PATENT CHOKING POINTS IN THE INFLUENZA-RELATED MEDICINES INDUSTRY: CAN PATENT POOLS PROVIDE BALANCED ACCESS?

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PATENT CHOKING POINTS IN THE INFLUENZA-RELATED MEDICINES INDUSTRY: CAN PATENT POOLS PROVIDE BALANCED ACCESS?

by Dana Beldiman

Abstract

This paper illustrates the fact that when biological materials are used for development of pharmaceuticals, the patent system may function sub-optimally and may give rise to patent “thickets” and “anti-commons” which prevent commercialization of adequate amounts of product. These circumstances include inventions based on the same biological resource, patenting of largely similar functionalities, gene patents and patents that are narrow and fragmented. As a result, in order to obtain freedom to operate, drug developers must license-in multiple patents, often from competitors. This situation gives rise to uncertainty and is prone to hold-outs. The number of players actually developing drugs is narrowed to a point of a “single player” or a “no player” scenario.

The conditions described above are examined in the context of the Pandemic Influenza Preparedness Framework, an agreement concluded in May 2011 by the World Health Organization, to facilitate availability to pharmaceutical manufacturers of influenza virus samples. Due to the fact that the Framework fails to establish an IP governance regime to control patenting activity, national patent laws apply. For the reasons explained above, their application results in sub-optimal functioning of the patent system and the inability to generate a broad based of affordable pharmaceuticals, as proposed by the Framework.

The paper proposes an alternate approach in the form of a patent pool or comparable cross licensing agreement. Requiring all recipients of biological materials to join such arrangement, would re-allocate rights to provide all players access to the technologies derived from the influenza samples. This approach would avoid patent thickets and holdouts, reduce transaction costs associated with individual licensing and avoid uncertainty regarding the ability to secure freedom to operate.

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PREAMBLE

In 2006 an outbreak of the H5N1 influenza claimed large numbers of victims worldwide. The international health community led by the World Health Organization (WHO) through its Global Influenza Surveillance Network (GISN) immediately sought to obtain influenza virus samples from affected countries, in order to start development of diagnostics and therapeutics.

Indonesia, one of the affected countries refused to release virus samples located on its territory, citing its rights under the UN Convention for Biological Diversity (CBD) in support of this refusal. Only upon intervention by the WHO did Indonesia finally release the virus samples in Sept 2007. In exchange, Indonesia demanded action by the WHO and industrialized countries to define terms of reference under which Indonesia and other developing countries would receive access at reasonable prices to technologies and medicines derived from virus samples that they might provide to the WHO in the future.

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2 WHO – GISN has been the sole mechanism for alerting the world to the emergence of influenza viruses with pandemic potential. Adam Kamradt-Scott and Kelley Lee, The 2011 Pandemic Influenza Preparedness Framework: Global Health Secured or a Missed Opportunity, 59 Political Studies, 831 (2011).


4 The Convention on Biological Diversity (CBD) concluded in 1993 under the auspices of the UN, http://www.cbd.int/convention/text/, is designed to preserve biological diversity and protection, conservation and sustainable use of resources. Its provisions place the responsibility for these actions with the nations on whose territory such resources are located. To this end, individual states are granted sovereign rights over their biological materials, including access and equitable sharing of benefits.

5 Reuters, Indonesia, Baxter sign pact on bird flu vaccine www.reuters.com/article/2007/02/07/idUSJAK76679_.CH_.2400


The substratum of Indonesia’s refusal to release virus samples is the deep-going rift between developing and industrialized countries over access to medicines and intellectual property rights. The rift is often blamed on the patent system. The patent system functions well in the context of industrialized countries because these markets can support prices sufficient to finance R&D. However, the system does not scale well internationally, due to the embedded structural inequalities among countries. A global solution for overcoming these IP-related issues in international context, or even a conceptual approach for one, has yet to be developed. For now, international IP issues are approached on a case-by-case basis.

Negotiation out of this particular impasse was left to the WHO, the international organization primarily responsible for furthering global health. Following the H5N1 crisis, the WHO established task forces with the mission of developing a framework for accessing influenza virus samples from member countries, in exchange for sharing the benefits resulting from the use of the samples released. Extensive negotiations finally resulted in the Framework for Pandemic Influenza Preparedness (PIP) agreed upon by all member states and representatives of the pharmaceutical industry and adopted by the World Health Assembly in May 2011.

INTRODUCTION

The WHO’s PIP Framework achieves an important first step toward ensuring widespread access to reasonable-priced H5N1 based products, in that it secures access to virus samples. However, it falls short of taking the requisite second step of establishing an IP governance regime that would help, rather than hinder the achievement of the Framework’s overall goals of availability and affordability in the influenza-related medicines market (IRM).

This paper’s topic starts at the point at which the PIP Framework leaves off: trying to establish the contours of an IP governance regime for inventions based on virus samples released by WHO Centers under the Framework.

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7 Kamradt-Scott and Lee, supra note 2, at 832.
8 Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP)
9 http://www.who.int/bulletin/volumes/89/7/11-091389/en/ This Framework raises many unprecedented international legal issues, including the role of private parties in international treaty negotiation, unanticipated use of the CBD to deny access to needed ingredient for drug development and the extraordinarily enhanced role of intellectual property.
The purpose of this article is twofold. First, it proposes to examine, from an IP perspective, the Framework’s ability to meet its objective of generating broad-based availability of affordable H5N1-based medicines. Given its virtual silence on IP issues, the Framework does not restrict the virus samples recipients’ ability to obtain IP protection in any significant way. However, the specific conditions created by the Framework and extant in the industry, place considerable hurdles in the path of drug developers. All recipients of the virus samples pursue development based on the same biological material - the H5N1 influenza virus, and seek to develop generally equivalent inventions - diagnostics and vaccines. They will compete with each other downstream for technologies and market share and tend to resist each other’s requests for licenses. All this occurs in the context of an already competitive and highly regulated industry. Cumulatively, these conditions result in a sub-optimal functioning of the patent system and exacerbate the natural process of narrowing of the number of players who place product on the market. The end effect may be a “single player,” or even a “no player” scenario at the commercialization stage, a result that cannot support the Framework’s availability and affordability objectives. A different approach to IP governance could change that.

