/110/5/Lemley.pdf.

[32] See Mark A. Lemley and Phil Weiser, Should Property or Liability Rules Govern Information?, 85 Texas L.Rev 783, 786 (2007),. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=977778

after large sums of money have already been invested.[33] Because each holder of a complementary patent seeks to license for a monopoly price, the combined product price will increase beyond what it would be in a competitive setting.[34]

In short, both patent thickets and anticommons tend to adversely affect commercialization of patented inventions, resulting in likely underuse of inventive resources.[35]

2. Risk of Underuse in R&D That Requires Input of Physical Materials

So far we have discussed R&D that requires input in the form of knowledge only, i.e. (patented) inventions. The following will focus on situations where, in addition to knowledge, the R&D process requires input of physical (tangible) biological materials as well.

Knowledge input can generally be replicated without incurring physical costs, and therefore, raises fewer access problems than tangible material.[36] Research that involves the need for physical inputs, on the other hand, is associated with certain practical necessities that add a component of "practical excludability."[37] Furthermore, legal regimes outside the patent system may impose further obligations. We will seek to evaluate the effect of these additional obligations in the context of the already existing risk of underuse.

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[33] "if a product must include components A and B and A and B are each covered by patents that grant different companies monopoly control over the components, each company will charge a monopoly price for its component," Merges, supra note 8 at 1298 n.9; Burk and Lemley, supra note 3, at 729, S Kumar and Arti Rai, Frontiers of IP: Synthetic Biology: the IP puzzle", 85 Text L Rev 1751, 1758 (2007).

[34] "[i]f society can remove form the market the valuation of each tract, decide the value collectively and impose it, then the holdout problem is gone." Guido Calabrese and A Douglas Melamed, Property Rules, Liability Rules and Inalienability, One View of the Cathedral, 85 Harvard Law Review 1089, 1107 (1972); A royalty burden would be imposed that is greater than if a single royalty were demanded of all patents essential to the production of a final product. Merges, supra note 8, at 1289 n 9; Gilbert, supra note 19, at 2; see also Geertrui Van Overwalle, Individualism, Collectivism and Openness in Patent Law. Promoting Access through Exclusion, Tilburg Law School Legal Studies Research Paper Series, No 08/2011, http://ssrn.com/abstract=1718687, p 16; see generally, Lemley and Shapiro, supra note 30.

[35] Ed Levy, Emily Marden, Ben Warren, David Hartell, and Isaac Filaté, Patent Pools and Genomics: Navigating a Course to Open Science?, 16 Boston University Journal of Science and Technology Law 75, 79 (2010). This situation "can raise prices and discourage innovation relative to a situation with fewer patents or with coordinated licensing of the overlapping patent rights". Shapiro, supra note 25, at 120; Gilbert, supra note 19, at 2.

[36] Eisenberg, Noncompliance, supra note 4, 1080-1086.

[37] Eisenberg, Noncompliance, supra note 4, at 1085-1086.

"Practical excludability" means that a researcher must incur transaction costs for obtaining the biological materials in advance of the research process.[38] Biological materials, such as plant or microbial cultures are generally obtained from culture collections maintained by third parties.[39] Collections regulate most aspects of the biological materials they maintain,[40] including the terms under which materials are released to researchers.[41] These terms are set forth in Material Transfer Agreements (MTAs) between the collection and the user/recipient. Of primary relevance here are IP related conditions, but MTAs may also include obligations imposed by legal regimes outside the patent system, in the form of costs, regulatory compliance, IP regimes, etc.[42] These obligations impose cost burdens on the user, over and above the costs inherent in the operation of the patent system.

Timing of the transaction costs also adds to the burden. A user of knowledge input only does not have to incur transaction costs prior to use. In other words, a user has the option of either negotiating permission to use a third party's invention or using it without permission. If use occurs without permission, transaction costs are postponed, and take the form of possibly having to defend an infringement action at a later date. This choice does not exist for the user of physical materials, as the cost of obtaining the material must in all cases be borne up front, prior to proceeding with the research.[43] In other words, when physical materials are required, the "burden of inertia" rests with the user.[44] Use will not occur unless the user meets transaction costs, whereas in the knowledge input

[38] "The result is …to aggregate the risk of an anticomons arising from a proliferation of resources that are characterized by practical excludability" Eisenberg, Noncompliance, supra note 4, at 1088.

[39] Collections contain genetic material deposits received from donors worldwide. There is push for harmonized models of distributing materials to the relevant community. Michael Halewood, Governing the management and use of pooled microbial genetic resources: Lessons from the global crop commons, International Journal of the Commons Vol 4, No 1, 404-436, 423, (2010). The collections' role is to maintain the materials and make them available to third parties for research or commercial purposes. Collections will undertake tasks such as validation of samples, characterization, implementing tracking mechanisms, etc.

[40] Collections have quasi-legislative powers over most aspects relating to the biological materials they maintain. See Aoki, supra note 1, at 2289.

[41] Recipients of ex situ genetic resources from collections are typically university laboratories, pharmaceutical companies or small R&D companies. Collections tend to leverage access to ex situ genetic resources for various operational or commercial purposes.

[42] Material Transfer Agreements are agreements in the nature of bailments, which govern the transfer of tangible property between parties. In addition to provisions relating the physical aspect of the property, the MTA may regulate its IP aspect as well, including rights to inventions derived from the bio-material. See Alan Bennett et al, Specific Issues with material Transfer Agreements, in INTELLECTUAL PORPEORTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATIONS: A HANDBOOK OF BEST PRACTICES 697, 689-99 (Anatole Krattiger, et al. eds 2007)

[43] Eisenberg sees "the burden of inertia may provide an adjustable mechanism for shifting the balance between ex ante incentives for innovation and downstream risks of an anticommons without changing the underlying property rights." berg, Non-compliance, supra note 3, at 1098.

[44] Eisenberg, Noncompliance, supra note 4, at 1085-1088.

only situation, use can occur regardless whether the user meets transaction costs. This creates an access problem for the user of physical materials. [45]

The fact that underuse is more likely when physical input is required, is also supported by empirical evidence. For instance, one study described by Professor Eisenberg shows that, within a two year period preceding the study, 19% of the requests for physical research materials were denied.[46] In 68% of the instances, projects were delayed by physical resources, leading in some instances to abandonment of the project.[47] The evidence also suggested that noncompliance with requests for research materials may be increasing.[48]

What added cost factors would a user of physical materials then face? Expanding on Eisenberg-Walsh, two categories of transaction costs become readily apparent. First, the *ex ante* transaction costs of procuring materials that impact access and second, a variety of post-acquisition obligations, such as IP related regimes, CBD obligations, etc., that must be factored into a cost-benefit analysis relating to commercialization. The first category, costs of procuring biological materials, includes identifying the location of the requisite materials and negotiating their release,[49] as a pre-condition to conducting research.[50] In an upstream environment,[51] commons-type initiatives and an academic sharing ethos frequently allow for materials to be obtained at no or low cost. Conversely, in a downstream environment, collections are more likely to charge for materials and services.[52] Users must also incur costs in order to qualify for handling of bio-materials under national health and safety provisions, such as lab equipment, personnel training, shipping of samples, etc.[53]

The second category - post-acquisition obligations - may impact ownership of inventions derived from the biological materials, and thereby the decision whether to invest in commercialization.[54] Individual collections' MTAs vary widely in their terms, ranging

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[45] Conversely, a user of knowledge input merely faces ex post burdens, in the form of defending potential infringement suits. The research process itself is not impacted by this burden. Rebecca S. Eisenberg, Patents and Data-Sharing in Public Science, 15 INDUS. & CORP. CHANGE 1013, 1019 (2006).

[46] Eisenberg, Noncompliance, supra note 4, at 1085-1086.

[47] Id.

[48] Id.

[49] Eisenberg, Noncompliance, supra note 4, at 1087.

[50] Walsh et al, supra note 15.

[51] See Eisenberg, Noncompliance, supra note 4, at 1075.

[52] Katherine J. Strandburg, Sharing Research Tools and Materials: Homo Scientificus and User Innovator Community Norms (May 23, 2008), at 42-45 (unpublished Manuscript) http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1136606), noting that the costs of sharing tangible materials make it more difficult to enforce a sharing norm for these resources." The American Type Culture Collection's (ATTC) is an example of a culture collection that operates primarily in a commercial setting. See also World Federation of Culture Collections (WFCC), www.wfcc.info

[53] Walsh et al, supra note 15.

[54] Some collections treat genetic resources as public goods. Tom Dedeurwaerdere, Global Microbial Commons: Institutional Challenges for the Global Exchange and Distribution of

from an open/non-proprietary approach to a fully proprietary approach that imposes restrictive conditions on recipients of the materials.[55] For instance, the owner of biological materials might condition release of the materials on the right to royalties from or access to the invention derived from the materials, by way of a reach through provision.[56] At the other extreme, a collection might prohibit appropriation of any invention derived from the materials, in the same way as an open source software license.[57] Institutional assent to the terms of material transfer agreements would probably be required in many instances.[58]

Separately, the materials themselves may be burdened with pre-existing obligations under international treaties. For instance, the Convention on Biological Diversity (CBD)[59] imposes benefit-sharing obligations in exchange for access to biological resources located on a country's territory.[60]

How do these additional transaction costs impact the likelihood of underuse of resources? As described earlier, knowledge-input only situations already display a propensity towards patent thickets in the biotech field, due to the existence of numerous, fragmented and overlapping patents. The additional requirements associated with use of biological materials can impose a burden that further reduces the chances of successful commercialization.[61] They can also diminish the number of players who place product on the market. Finally, proximity to the commercial endpoint increases the competitive environment, which in turn results in higher transaction costs.[62] Combined, these

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Microorganisms in the Life Sciences, 161 Research in Microbiology, 414-421 (2010). http://perso.uclouvain.be/tom.dedeurwaerdere/articles%20Tom/2011_res100048_LD050410_TD_accepted%20modif%20_is%20last%20version_.pdf.

[55] See e.g. the American Type Culture Collection's (ATTC) model MTA at http://www.lgcstandards-atcc.org/Portals/5/PDF/2012_MTA_with_Explanatory_Notes.pdf

[56] Reach-through license agreement (RTLA)– granting the owner of upstream entitlements, rights in subsequent downstream developments, including royalties, exclusive or non-exclusive licenses, etc. See Heller & Eisenberg, Can Patents Deter, supra note 6, at 699

[57] See Robin Feldman, The Open Source Biotechnology Movement: Is It Patent Misuse? 6 MINN. J.L. SCI. & TECH.117, 118 (2004).

[58] Eisenberg, Noncompliance, supra note 4, at 1061-62.

[59] UN Convention on Biological Diversity, www.cbd.org

[60] The UN Convention on Biological Diversity (CBD) provides that "Each Contracting Party shall take … measures, … with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources." Art. 15.