The article’s second objective is, then, to propose an IP governance regime that avoids the hurdles mentioned above and can better serve the Framework’s goal of availability and affordability, by way of cross-licensing agreements structured in form of a patent pool. Its goal is to “unblock” the congested and adversarial downstream environment, by requiring all virus-sample recipients to contractually re-allocate IP rights in a way that gives all parties freedom to operate from a patent perspective.

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10 The 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 (Framework, supra note 8, Principles, PP17) and expanding the global capacity to produce influenza vaccine, including in developing countries (Framework, supra note 8, Objective 2.1).

11 For present purposes, the terms “upstream” and “downstream” denote the sequence of stages followed in product development, starting with research and development to the endpoint of commercialization. These terms have also been used to refer to research intended to yield information or knowledge, or basic research, (upstream) and research that can directly form the basis of a product (downstream). 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); Patrick Gaule, Towards Patent Pools in Biotechnology? Ecole Polytechnique Federale de Lausanne, Coll. of Mgmt. of Tech., CDM Working Papers Series, CEMI-Report-2006-010 (2006).
The number of parties with access to proprietary technology would thus increase and improve the chances of broad based affordable commercialization.  

1. The WHO Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits (“PIP”)

The PIP Framework’s intent is to facilitate access to H5N1 virus samples for purposes of drug development. Its mechanics are as follows: National Influenza Centers of WHO member states make available PIP biological materials to WHO Centers and agree to their onward transfer to third parties for purposes of development of influenza related medicines (IRM). The WHO Centers then provide material samples to qualified recipients, including influenza vaccine manufacturers, laboratories of the originating and other member states, as well as other laboratories that meet the requisite biosafety standards. In exchange, recipients of the virus sample material are required to comply, *inter alia*, with certain benefit sharing obligations in the form of monetary support, medicine donations or technology transfers or licenses. The benefit sharing provisions are designed in the form of options, which require recipients to make a selection. Due to the structure of options, the recipients can meet their obligations by providing product (vaccines or treatment courses) or monetary compensation, instead of licenses and technology transfers.

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12 It is recognized that the IP regime is only one factor in a broad array of complex public health considerations that contribute to the ultimate success. See generally, Eileen Kane, *Achieving Clinical Equality in an Influenza Pandemic: Patent Realities*, 39 Seton Hall Law Review 1137 (2010). However, discussion of the remaining considerations is beyond the scope of this paper.

13 Collaborating Centers and WHO H5N1 Reference Laboratories PIP Framework, *supra* note 8, Art. 5.1.2)

14 PIP Framework, *supra* note 8, Arts. 5.4 and 6.3.

15 A recipient may select from two out of six different choices, four of which relate to payment and pricing benefits. The remaining two relate to licensed and transfer of IP. Recipients may (a) Grant to manufacturers in developing countries licenses on mutually agreed terms that should be fair and reasonable including in respect of affordable royalties, taking into account development levels in the country of end use of the products, on technology, know-how, products and processes for which it holds IPR for the production of (i) influenza vaccines, (ii) adjuvants, (iii) antivirals and/or (iv) diagnostics or (b) Grant royalty free licenses to manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the production of pandemic influenza vaccines, adjuvants, antivirals products and diagnostics needed in a pandemic. PIP Framework, *supra* note 9, Art 78, SMTA 2, Art. 4.1.1. A5. To the extent technology is licensed to WHO, it may be sublicensed to manufacturers in developing countries, grant licenses to manufacturers in developing countries with a right to sublicense. PIP Framework, *supra* note 8, Art 78, SMTA 2. Art. 4.1.1. A5 and A6.
The Framework covers the “H5N1 virus and other influenza viruses with human pandemic potential.” From a structural standpoint it consists of (1) a framework agreement that governs its general operations, including, *inter alia*, the deposit and transfer of virus samples and (2) proposed Standard Material Transfer Agreements (SMTA) which bind recipient/developers to the terms of the Framework.

In its approach to IP issues, the PIP seeks to strike a balance between public health needs and creating an incentive for private industry to develop and commercialize the medicines, including commercialization in “small and uncertain” markets. Its guiding Principles recognize both that “intellectual property rights do not and should not prevent Member States from taking measures to protect public health” and “that intellectual property rights are an important incentive in the development of new health care products.” The tension inherent in these guiding principles is reflected in the negotiations and the ultimately agreed upon version of the Framework. During the Framework’s negotiation, a variety of proposals were made with respect to governance of IP rights to downstream improvements. Some proposals sought to prohibit patenting of influenza biological materials outside the WHO system altogether. Others required parties who made “patent or other intellectual property rights” claims based on the virus samples received, to “disclose in the patent

16 PIP Framework, *supra* note 8, Art 78, Art. 2.1 (i)
17 PIP Framework, *supra* note 8, Art 78, SMTA, Art. 1 and 2. Two different standard MTA forms are provided, depending on whether the recipient party is a “participating” or “non-participating” in funding the WHO Global Influenza Surveillance and Response System (GISRS) Centers, hereafter SMTA1 and SMTA2.
18 “[I]ntellectual property rights do not and should not prevent Member States from taking measures to protect public health” and “intellectual property rights are an important incentive in the development of new health care products. However, this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain.” PIP Framework, *supra* note 8, Art 78, Preamble, PP13.
application, the country from where [the samples] were collected.”

If commercialization were to result in financial gain, contributions should be made to the WHO’s Coordinated International Sharing of Influenza Viruses & Benefits Agreement. Alternatively, it was proposed that as to “IPR ...obtained on inventions derived from the use of the Materials, the holder [provider] of such rights should grant to WHO a non-exclusive, royalty free license, which WHO will sub-license to interested developing countries for the purpose of maximizing availability of critical benefits on a non-profit basis, such as vaccines and antivirals for pandemic influenza preparedness purposes.” Ultimately, none of these proposals was included in the final version and the Framework remains virtually silent on the divisive issue of IP rights.

Our analysis will focus on the effect of the lack of any significant IP governance provisions in the Framework. To this end, the discussion will follow the virus samples’ downstream path of development, and seek to identify conditions that might develop into blockages or chokepoints. The goal is to develop data points that will inform the alternate IP regime proposed by this paper.