[61] Lisa Larrimore Ouelette, Access to Bio-Knowledge: From Gene Patents to Biomedical Materials, 2010 Stan. Tech. L. Rev. N 1, http://stlr.stanford.edu/pdf/ouellette-access-to-bio-knowledge.pdf (arguing that need for using bio-materials under MTA tends to create an access to materials problem through increased transaction costs that risk having an adverse impact on biomedical innovation).

[62] Each party seeks to obtain exclusivity over the technology in order to position itself most advantageously on the market. This results in refusals to deal, holdouts, etc. See also Eisenberg, Noncompliance, supra note 4, at 1062, 1074, suggesting that commercial users would be subject to more stringent conditions in their relations with owners of materials and tend to be more likely enforcement subjects by patent owners.

transactions operate like "tollbooths," borrowing the analogy from Professor Michael Heller to describe a succession of rights or entitlements which tax users to a point that commercialization becomes economically uninteresting.[63]

II. APPLICATION OF THEORETICAL CONCEPTS ON UNDERUSE TO DEVELOPMENT OF THE H5N1 INFLUENZA VIRUS

Part II will explore how these dynamics work in practice by applying the concepts relating to underuse developed above to an empirical framework.

1. The Empirical Framework

Selection of this particular empirical framework reflects the trend of increasing importance of microbiological materials.[64] While traditionally microbiological materials were primarily used in upstream research, advances in biotechnology, shipping and handling technologies of biological materials are opening up a broad spectrum of commercial applications.[65]

The framework involves research on the influenza virus. Its clear and imminent commercial endpoint is development of diagnostics and vaccines based on the H5N1 influenza virus. In the influenza field, R&D is often associated with pandemics. When a pandemic outbreak occurs, drug developers will seek to obtain samples of the virus strain as input for developing vaccines and diagnostics. Because pandemics know no borders, samples must be obtained from different countries, an endeavor, which, historically, has not always been easy.[66] In May 2011 the UN World Health Organization (WHO) reached

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[63] Heller, supra note 14, at 3-5. The analogy is to the numerous robber barons' castles along the Rhine, which in medieval Germany exacted toll from passing boatmen, to a point that the boatsmen stopped using that trade route.

[64] Microbial and plant resources form the basis of research in industries such as human health and pharmaceutics - approximately one half of the world's medicines are estimated to contain compounds of plant origin; agricultural productivity and food security adaptation to climate change and sustainable agriculture. Halewood, supra note 39, at 428. The understanding of possible uses of such resources is still evolving as only 1% of the world's microbial resources have been characterized. Jerome H. Reichman, A Compensatory Liability Regime to Promote the Exchange of Microbial Genetic Resources for Research and Benefit Sharing, in Proceedings of the Symposium on Designing the Microbial Research Commons (Paul F. Uhlir, ed., National Academies Press, Washington DC, 2012).

[65] Only about one percent of all microbes on the planet are known to science. New technologies are accelerating the pace of research of new commercial application. See DESIGNING THE MICROBIAL RESEARCH COMMONS: Proceedings of an International Workshop, National Academies Press, Washington DC, Paul Uhlir (ed) (2011). The collections' holdings are growing exponentially. Id at p. 27.

[66] In 2006, Indonesia one of the countries affected by the H5N1 virus, refused to release virus samples located on its territory to the international research community, citing rights to benefit-sharing under the UN Convention on Biological Diversity in support of its refusal. Reuters, Indonesia, Baxter sign pact on bird flu vaccine www.reuters.com/article/2007/02/07/idUSJAK76679._CH_.2400

a framework agreement,[67] under which affected countries will release virus samples to WHO affiliate centers (GISRS Centers).[68] The Centers in turn, release samples to qualifying research labs, governed by a Standard Material Transfer Agreement (SMTA) between the Centers and the recipients of virus samples.[69]

The WHO makes available virus samples to researchers in order to achieve a diverse market supply of vaccines and diagnostics, accessible to all income levels.[70] Overall welfare is, therefore, promoted by multiple players producing competitively priced products. A patent thicket and associated transaction costs would diminish the chances of successful commercialization.

The downstream environment, close to commercialization, is characterized by two main elements, which are absent in its upstream counterpart. First, an MTA is required for obtaining physical materials that may add to the user's existing obligations, and second, negotiations for securing freedom to operate take place among competitors. Given this context, what are the dynamics that give rise to transaction costs in the course of developing drugs based on the H5N1 virus?

2. Transaction Costs Relating to Dynamics of Patenting and Competing for the Market

All recipients of H5N1 virus samples seek to develop and commercialize vaccines and diagnostics from the samples received. Players will tend to compete, rather than share resources, as is customary in upstream research. This competitive setting generates a race which has two primary focus points: first, filing of patent applications and second, assembly of the necessary technologies to place product on the market.[71]

This first race is part of the regular operation of the patent system. It is designed to reward the winner of the race, and to eliminate identical or virtually identical inventions filed at a later time.[72] The first race may also impact transaction costs downstream. Most applicants tend to file patents broadly, in order to cover as many functional equivalents as

[67] Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits ("PIP Framework")
http://www.who.int/csr/disease/influenza/pip_framework_16_april_2011.pdf
[68] WHO Global Influenza Surveillance and Response System (GISRS) PIP Framework, supra Art 78, Art. 6.14.
[69] The PIP Framework operates with two Standard Materials Transfer Agreements (SMTA), under which materials may be distributed to recipients "outside the WHO GISRS", under SMTA1 governs, or "within the WHO GISRS", under SMTA2.
[70] The PIP Framework's objectives include access to and distribution of affordable diagnostics and treatments, including vaccines to those in need, especially in developing countries in a timely manner, as well as expanding the global capacity to produce influenza vaccines, including in developing countries (PIP Framework, supra note 67, Principles PP17; Objective 2.1.)
[71] Dana Beldiman, Patent Chokepoints in the Influenza-Related Medicines Industry: Can Patent Pools Provide Balanced Access?, 15Tulane Journal of Intellectual Property and Technology (forthcoming 2012).
[72] Beldiman, supra note 71.

possible and to exclude potential competitors. This strategy enhances the likelihood of a patent thicket because it increases the potential overlap between patents and causes uncertainty, as patents become more vulnerable to rejection and invalidation.