2. Attractiveness of the Influenza-Related Medicines (IRM) Market to Potential Developers

A threshold question to be addressed is whether the IRM market will be sufficiently attractive to potential developers, i.e. will there be takers for the virus samples released by the WHO Centers for purposes of development? This question must be viewed in the context in which the development costs for a drug exceed $1 billion and, as a result, many inventions remain on the shelves. In this setting, only a strong market will attract developers and investors.


22 Id. However it is unclear whether the influenza virus can properly be considered a “genetic resource” covered by the benefit sharing provisions of the CBD has apparently been resolved in favor of including the influenza virus among genetic resources. 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

23 Lawson, supra note 21, at 569 citing A63/48, n 162, Annex (Appendix 2, White Paper 1 and at [4.1.3], [4.1.5] and [4.3]).

Review of the IRM product market indicates high growth rates. Following the 2005 and 2009 pandemics of the H1N1 and H5N1 influenza strains, governments, national health care organizations and international organizations started to provide increased support and funding for R&D and product development in influenza-related medicines (IRM), including diagnostics, prophylactics and therapeutics. These and other players further began stockpiling treatments as a method of preparedness and disease containment in case of a pandemic. Partly, as a result, sales in the influenza related drug industry have grown at a much faster rate than the overall pharmaceutical market. Statistics show that sales have more than tripled from $2.2 billion in 2004 to $7 billion in 2009, and the total market is expected to reach $10 billion by 2015. These conditions would ensure that, at least at the outset, there is sufficient interest among potential developers of IRM to consider developing medicines in this field.

3. Patenting under the Framework

We will next examine whether potential developers face barriers to entry, first, with respect to obtaining virus samples under the Framework, and second, with respect to being able to secure patent protection.

a. Qualified Recipients of Virus Samples under the Framework

Under the Framework, any manufacturers or laboratories that are “qualified” may obtain virus samples from WHO Centers. “Qualified” recipients are those who meet the appropriate biosafety guidelines and best practices. No other apparent

25 Influenza-related medicines are part of the “biologics” subset of the pharmaceutical industry in which products are created from living organisms (such as vaccines, antibiotics, rDNA products). Hillary Greene, Patent Pooling Behind the Veil of Uncertainty: Antitrust, Competition Policy, 90 Boston University Law Review 1397, 1407 (2010). www.healthcarepackaging.com/archives/2009/09/global_influenza_market_to_be.php.

26 The WHO alone proposes to stockpile around 150 million doses of H5N1 vaccines. Kamradt-Scott and Lee, supra note 2 at 841.


28 Id.

29 This conclusion is also supported by the presence of numerous pharmaceutical manufacturers during the Framework’s negotiations and their ultimate agreement to fund part of the operation. PIP Framework, supra note 8.

30 PIP Framework, supra note 8, Art, 6.3 bis.

31 PIP Framework, supra note 8, Art, 6.3 bis. Recipients may be “outside the WHO GISRS”, in which case SMTA1 governs, or “within the WHO GISRS”, governed by SMTA2.
limitations are placed on manufacturers or laboratories becoming “qualified” within the terms of the Framework. Nonetheless, the economic burden of meeting the requisite biosafety standards would have an inherently limiting effect on the number of potential recipients.

b. **Patenting of the “Materials” (virus samples)**

Recipients of virus samples are bound to a single mandatory provision regarding IP rights, namely that “[n]either the Provider nor the Recipient should seek to obtain any intellectual property rights on the Materials.”

The meaning of the term “materials” in this context is ambiguous: Does the prohibition against obtaining IP rights merely cover the sample’s physical layer or does it extend to its informational layer, including its DNA structure? The only other section that makes reference to the issue of genetic data does not further illuminate the situation either. It requires that “[g]enetic sequence data … should be shared in a rapid, timely and systematic manner with the originating laboratory…” The framers clearly envisioned that genetic sequence data will be obtained and shared for purposes of follow-on research. This fact would tend to imply unpatented genetic sequences, even though, the possibility of sharing patented sequences cannot be ruled out. Two possible explanations for this lack of further specificity are (1) that genetic sequences are assumed to be part of the “Materials” and fall under the prohibition against obtaining IP rights or (2) that they are assumed not to be

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32 As mentioned earlier, the Framework does however contain a number of voluntary IP related requirements, see supra note 17.

33 PIP Framework, supra note 8, Art 78, Standard Material Transfer Agreement (PIP SMTA), Art. 6.1.


35 PIP Framework, supra note 8, section 5.2.1.

36 The Framework clearly contemplates further development of the samples, in that it provides for “onward transfer and use.” PIP Framework, supra Art 78, Art 5.1.2. and SMTA, Arts. 1 and 2.

37 PIP Framework, supra note 8, section 6.1
patentable inventions under national patent laws. Alternatively, the most plausible explanation is that these provisions simply did not undergo a thorough evaluation from a patent perspective. This leaves the question of patentability to be determined under national patent laws.

Most jurisdictions would preclude patentability of the virus samples as materials “occurring in nature.”\[^{40}\] Courts in some jurisdictions have however, viewed isolated genes as “markedly different” from what exists in nature and considered them patent eligible.\[^{41}\] Other jurisdictions view isolated genes as patentable even if they are similar to what exists in nature, albeit only if a specific useful function can be articulated.\[^{42}\] The interpretation of the usefulness/industrial application requirement, however, varies quite significantly among jurisdictions.\[^{43}\] Some recipients will, in all probability, seek and obtain early stage upstream patent protection for gene sequences, and in some cases patents may be granted based on relatively poorly articulated functions.