The second race, for assembly of the necessary technologies, occurs at a time when the technological relation among the patent applications becomes known.[73] Its goal is to identify complementary technologies that are necessary to assemble a product[74] and to secure rights to them. Because patents are broadly claimed, many are likely to overlap. Freedom to operate must be obtained from other patent owners. The difficulty is that most other patent owners are working on functionally equivalent products and plan to compete for the same market. Transactions whose costs are already high due to the need to negotiate with multiple players, become more costly or even impossible, as a result of strategic behaviour among competitors.

Two simple scenarios point to how underuse might occur: A, B and C are recipients of H5N1 virus samples and have each filed several patent applications. The technological relation is that patent owners A and C both need B's patent in order to assemble a product. Because B is in a hold-out position, it can charge monopoly royalties. Either A or C will likely win the negotiation with B, assemble a product and preclude the other from commercializing. The result is a single producer on the market, offering product at prices which are inefficiently high.

Alternatively, A wins the license negotiation with B and enters an exclusive license. Subsequently A's patent is rejected. C's patent issues, but B has now licensed to A. A is unwilling to release the technologies in order to prevent C from assembling a product.[75] In this case none of the parties is able to commercialize; the inventive activity of all players is wasted and the market is deprived of a necessary pharmaceutical.

Numerous considerably more complex permutations of these scenarios are imaginable, but no matter how complex the scenario, the risks remain the same: players may exit the race due to the prospect that transaction costs will become disproportionately high compared to the expected gain. Alternatively a single party may gain exclusive rights over the technology and emerge in a monopoly position. The combined result is a market with either a single producer or no producer. Neither scenario meets the welfare goals sought in distributing the virus samples.[76] This outcome is obtained as a result of the suboptimal functioning of the patent system in the particular setting described.

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[73] Usually about eighteen months after the filing of the applications, a time at which most patent offices, in the normal course of business, will disclose the content of the applications.

[74] I.e. to determine the technological relationship among patents

[75] See Mark Lemley, The Myth of the Sole Inventor, 110 Michigan Law Review 709, 759 (2012) http://www.michiganlawreview.org/assets/pdfs/110/5/Lemley.pdf , questioning the conventionally accepted motivations for entering patent races.

[76] Somewhat comparable is the case of Medimmune's reverse genetics technology for rapid development of vaccines. Several patents had been issued on this technology and commentators viewed this as a "classical case of patent thicket with fragmented IP rights and uncertainty about technology ownership. The thicket was ultimately resolved by Medimmune acquiring exclusive

In the analysis so far, "practical excludability" resulting from use of physical biological materials has not played a role. The next section will examine its impact on transaction costs.

3. Transaction Costs Relating to Procuring Biological Materials

(a) *Ex ante* obligations

Clearly, the initial effect of *ex ante* transaction costs is to limit the number of players, because prospective recipients must qualify for handling biological materials[77] and successfully negotiate the SMTA.[78] It is, however, unclear how this limitation impacts a possible patent thicket. On the one hand, a larger number of players would involve a greater number of variables with uncertain outcomes that could "grow" into a truly impenetrable thicket. A smaller number of players would present a more manageable situation, and perhaps allow some parties to assemble products, because fewer negotiations are required. On the other hand, a larger number of players might offer additional technological alternatives. On the assumption that the number of technological permutations is not infinite, in a larger pool of players the chances that more than one player would develop the same technology are greater. For instance, if, in the example above, B's technology were available from D or E as well, multiple opportunities for accessing the respective technology would prevent B from charging a monopoly price. More players might successfully place product on the market. If this conclusion is accurate, then the narrowing of the number of players by *ex ante* obligations resulting from use of physical materials would appear to enhance the likelihood of a patent thicket.

(b) *Ex post* obligations

The most significant *ex post* obligations imposed by MTAs relate to the IP regime and to obligations under the CDB.[79] Relevant for present purposes is the IP regime and its impact on transaction costs.

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licenses to the remaining three technologies and emerging as the sole owner of patents in the field of reverse genetics. Patrick Gaule, Towards Patent Pools in Biotechnology? at 129 (2006). http://cemi.epfl.ch/webdav/site/cemi/shared/misc_files/IST-vol-2-No-2-2006-Patrick-Gaule.pdf

[77] Under the PIP Framework, any manufacturer or laboratory that is qualified, i.e. which meets appropriate biosafety guidelines and best practices is entitled to receive virus samples. PIP Framework, supra note 67, Art, 6.3 bis.

[78] See supra note 69.