Such patents are difficult to invent around. A patent granted on a natural biologic, such as a gene, embodies the process of understanding and experimenting with

\[^{38}\] See infra text accompanying notes 39-41.
\[^{39}\] Members of the Trade Related Aspects of Intellectual Property Agreement (TRIPS), protect inventions in “all fields of technology,” including biotechnology, that are new, display an inventive step and are capable of industrial application. Patentees of such inventions have the right "to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing” the patented product or process. TRIPS, Art. 27 et seq.
\[^{40}\] The materials would be viewed as discoveries or materials occurring in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); European Patent Convention, Art. 52.2(a).
\[^{41}\] The treatment to be given isolated or purified genetic sequences remains unclear both under patent laws. *Association for Molecular Pathology v Myriad Genetecis*, United States Court of Appeals, Federal Circuit, No. 2010–1406, July 29, 2011 holding that an isolated gene is “markedly different” in chemical structure from the one found in nature, which makes it a distinct chemical entity that is patentable, while questions remain as to purified genes.
\[^{42}\] EU Biotech Directive 98/44/EC. “An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.” Art. 5 (2); “a mere DNA sequence without indication of function does not contain technical information as is therefore not a patentable invention” (Recital 23).

\[^{43}\] See e.g. *Burroughs Wellcome v. Barr Laboratories*, 40 F.3d 1223 (Fed. Cir. 1994); *Aptex Inv. V Wellcome Foundation Ltd.*, Supreme Court of Canada, 2002 SCC 77, File Nr. 28287 (2002).
foundational material over an extended period of time. The party that isolates the respective gene holds considerable advantage over other researchers. Its patent may control all uses of the gene, including diagnostics, prophylactics and treatment based on the respective sequence. The owner of an upstream gene patent may therefore be able to exclude other sample recipients from developing technologies based on the respective patent and thus block or deter further downstream development.

c. Patenting of Derivatives and Improvements

Most inventions based on the virus samples will involve derivatives of the materials received, or improvements thereto. Improvements and derivatives are likely patentable under the laws of TRIPS member countries, to the extent they meet the requirements for patentability.

The right to make improvements to an existing invention is reserved to the patent owner, as the process of follow-on invention requires use of the underlying invention. An upstream patentee may therefore prevent third parties’ development efforts, unless national law provides for anti-blocking mechanisms. Consequently, derivatives and improvements of the virus samples tend to remain under the control of the initial sample recipients or their licensees engaged in development.

4. Summary of Upstream Conditions

45 Greene, supra note 25, at 1404.
47 TRIPS Art. 31 (l) permits use without the authorization of the rightholder of a first patent for exploitation of a second patent provided “the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent.” Treatment differs depending on the degree of “significance” the dependent patent is required to have. E.g. the UK Patents Act of 1977, § 48A(1)(b)(i)(4) requires an “important technical advance of considerable economic significance”; the German Patent Law Art. 15 (2001) requires an “indispensable in the public interest.” Given these limitations, anti-blocking statutes may not provide a significant amount of relief.
48 For the view that the issue of allocation of rights to such improvements is not well solved by the patent system, see Reichman, Will Developing Countries Lead, supra, note 46.
Next we will take stock of the findings so far. Review of the Framework’s IP provisions reveals that from an economic standpoint, the IRM industry appears sufficiently attractive for firms to consider investing into R&D and commercialization. From a legal standpoint recipients of virus samples are free to seek patent protection for sample-based inventions. Allowable patenting is coextensive with national patent laws.

It is then reasonable to assume that all, or the majority of sample recipients, would pursue development based on the virus samples received from the WHO Center. If so, they would seek to develop either diagnostics or vaccines, both of which require use of the actual H5N1 strain. Several, if not all recipients will seek patents based on the sample’s genetic structure. All inventors will race to be the first to patent the invention in the most favorable jurisdiction possible. Inventions which are identical will be eliminated at the patenting stage, as only the first party to file a successful patent application is rewarded with a patent. Any subsequently filed identical inventions are deemed to fail the novelty requirement. Inventions which are not identical, but generally functionally equivalent, remain patentable in most jurisdictions, despite potential overlaps among them, that result from the fact that they are based on the same biological resource and seek to patent similar functionalities. These overlaps will ultimately require the patentees to seek licenses from each other in order to gain freedom to operate from a patent perspective. Because the virus sample recipients/patentees will be competing against each other for a share of the same market, this may become problematic further downstream.

5. Downstream Conditions that Impact Patenting under the Framework

a. Numerous Fragmented Patents Give Rise to Patent Thickets

Continuing the journey downstream, the next step is to consider how downstream conditions impact the ability to develop a product in the IRM industry. In the biotechnology field, inventions tend to be numerous and narrow. Often many different technologies are required to make up a product. The virus sample alone may yield different types of inventions, such as recombinant gene sequences, extracts and derivatives of the virus genome and new genetic constructs making use

49 Subject to the fact that some inventors may drop out due to inability to achieve an invention.
50 U.S. law grants patent rights to the first party to invent. 35 USC 102. Starting March 16, 2003, the US will grant patent rights to the first party to file.
51 See e.g. European Patent Convention Art. 54.
of material, diagnostics.\textsuperscript{52} A product would further require use of non-virus based technologies, such as adjuvants and other formulation technologies, production technologies or combinations thereof, etc. These various technologies are generally the subject of different patents, likely owned by different patent holders.\textsuperscript{53}

The rapid growth of the IRM industry, discussed above further adds to the complexity of the technological landscape.\textsuperscript{54} The availability of funding and the high market growth rate have attracted a wide array of private or public players - governments, university research, small R&D companies and vaccine manufacturers - into the upstream influenza drug space.\textsuperscript{55} This heightened research activity is correlated with intensified patenting. A sharp rise in patent applications based on the H5N1 virus was noted just shortly after the outbreak of the H5N1 2005 pandemic.\textsuperscript{56} Specifically, 63 H5N1 and H1N1 virus strains related vaccine applications were filed under the PCT in 2010, compared to 19 applications in 2001,\textsuperscript{57} by pharmaceutical manufacturers, biotech companies, and research centers, mainly from the United States, Belgium, Switzerland, the Netherlands, and France.\textsuperscript{58} As a result of this heightened activity, the IRM industry is a congested and competitive scene, which adversely impacts the ability to put together a product.

\textsuperscript{54} See supra accompanying notes 25-29.
\textsuperscript{55} Greene, supra note 25, at 1410.
\textsuperscript{57} The applications considered in this study include only the patents narrowly derived from this particular strain.
\textsuperscript{58} A further study performed under the auspices of WIPO indicates a similar rise in patent applications for the H5N1 and the H1N1 viruses. While providing valuable analysis on the types of patents filed, the WIPO study, in its own terms, does not evaluate the situation from a "freedom-to-operate" perspective. WIPO Patent Search Report, supra note 52 at 3.
To assemble the requisite "technology package", i.e. to gather all the technologies necessary for development of a product, a drug developer must identify the technologies, locate their owners and negotiate a freedom to operate arrangement for each technology. The entire development process is governed by uncertainty: uncertainty regarding the grant of the own patent applications, uncertainty as to the fact that multiple licenses must be secured in a competitive market, uncertainty regarding the ability to secure all requisite licenses and uncertainty regarding the patent grants on technologies licensed in and high transaction costs.

Cumulatively, the difficulties that face a developer diminish the incentive to invest into commercialization. They form what is known as "patent thicket" or "anticommons."

b. Patent Thickets, Hold-outs and Anti-commons

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61 The validity of a patent is only determined once an appellate level court has ruled on it.

62 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. Rebecca Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the AntiCommons in Biomedical Research*, 45 Houston Law Review 1959, 1064, note 27 (2008) (Eisenberg, Noncompliance).

63 See Krattiger, supra note 59, at 56.

64 Greene, supra note 25, at note 18. 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). An anticommons, a related concept, is an accumulation 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." Michael Heller and Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698 (1998); Rebecca Eisenberg, *Noncompliance*, supra, note 62 at 1060. A player would be faced with an anticommons if the burden of negotiating the licenses necessary is disproportionate to the expected value of the product or the expected gain.
Patent thickets occur when multiple owners hold patents that are necessary for a particular product. A product developer is confronted by a dense web of overlapping IP rights which it must negotiate through in order to be able to commercialize its product. The greater the number of patents required to assemble the product, the more daunting the hurdles, as each license involves separate negotiations, uncertainty of outcome, delays and costs. These conditions are prone to hold-outs, strategic behavior which prompts the holder of a technology essential to the product, to refuse to license. "Because a given project will fail without their cooperation, “holdouts” may be prompted to demand a bribe close to the value of the entire project. And of course, every property holder needed for the project is subject to this same incentive; if everyone holds out, the cost of the project will rise substantially, and probably prohibitively."

An anticommons, first referred to in the seminal article by Heller and Eisenberg, is described as “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.” An anticommons, an overlapping, impenetrable rights structure, would result in an “underuse [of] scarce resources because too many owners can block each other." A developer would have to obtain “rights to many different discrete components” of the product and, if unsuccessful, will not make use of the technology. It seems that this theory is a good fit for the biotechnology space, where “patents are numerous and narrow and where production of any given product may require bargaining with multiple patent holders.

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66 “The greater the number of essential licensors, the greater the total risk of bargaining breakdown.” Eisenberg, Noncompliance, supra note 62, at 1073. See generally, Greene, supra note 25.


68 Heller and Eisenberg, supra note 64.

69 Levy, supra note 11, at 81.

The potential for divided patent entitlements to prevent efficient integration into products is particularly high.”

A study conducted by Rebecca Eisenberg re-affirms the fact that, instances which involve a scarce physical resource and a commercial setting such as the PIP Framework, give rise to greater difficulties in obtaining access to research and technologies.

Under the definition provided by Professor Lemley, the instant situation presents characteristics of both thickets and anticommons, in that (i) a developer in the IRM space must obtain “rights to many different discrete components” of the product (anticommons) and (ii) in order to practice any invention based on the virus sample, licenses are likely necessary to overlapping virus sample patents (thicket).

Under either definition, the existence of a large number of patents, particularly genetic

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71 Burk and Lemley, supra note 60 at 728. Following the seminal article by Heller and Eisenberg, supra note 64, there has been a great deal of debate on the concept of anticommons, see Levy, supra note 11, at 80; 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.

72 In her paper Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommmons in Biomedical Research, Rebecca Eisenberg points to circumstances in which an anticommons would be more likely than in others, specifically listing situation which involve a physical resource developed for immediate commercial use. Eisenberg, Non-compliance, supra note 62, at 1098.

73 “…both "anticommons" and "patent thicket" are terms used to describe situations in which a party must license multiple patent rights....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.” Mark , Contracting Around Liability Rules note 27, February 2012, Stanford Law and Economics Olin Working Paper No. 415. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1910284. Aoki describes a similar situation in the field of genetic resources which result in an anticommons in the field of biology. “These "transformation technologies" combine information "from many areas of biology, including crop genetics, breeding, agronomy, pest control and agro-ecology" that make "innovation ... 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.....What these various proprietary claims on plant phenotype, genotype, and gene sequences within the plant begin to create is an "anticommons." Here, 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.” 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).
patents, presents the potential of blockage. The end effect is that a congested patent scene makes it difficult for innovators to conduct research and for developers to effectively access necessary patents. Parties that develop in this space may be eliminated because they are unable to negotiate freedom to operate. Depending on the density of the thicket (number of patents to be licensed, economic and political dynamics among the players, etc) it is possible that none of the players will be able to assemble all the requisite rights to a product.

b. Burdensome Regulatory Requirements

Finally, once the product has been developed and all rights have been assembled, manufacturers must contend with complex regulatory environments and clinical trial requirements. Many patented or patentable inventions remain on the shelves at research centers because bringing the invention to the market stage is too costly and uncertain. Furthermore, the biologics industry, of which IRM are a part, is subject to particularly rigorous manufacturing standards. Combined, these conditions result in a cost of bringing a drug to the market that ranges in excess of $1 billion, a fact which may further reduce the number of players that ultimately bring product to market.

5. Summary of Downstream Conditions

The journey along the downstream path of the virus samples yields the following conclusion.

The absence of any IP governance provisions in the Framework has significant potential of undermining the Framework’s overall goal of achieving broad-based availability of affordable medicines in the IRM space.

The upstream segment, from receipt of the samples through filing of applications for patent rights, unfolds normally, as intended by the patent system. All sample recipients/inventors are likely to race to patent their invention in a favorable jurisdiction. Nonetheless, several factors signal the possibility of problems emerging downstream: early filing of gene patents, multiple parties conducting research on the

74 Levy, supra note 11, at 80.
75 Levy, supra note 11, at 80.
77 Greene, supra note 25, at 1411.
same biological resources, and the fact that many will seek patents for functionally equivalent products.