[79] These requirements would, in theory, allow a source country to exact compensation from the developer of bio-resources originating from its territory.[79] The legality of such claims is as yet unclear. However, as biological resources increasingly serve as bases for commercially successful products, such claims may arise. In theory national governments are not precluded from claiming that benefit sharing obligations under the CBD "run" with the materials to the party that ultimately commercializes the derivatives. Frederick Abbott, Unweaving our Tangled Patent Web: Negotiating a Framework for the Sharing of Influenza Viruses with Human Pandemic Potential, Presentation at Swiss Federal Institute of Intellectual Property, March 26, 2009, http://ebookbrowse.com/abbott-untangling-web-pdf-d72377873; see also Dana Beldiman,

As mentioned earlier, an MTA's IP regime can vary widely, from highly restrictive prohibitions on appropriation of derivatives and RTLA's, to open access regimes. The PIP SMTA merely prohibits patenting of the materials as received,[80] but does not restrict the recipients' freedom otherwise. Recipients are, therefore, free to appropriate any virus sample-based inventions under prevailing patent laws. At first sight, this unrestricted regime would seem to be optimal for achieving broad commercialization. Yet as the preceding discussion shows, the internal functioning of the patent system does not support this outcome, at least not in the context of biotechnology close to commercialization. Instead, this regime adversely affects the ability to commercialize[81] because fragmented and overlapping patents give rise to patent thickets and because close to commercialization recipients engage in a competitive race.[82] A SMTA provision that allows unrestricted patenting merely encourages this dynamic.

From a normative perspective, this outcome could be changed by altering the IP regime imposed by the SMTA. The following section will discuss the theoretical underpinnings of such a possible different regime.

PART III

III. THEORETICAL MODEL FOR A SOLUTION

1. Entitlements and transaction costs

To this end we will review the essence of the seminal theories of Calabrese and Melamed and Ronald Coase regarding legal entitlements and transaction costs.[83] Legal entitlements can be enforced primarily in two ways: by way of property rules – under which an entitlement cannot be alienated without the owner's agreement at a prices the owner subjectively sets, or by way of liability rules, where property can be transferred on a non-consensual basis, giving the owner a right to compensation.[84] Parties will generally attempt to reach the most efficient allocation of entitlements through bargaining, so that the party best suited to exploit the resources will end up owning it.[85] Whether this effort

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Commercialization of Genetic Resources: Leveraging *ex situ* Genetic Resources to Shape Downstream IP Protection, in INTELLECTUAL PROPERTY AT THE CROSSROAD OF TRADE, Jan Rosen ed., forthcoming Edward Elgar, (2012).

[80] "[neither] the Provider nor the Recipient should seek to obtain any intellectual property rights on the Materials" PIP Framework, supra note 67, Art. 78.

[81] See text accompanying notes 72-76 supra.

[82] See text accompanying notes 72-76 supra.

[83] Guido Calabrese and Douglas Melamed, Property Rules, Liability Rules and Inalienability, One View of the Cathedral, 85 Harvard Law Review 1089, 1106 (1972); Ronald Coase, The Problem of Social Cost, 3 J.L. & ECON. 1, 15 (1960); see also Robert P. Merges, Of Property Rules, Coase, and Intellectual Property, 94 Columbia L. REV. 2655, 2667 (1994).

[84] Calabrese and Melamed, supra note 34, at 1106, Coase, supra note 11; see also Lemley and Weiser, supra note 32.

[85] See Coase, supra note 11, at 15.

will be successful depends on transaction costs.[86] Transaction costs are all the costs involved in using a contractual solution to facilitate creation.[87] When transaction costs are low, bargaining to reallocate entitlements will successfully take place; conversely, when they are high, no bargaining will take place, resulting in an economically inefficient outcome.[88] Consequently, allocations of initial entitlements should be such as to minimize transactions costs, in order to prevent them from jeopardizing consensual arrangements among the parties for access to resources.[89]

From a normative standpoint, the conventional approach to the Calabrese and Melamed and Coase theories is that where transaction costs are high, choice of a property rule is not optimal, as it can result in misallocations, [90] which in turn, may impose welfare costs, such as discouraging innovation and commercialization.[91] Where transaction costs are high, a liability rule is thus better suited to facilitate bargaining among the parties.[92]

2. Alternative approaches

The earlier discussion shows that the H5N1 influenza virus scenario presents a high risk of underuse of inventive resources,[93] attributable to the fact that multiple overlapping patents, compounded by uncertainty, give rise to patent thickets. Consequently, transaction costs are likely disproportionate to the parties' expected economic gain. Reallocation of the entitlements through bargaining will, therefore, not be successful. The social cost of this misallocation of resources is reflected in the difficulties encountered when seeking to assemble and commercialize a product.

(a) A liability rule

[86] "Ever since Calabrese and Melamed, transaction costs have dominated the choice of the proper entitlement rule, with a liability rule being the entitlement of choice when transaction costs are high." Merges, supra note 83, at 2655.

[87] Transaction costs are required to "discover who it is that [it] wishes to deal with, to inform people that [it] wishes to deal and on what terms, to conduct negotiations leading up to a bargain, to draw up the contract, to undertake the inspection needed to make sure that the terms of the contract are being observed, and so on." Heald supra note 11, at 453.

[88] As summarized by Lemley and Weiser "the essential insight of the Coase Theorem [is]—that transaction costs often dictate whether parties will reach an efficient outcome through bargaining over property rights. As Coase explained, if transaction costs are low, the parties themselves will reach an efficient outcome through bargaining over the property right in question. By contrast, where such bargaining is unlikely to take place, a liability rule can ensure that the law reaches an efficient outcome even in the absence of bargaining." Lemley and Weiser, supra note 32, at 788.