This latent problem is then exacerbated by the specific conditions prevailing in the downstream IRM space: narrow and fragmented patents, a congested patent scene and lengthy and expensive regulatory review and manufacturing. Most important, however, is the fact that all sample recipients/inventors will be competing for the same market. This may lead to strategic behavior such as seeking exclusive rights and implicitly barring others from use of ancillary technologies, such as adjuvants, or refusals of competitors’ license requests.

Two phenomena may occur as a result: players may exit the race due to impenetrable patent thickets or, alternatively, the market may be monopolized by a single party based on a hold-out position. This could produce a “single player”, or alternatively, a “no player” outcome when it comes to commercialization. Otherwise described, the cumulative effect of the conditions discussed above, is akin to a funnel that progressively narrows the number of parties who successfully bring medicines to market.

While many different conditions contribute to the funnel effect, IP rights have the ability to exacerbate it, and, under certain circumstances, even block it, with the result that product cannot be commercialized. An alternative IP governance regime could help defuse the competitive tensions that exist in the downstream space and remove IP related chokepoints, sufficient to allow products to reach the market.

6. Alternative Models

The following will examine models that could help eliminate IP-related chokepoints.

a. Non-proprietary, Open Source and Compulsory License Approaches.

For the broadest accessibility of materials and technologies, patenting of both materials and improvements would be prohibited altogether. Because no patent protection is involved, the thicket problem can be avoided and no competitive tensions would arise downstream. However, absence of exclusivity in the context of

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78 This solution was proposed by some of the Member States. See supra text accompanying note 7.
the investment-intensive pharmaceutical industry is likely to deter firms from investing.

A semi-proprietary, yet open option is offered by the open source model, frequently encountered in the software industry. Its goal is to allow contributors and users freedom of access and use of existing innovation. A biotechnology context, an open source model would start out with certain patented material. Subsequent transfers would be based on open source terms. Such terms generally include non-exclusive licenses and reach-through obligations that bind successive transferees to share improvements on the terms set forth in the original license. A grant-back provision might require that improvements be licensed back to the original patentee/licensor who would then act as a repository of knowledge related to the particular technology and make it openly available.

This solution is conceptually akin to the General Public License (GPL) open source license in the software field. Initially this form of software licensing met with considerable resistance from larger software producers. However, in recent years, large software companies have begun to rely increasingly on open source software as part of their enterprise software strategy. Would an open source model in a biotechnology/pharmaceutical setting follow the same course? The oft-cited differences between the two fields, including the long development timeline, the need for elaborate laboratory infrastructure and the regulatory oversight imposed on the biotechnology and pharmaceutical industries, would probably make open source difficult to accept in the traditional commercial biotechnology/pharmaceutical context. Nonetheless, the model remains viable for non-traditional applications, such as, platforms to share biotechnological knowledge for use and underserved communities that are funded by means other than the patent system.

Finally, a compulsory license type approach, would require recipients to grant licenses under specified terms and conditions to parties such as the WHO or member

80 Goulding, supra note 11, at 207.
81 http://www.opensource.org/licenses/gpl-license.php
83 Goulding, supra note 11, at 207.
84 Goulding, supra note11, at 207; an example of such a platform is non-profit research institute set up as the Center for Applications of Molecular Biology to International Agriculture (CAMBIA), www.cambia.org
In principle, a compulsory license would be only marginally more appealing to potential patentee/developers than a non-proprietary or semi-proprietary solution. Nonetheless, the ultimate acceptability of a licensing solution is a function of the specific terms and conditions imposed. A related alternative will be explored below.\textsuperscript{85}

\textbf{b. Compensatory Liability Type Approach}

In situations involving microbial samples, Professor Reichman proposes implementation of a compensatory liability model\textsuperscript{86} 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.”\textsuperscript{87}

Unlike the PIP Framework’s purely proprietary approach, the compensatory liability model envisions a semi-commons that would allow members to freely use microbial material deposited in collections, without prior permission. If the research is put to commercial use (regardless whether based on a proprietary invention or not), recipients are required to pay royalties of 4% of gross sales. This obligation is incurred contractually, \textit{ex ante}. It gives recipients of the microbial material a conditional right to use, and the owner/depositors a conditional entitlement to collect royalties, in the event of successful commercialization.\textsuperscript{88} Downstream transfers of the materials are subject to the same obligations.

In situations with imminent prospects of commercialization in the context of a strong market, the compensatory liability model would however not avoid the patent thicket effect likely to evolve in the downstream space. This model therefore remains better suited for situations where the commercial end point is more remote, and where funding through the patent system plays a less significant role.

\textbf{7. Conceptual Basis for an Alternative Solution.}

\textsuperscript{85} See \textit{infra} text accompanying notes 92 et seq.


\textsuperscript{87} Reichman, \textit{A Compensatory Liability Regime, supra} note 86, at 11.

\textsuperscript{88} “[T]he depositor would not forfeit all rights to benefit from downstream commercial applications, and instead share in them, should such applications emerge.” Reichman, \textit{Microbial Research Commons, supra} note 86; see also Jerome H. Reichman, \textit{Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation}, 53 Vanderbilt Law Review 1743 (2000).
Review of the models discussed above, reveals that none appears suited to resolve the specific issues presented by the PIP Framework. We will therefore seek to develop a new approach to IP governance that addresses these problems, drawing on the data points gathered in the foregoing discussion. Here are some of the considerations that should inform its structure.

First, the ability to patent inventions based on the virus samples must be preserved. Absent the prospect of patent exclusivity, players would be reluctant to invest into development.

Second, a solution would have to be directed primarily at the competitive situation downstream. Sample recipients typically compete for two reasons. The first reason is in order to gain priority in patenting. This race is part of the normal operation of the patent system, which is designed to reward the winner of the race, and to eliminate identical or virtually identical inventions filed at a later time. The second reason for which players compete is in order to gain a share of the market. This race takes place among the winners in the first race, i.e. patentees of inventions that are largely functionally equivalent. Their goal is to seek to gain as large a share of the market as possible and, concomitantly, to exclude each other from the market. These efforts are not based on actual patent rights, but they are related to patent rights, in that they would not occur but for the existence of patent rights. They could be described as “patent related interests” and would probably form a gray area between acceptable competitive practices and practices that might violate antitrust laws. By way of example, practices prompted by “patent related interests” might include seeking to obtain an exclusive license on the only adjuvant suitable for production of vaccines of this particular influenza strain, or alternatively, denying a license needed by another recipient/patentee for freedom to operate.

Intervention by way of an alternative approach would have to occur at the level of the second “race” and would prohibit patentees from acting in pursuit of such “patent related interests.” Instead of competing against each other, the patentees would be required to license to each other the rights necessary for freedom to operate. Would this deal be sufficiently attractive to keep the players in the game? The conceptual premise is that “freedom to operate” from a patent perspective generally suffices for a player to function in the market and make at least a modest profit. While by cross-licensing, the patentees do indeed give up their exclusivity and their “patent related interests,” their freedom to operate is assured, since they gain rights from all other patentees, that they would otherwise have had trouble acquiring. Requiring all players to cross-license to each other, would reduce the individual player’s profit potential, but at the same time it would reduce the risk of not being able to
commercialize at all (e.g. as a result of the hold-out by another player). 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. Another way of conceptualizing this approach, is to view the patentee’s overall interest, as consisting of the patent right plus the “patent related interest.” Combined, the two form too capacious a right and risk crossing the line into anti-competitiveness. To avoid this result, a certain quantum of this right would need to be relinquished. This could occur by re-bundling the combined rights of the patentee/developers in a manner that prevents each individual’s interest from becoming overcapacious. Of course, this solution would have to be carefully calibrated, to avoid an excessive reduction of the profit potential, in which case, 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.

8. Leveraging the Asymmetry in Bargaining Power

On the assumption that a sufficiently well-calibrated re-allocation can be reached, an obvious question must be addressed. By what means can patentees be persuaded to relinquish some of the patent exclusivity to which they are entitled?

The Framework is actually well positioned to impose conditions on sample recipients. The fact that the WHO acts as gatekeeper to the virus samples, gives rise to a certain bargaining asymmetry in its favor and allows it to act in a quasi-legislative capacity with respect to downstream IP treatment. By way of the SMTA, the Framework can affirmatively shape the recipients’ downstream behavior, including obligating them to enter licensing arrangements. Nonetheless, because the Framework is reached by consensus among participants, this asymmetry is not so strong as to give the WHO unlimited discretion. A viable approach must not deprive the recipients of profit potential and must achieve an acceptable balance between the Framework’s policy objective, the interests of member states and those of the pharmaceutical industry present.

90 The legal vehicle by which the Framework imposes obligations on virus sample recipients is a Standard Material Transfer Agreement (SMTA). See supra text accompanying notes 14-15.
91 In connection with the Framework’s negotiation balancing is of great importance as there is always a “risk that pharmaceutical manufacturers might chose to exit the industry if too many barriers or obligations were imposed upon them” Kamradt, supra note 2, at 839.

This section will explore the more precise contours of the alternate approach discussed above.

As formal structure for a cross-licensing requirement we propose a patent pool. Patent pools are conceptually premised on a contractual variance of legislatively allocated intellectual property rights. Full patent rights are "re-bundled" to grant participants sufficient rights to ensure freedom to operate from a patent perspective.\(^{92}\) In a congested space, "re-bundling" in the form of a patent pool provides a more flexible and efficient allocation of rights. Pooling helps players assemble the necessary technologies, it reduces transaction costs and avoids the inefficiencies that result from patent thickets.\(^{93}\) Under certain circumstances pooling may also support non-commercial uses and allowances for CBD obligations. A pool is likely to enjoy broader overall acceptance because it seeks to reconcile the interests of all stakeholders.

Patent pools are informally defined as agreements "between two or more patent owners to license one or more of their patents to one another or third persons."\(^{94}\) Members of a pool assign their rights in patents and patent applications to a separate administering entity,\(^{95}\) which then licenses these rights in re-bundled form to pool members and third parties, upon terms and in accordance with rules agreed

\(^{92}\) The concept of contractually re-bundling IP rights with the intent to direct the innovation process has been given relatively little attention. But see Michael Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, 70 Ohio State Law Journal 1361 (2009) proposing a tailoring framework for IP rights.

\(^{93}\) Levy, *supra* note 11, at 78.


\(^{95}\) Merges, *supra* note 64, at 1299.
upon by the members. By providing participants with freedom to operate from a patent perspective, product development is stimulated.

With the growth of the biotechnology industry, bioinformatics and related industries, patent pools have increasingly come under consideration in the life science field. Industry resistance to patent pools is decreasing and governments tend to encourage at least those pools perceived to provide a social benefit.

10. Considerations in Establishing a Patent Pool

Depending on their specific licensing terms, patent pools present the risk of being viewed as anticompetitive by antitrust/competition authorities. The underlying licensing agreements are therefore subject to review as to whether their competitive benefits outweigh the potential harm to competition.


97 Josh Lerner and Jean Tirole, Public Policy, supra, note 96, at 159; Krattiger, supra note 59, at 56; Merges, supra note 64, at 1299.

98 “The value of patent pooling within the biotechnology and related fields has received considerable attention, primarily by commentators, owing to the perceived promise of improved social welfare (including decreased transaction costs, increased pricing efficiency, and faster innovation) and despite the acknowledged potential for antitrust issues.” Greene, supra note 25, at note 69.


100 The DOJ inquiry is focused on the issues of (1) whether the proposed licensing program is likely to integrate complementary patent rights, and if so, (2) whether the resulting competitive benefits are likely to be outweighed by competitive harm posed by other aspects of the program. DOJ U.S. Antitrust Guidelines for the Licensing of Intellectual Property (1995). www.usdoj.gov/atr/public/guidelines/ipguide.htm. (IP Guidelines) The Department of Justice’s assessment of whether patent pools would be deemed pro or anti-competitive are set forth in the DOJ U.S. In essence the IP Guidelines provide that pooling arrangements are procompetitive when they (a) integrate complementary technologies, (b) reduce transaction costs, (c) clear blocking positions, (d) avoid costly infringement litigation, and (e) promote the dissemination of technology. On the other hand, indicia of anticompetitiveness would be that (a) the excluded firms cannot effectively compete in the relevant market for the good incorporating the licensed technologies, (b) the pool participants collectively possess market power in the relevant market, and (c) the limitations on participation are not reasonably
In general, competition authorities view patent pools as a pro-competitive. The U.S. Department of Justice Guidelines (IP Guidelines) point to the fact that pools provide benefits such as “integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation.”\textsuperscript{101} The USPTO has also opined favorably on the formation of patent pools, because “the social and economic benefits of the pooling of biotechnological products outweigh their costs.”\textsuperscript{102}