[89] See Lemley and Weiser mention that there are" important cases in IP law that demonstrate the merits of liability rule and the pitfalls of a property rule." Lemley and Weiser, supra note 32, at 788.

[90] Lemley and Weiser, supra note 32, at 786.

[91] The notion that emerged from Calabresi and Melamed's classic article is that courts should rely on liability rules when transaction costs are high. Lemley and Weiser, supra note 32, at 786.

[92] See generally Lemley and Weiser, supra note 32, Merges, supra note 8.

[93] See text accompanying notes 82 supra.

If the outcome described above is attributable to the functioning of the patent system, then a remedy should be sought in relation to the patent system. Patents operate under a property rule: a patent is protected by a right to exclude and enjoin a third party's use of the invention. Conversely, a liability rule gives a party the right to collect compensation as a result of a transaction, but not to exclude.[94] In addition to protecting the entitlement itself, a liability rule involves an additional stage of regulatory intervention, by determining the value of the property objectively, instead of allowing a subjective determination by the owner of the resource.[95] Liability rules can facilitate bargaining and are therefore better suited to achieve significant welfare effects[96] in situations in which bargaining is very costly.[97]

The operation of a liability rule in the present factual scenario could take the following form. Owners of patented inventions would not be allowed to deny use of their inventions to third parties. Instead, they would be entitled to payment. Parties who make (commercial) use of the invention are required to pay its owner a certain percentage (or other pre-established royalty of their sales). The advantage of this scenario is that the subjective valuation of the invention is replaced by one that is pre-set. Uncertainty would therefore be avoided. Overlapping patent rights could be easily re-allocated. Multiple firms would place products on the market. Finally, the competition among players would take place in the marketplace, and not as under the property rule analyzed above, prior to commercialization.[98]

Solutions of this type have been advocated for upstream use in research.[99] Whether they would also work in commercial settings is questionable. In investment-intensive

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[94] Unlike a property rule which grants an entitlement to the effect "that someone who wishes to remove the entitlement from its holder must buy it from him in a voluntary transaction in which the value of the entitlement is agreed upon by the seller." Calabrese and Melamed, supra note 34, at 1092.

[95] "Obviously, liability rules involve an additional stage of state intervention: not only are entitlements protected, but their transfer or destruction is allowed on the basis of a value determined by some organ of the state rather than by the parties themselves." Calabrese and Melamed, supra note 34, at 1092.

[96] Heald, supra note 11, at 448.

[97] Calabrese and Melamed, supra note 34, at 1106 et seq.

[98] Under a property rule, the decision of which product reaches the market is made based on a pre-market race, based on the parties' ability to position themselves vis-à-vis each other in the competition for cross-licensing technologies necessary for FTO. Yet this race should occur in the marketplace, in order to give each player a chance to market the product, and not before the products reach the marketplace. The market benefits from a diversity of products, and filters out non-deserving products. In the contrary situation, one of more inventions will not be placed on the market, irrespective of their merit and the inventive activity that went into development of these technologies is not used.

[99] As a result, liability rules are becoming increasingly popular. In situations involving microbial samples, Professor Reichman proposes implementation of a compensatory liability model[99] that "provides an intermediate zone, where Creative Commons licenses are insufficient, but exclusive rights and concomitant restrictions on research would impose unnecessary overkill in relation to the still uncertain value of the upstream inputs." Reichman, supra note 64.

industries, such as the pharmaceutical industry, pharmaceutical product developers typically invest in anticipation of the appropriability offered by the patent system, as revenue from sales must cover future research and the cost of obtaining regulatory approvals, clinical trials, manufacturing, etc. In the liability rule scenario above, the absence of exclusive rights might prove troublesome to a pharmaceutical manufacturer because it could threaten the product's competitive position in the market. Similarly, a pre-established royalty rate might not be acceptable, as it would detract from upside profit potential. As a result, absent the incentive of patent exclusivity, investments might not occur.[100]

Consequently, a liability rule would probably not provide a suitable solution to the commercialization problem, because it would not attract investment into R&D.

(a) A mixed property and liability rule

Since neither a pure liability rule nor a pure property rule ultimately supports the most efficient use of resources, we return to Calabrese and Melamed, who helpfully remind that "most entitlements to most goods are mixed."[101]

A mixed entitlement would combine characteristics of both property and liability rules. As will be explained in detail below, the proposed solution would consist of a liability rule among the recipients of biological material, whereby the patent owner retains the right to be compensated for use of the invention, but not to exclude. Use of the liability rule is also intended to stimulate bargaining among the players. A property rule would apply to the remaining entitlement whereby the patent owner has exclusivity vis-à-vis the rest of the world.

Based on the insights from the discussion in Part II, a solution would have to achieve the following objectives: preserve the exclusionary effect of a patent, stimulate bargaining in order to break the logjam created by the patent thicket, allow parties to freely negotiate royalty rates and finally, be sufficiently attractive to prompt parties to invest into R&D. Two main conceptual premises underlie this solution: first, that "freedom to operate"

For instance, in the field of plant resources a form of liability rule has been adopted by the International Treaty for Plant and Genetic Resources in Food and Agriculture (ITPGRFA) www.planttreaty.org. "In exchange for access to this communal seed treasury held in governmental and international seed banks, private parties that incorporate materials from the multilateral system into commercial products must pay a percentage of their profits into a trust account... to promote benefit-sharing and conservation of genetic resources, particularly with regard to farmers in developing countries." Laurence R. Helfer, Using Intellectual Property Rights to Preserve the Global Genetic Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 217, 219-220 (Keith E. Maskus & Jerome H. Reichman eds., 2005

[100] "[T]he ability to threaten a firm with an injunction stems not only from the recognition of a legal entitlement, but also from the choice of a property rule to enforce that right." Lemley and Weiser, supra note 32, at 786

[101] Calabrese and Melamed, supra note 34, at 1093.

(FTO)[102] from a patent perspective generally suffices for a player to place product on the market, and second, that developers of drugs are willing to relinquish exclusivity in exchange for being free of the risk of a patent thicket.

From a practical standpoint, the MTA would serve as a contractual vehicle for varying the existing rules for protecting entitlements.[103] Because all recipients of physical materials are parties to the MTA, they would be bound its provisions. The MTA would simply require all recipients of virus samples to agree *ex ante* to license to each other all patents derived from the virus sample.[104] Otherwise, the patent right would remain intact. Royalties would be negotiated freely among the players.

Returning to the two scenarios examined in Part II and evaluate how they play out under this proposed solution.[105] In the first scenario, B, a recipient of biological materials would be required by the MTA to license its patent to both A and C. No hold-out position would arise. Furthermore, both A and C would be able to assemble a product and place it on the market. Otherwise stated, the competition between A and C would occur on the market and not prior to commercialization. In the second scenario the outcome is comparable. Because B cannot, under the MTA, enter an exclusive license with A, once A's patent does not issue, B is free to license to C, who can assemble a product and place it on the market. In both scenarios the impact of multiple overlapping patents and of the race for technological exclusivity are neutralized. Both scenarios display higher chances of commercialization. Certainly, from an overall welfare perspective, this outcome presents considerable benefits.

Importantly however, one must ask whether from the players' perspective, adoption of a partial liability rule would be sufficiently beneficial to keep them in the game. Relinquishing exclusivity, even in part, might initially seem to be a dealbreaker.[106] The question is whether the developers receive sufficient countervailing benefits. The benefits from agreeing to the MTA are access to the biological materials and a smooth path towards commercialization. As for the first benefit, access to the materials is a condition *sine qua non* for participating in the race. At least as far as the H5N1 virus is concerned, GISRS Centers are the only source of authenticated and validated virus samples. Access

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[102] Broadly defined, freedom to operate (FTO) means the ability to proceed with the research, development and/or commercial production, marketing or use of a new product or process with a minimal risk of infringing the unlicensed IP rights or TP rights of third parties. Stanley Kowalski, in Anatole Krattiger, et al, IP Handbook, Chapter 14.2, Freedom to Operate: The Preparations. http://www.iphandbook.org/handbook/ch14/p02/

[103] While this mechanism sounds simple, it raises a host of broader policy issues relating to this aspect should be regulated in order to avoid a patchwork of terms and conditions imposed by individual collections. See Beldiman, supra note 78. In depth discussion of this topic is beyond the scope of the present paper.

[104] A cross license could take the form of an ex ante patent pool in which participants commit ex ante to contribute patents to the pool, Gaule, supra note 76. On cross licenses see van Overwalle, supra note 21.

[105] See text accompanying notes 74-76 supra.

[106] The fact that exclusivity is retained vis-à-vis non-recipients of materials is illusory, since the other recipients are the competitors.

to the materials can therefore weigh heavily in favor of agreeing to the MTA. Second, developers would gain rights to use the other players' technologies. That means that the patent thicket would be dissolved and transaction costs would decrease considerably, because negotiations would not take place in competitive "winner takes all" environment. It is true, that in terms of potential gain, each individual player's profit potential would be reduced, but so would the risk of not being able to commercialize at all. In effect, the patentee/developer would swap the chance of gaining a large market share, associated with the risk of gaining none, against the strong probability of gaining a smaller market share.[107] Whether these benefits will outweigh the loss of exclusivity is the developer's individual decision on a case by case basis. Further research that might lend insight into the economics of this decision would be beneficial.

Another way of looking at this, is to view the patentee's right as too capacious a right.[108] To place product in the market, a player merely needs FTO, rather than exclusive rights to (multiple) patents, i.e. a smaller quantum of rights than the player would have under full patent right. If a certain quantum of all players' rights were removed by eliminating exclusivity among sample recipients, the competitive tension due to the IP right's overcapaciousness would be defused. Of course, this solution would have to be carefully calibrated, to avoid an excessive reduction of the profit potential, as players might drop out or refrain from participating in the first place. However, if applied carefully the solution has the potential of keeping multiple players in the game and would likely avoid a no player/single player scenario."[109]

In summary, because neither a pure property nor a pure liability rule alone were able to ensure a satisfactory outcome in the influenza virus scenario, a mixed liability/property rule was proposed. Recipients of biological material would be required by the MTA to cross-license their inventions to all other recipients. All technologies would thus be accessible to all players, potential patent thickets would be dissolved. The further effect would be to diffuse the competitive tension at eh level of the second race, the race for technological exclusivity. On the assumption that these benefits constitute a sufficient quid pro quo in exchange for relinquishing exclusivity, this solution promotes overall welfare.

Some remaining questions

While from a broad perspective the proposed solution appears to solve the underuse problem in the influenza virus case, several details remain to be addressed. An in-depth discussion is beyond the scope of this paper,[110] however, some of the main remaining issues should be mentioned here.

[107] See generally, Beldiman, supra note 71.
[108] Such conduct risks crossing the line into anti-competitiveness when competing players engage in refusal to license.
[109] Beldiman, supra note 71.
[110] Certain aspects have been addressed in Beldiman, supra note 71.

The first issue relates to the parties' freedom to negotiate license fees under the solution proposed above.[111] This freedom comes at a price: the possibility that parties for various strategic reasons seek to prevent transactions by e.g. demanding unreasonably high royalties. However, if recognized and addressed by the MTA, this risk can probably be neutralized.

Second, the cross licensing arrangement could take the concrete form of a patent pool.[112] Pooling presents many benefits: it is effective in reducing transaction costs, and inefficiencies resulting from patent thickets and anticommons[113] and can help players assemble the necessary technologies.[114] A patent pool is also likely to enjoy broad acceptance because it seeks to reconcile the interests of all stakeholders.[115] On the other hand, formation of a patent pool may be a complicated and long-drawn process.[116] Its structure must be in compliance with antitrust laws.[117] In certain cases transaction costs may arise, which rival the ones resulting from the patent thicket.

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[111] As mentioned earlier, under a pure liability rule a pre-set royalty rate would be, but that would risk deterring investment because it would be perceived as limiting investment.

[112] One precedent of a commercially oriented pool exists. Following the SARS (severe acute respiratory syndrome "coronavirus") outbreak in 2003, a number of institutions, including major research centers such as Berhardt Nocht Institute, British Columbia Cancer Agency (BCCA), the US Center for Disease Control (CDC), and the Hong Kong University began simultaneously to sequence the SARS virus. Each of these institutions had filed patent applications with the USPTO on the coronavirus' genomic sequence, along with a general description of how the knowledge contained therein would be converted into diagnostics and treatments. The number of prospective patent holders gave rise to the concern that patent rights to the SARS genomic sequence would be excessively fragmented. As a result of the quasi-simultaneous filing by multiple entities, interference proceedings were anticipated and the uncertainty over patent rights was feared to cause manufacturers to delay investment decisions. To overcome these concerns, all patent holders agreed to a "cooperative pooling," combining their technologies by licensing them to a separate entity that would make them available to licensors and third parties by way of non-exclusive licenses. James H.M. Simon, Eric Claassen, Carmen E. Correa, & Albert D.M.E. Osterhaus, Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling, Bulletin of the World Health Organization, vol.83 no.9 Sept. 2005, www.scielosp.org/scielo.php?pid=S0042-96862005000900017&script=sci_arttext&tlng=e; Communicable Disease, Surveillance and Response, WHO, Summary of Probable SARS Cases with Onset of Illness from 1 November 2002 to 31 July 2003 (2003) www.who.int/csr/sars/contry/table2003_09_23/en, at 1 October 2004; see also Matthew Rimmer, The TRIPS Agreement and Access to Essential Medicines [2004] Melbourne Journal of International Law, 335, 336.

[113] Levy, supra note 35, at 78.

[114] See Geertrui van Overwalle, Designing Models to Clear Patent Thickets in Genetics, in WORKING WITHIN THE BOUNDARIES OF INTELLECTUAL PROPERTY, pp. 305-324, R. Dreyfuss, H. First, D. Zimmerman, eds., Oxford University Press (2010), suggesting that patent pools and clearing houses might help resolve the patent thicket issues.

[115] See generally, Beldiman, supra note 71.

[116] Id.

[117] See e.g. U.S. Department of Justice Guidelines for the Licensing of Intellectual Property (1995) www.usdoj.gov/atr/public/guidelines/ipguide.htm; Josh Lerner and Jean Tirole, *Public Policy toward Patent Pools*, in INNOVATION POLICY AND THE ECONOMY, Volume 8,

Finally, formation of a pool may be thwarted by unwilling participants.

Other obstacles to smooth commercialization of influenza virus based products can easily be imagined. However, because the solution is contractually based, if anticipated these obstacles can likely be neutralized by proper planning and do not have to be fatal to the proposed solution.

CONCLUSION

As microbiological materials increasingly provide input into research and development of commercial applications, a multitude of new IP issues are raised. This paper addresses the subset of those issues that deals with potential underuse of inventive resources as a result of transaction costs facing a product developer

Because biotechnology patents are well-known to be fragmented and overlapping. Developers must negotiate with multiple owners to obtain freedom to operate from a patent perspective. Use of tangible biological materials adds a further layer of complexity, in that users must sometimes agree to onerous terms of MTAs and to qualify for handling of biological materials, while owners of the materials may demand IP rights to derived inventions. Finally, proximity to commercialization means that competition among a small number of players will intensify and strategic behaviour can be expected. Combined, these hurdles translate into transaction costs. When transaction costs are disproportionately high compared to the prospective gain, further pursuit of commercialization becomes uninteresting. Failure of such inventions to be placed on the market constitutes inefficient underuse of such inventive efforts and detracts from overall welfare to society.

Analysis of the optimal means to protect entitlements to an invention, indicates that in this setting, neither a pure property rule nor a pure liability rule achieves the desired results of placing on the market diverse products at competitive prices. Consequently, relying on the seminal theory of Calabrese and Melamed, a mixed property - liability rule is proposed. The liability rule would require patentees to relinquish patent exclusivity vis-à-vis other players in the final game, in exchange for a commitment to cross-license. The property rule side would preserve patent exclusivity vis-à-vis the rest of the world. The MTA is used as a vehicle to contractually re-allocate entitlements among players. As a formal structure, a patent pool might be adopted.

This solution is developed in the narrow context of work with samples of the H5N1 virus. However, its general mechanism could apply to reduce transaction costs and improve chances of commercialization in any setting in which microbiological or plant materials are used for commercial purposes.

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