In evaluating the acceptability of an individual patent pool in the biotechnology area, it must be kept in mind that the IP Guidelines contemplate primarily patent pools in the electronics industry, which are largely organized around industry standards and may respond to different needs. Much of antitrust law in the biotech area is still limited to “merely importing existing norms developed within the standard-setting context” without addressing specific issues raised by the biotechnology industry,\textsuperscript{103} despite the existence of a good number of scholarly writings on the topic.\textsuperscript{104}

Electronics industry precedents limit pool membership to “essential” patents\textsuperscript{105} and concomitantly exclude “substitute” patents.\textsuperscript{106} This requirement could be an obstacle in the case of early pool formation, such as in an influenza virus-based pool, because the technological relations among the patents are still undefined. Some authors have

related to the efficient development and exploitation of the pooled technologies. See also Krattiger, \emph{supra} note 59, at 142.

\textsuperscript{101} IP Guidelines, \emph{supra} note 100, at 127.

\textsuperscript{102} Jeanne Clark et al., \emph{supra} note 121, at 2-3 (2000),

\textsuperscript{103} Greene, \emph{supra} note 25, note 171, citing Josh Lerner & Jean Tirole, \emph{Efficient Patent Pools}, 94 Am. Econ. Rev. 691, 691 (2004) “(questioning whether, though not addressing specifically the biotechnology industry, “the reluctance to form pools may be due to the ambiguities surrounding the manner in which proposed pools will be evaluated”)”.

\textsuperscript{104} E.g. Krattiger et al., \emph{supra} note 59; Courtney G. Scala, \emph{Making the Jump from Gene Pools to Patent Pools: How Patent Pools Can Facilitate the Development of Pharmocogenomics}, 41 Conn. L. Rev. 1631 (2009); Goulding, \emph{supra} note 11; Patrick Gaule, \emph{supra} note 11.

\textsuperscript{105} Because the IP Guidelines require that the pool contain only "essential patents", i.e. those which are necessary to implement the technology, the implication is that substitutes, either within or outside the pool should not be accepted. Lerner Tirole, \emph{Public Policy}, \emph{supra} note 96, at 160.

\textsuperscript{106} The DOJ business review letters exclude “substitute” technologies. Greene, \emph{supra} note 25, at 1439. Whether government pronouncements in this regard hold true with respect to the biotech, and in particular the antiviral industry remains to be seen. In general, an individual pool is likely to pass muster under competition rules, if it (1) serves no ancillary purpose, (2) allows independent licensing by participants, (3) includes only essential patents and (4) avoids grant-backs.
proposed a more liberal interpretation of the “essentiality” requirement for biotechnology pools. In general development of biotechnology or pharmaceutical products requires assembly of a large number of patents. Pool formation occurs necessarily at an early stage, as part of the product development strategy. Because at this stage the products are not in existence yet, it is difficult, if not impossible, to determine whether any given patent pool is “essential”, rather than “substitutable”. Applying the “essential” patent limitation in the context of an influenza virus patent pool, for instance, would be based on a mere assumption of their technological relation. An erroneous decision in this regard could render the pool useless. This constitutes a strong argument in favor of forgoing the essentiality requirement in the case of biotechnology pools, but it is, as yet, untested. As a precaution, a potential pool’s legal position would have to be bolstered by additional arguments. Lerner and Tirole suggest that a pool that allows independent licensing by the parties, would stand good chances of passing antitrust muster. In fact Lerner and Tirole suggest a “safe harbor” model according to which prima facie antitrust compliance could be achieved by meeting only two criteria: that the pool (1) serve no ancillary purpose and (2) allow for independent licensing of the individual patents by their owners. A structure based on this approach, would have a better chance of not being found anti-competitive, even in the absence of clarity on the question of patent essentiality.

11. The SARS Patent Pool

Relatively few precedents of biotechnology patent pools exist. The only pool in the influenza field is the genomic patents pool involving the SARS virus (severe acute respiratory syndrome “coronavirus”).

107 Some scholars believe that there is no harm to competition as long as at least one valid essential patent is included in the pool and independent licensing by all patentees is permitted. See generally, Richard Gilbert, Antitrust for Patent Pools: A Century of Policy Evolution, 2004 Stanford Technology Law Review 3 (2004). See also Lerner and Tirole, Public Policy, supra note 96.

108 Greene, supra note 25, at 1437. Whether government pronouncements in this regard hold true with respect to the biotech, and in particular the antiviral industry remains to be seen.

109 Lerner and Tirole suggest, based on a study of 63 different patent pools, that uncertainties with respect to antitrust scrutiny can be reduced by adhering to a “safe harbor” model, which (1) serves no ancillary purpose and (2) allows for independent licensing of the individual patents by their owners. Lerner Tirole, Public Policy, supra note 96, at 172.

110 E.g. the Medicines Patent Pool UNITAID pool for antiretroviral medicines www.medicinespatentpool.org and www.wipo.int/wipo_magazine/en/2011/03/article_0005.html; the AvGFP Green Fluorescent Protein, see E. van Zimmeren, From One-Stop to One-Stop-Shop: Patent Pools and
Following the SARS 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. Because it took an extended period of time to agree which patents to include, to craft the pool structure agreement and its licensing terms and to ensure that antitrust and other regulations were met, the SARS outbreak was contained before the pool’s completion. While the pool’s activity continues, it does so with less intensity. Because a business review was not requested, and the proposed structure has not been ruled upon by the DOJ and remains inconclusive as to its ultimate success.

112 Levy, et al. supra note 11, at 90.
114 Simon, et al. supra note 140, at 708.
115 Levy, et al, supra note 11, at 91; Goulding, supra, note 11, at 211
116 Id.
117 A number of other pooling arrangements exist, such as the pool for neglected tropical diseases formed by drug manufacturer Glaxo Smith Kline and one for diagnostic genetics, which creates patent pools for technical standards and other technology platforms. www.wipo.int/wipo_magazine/en/2011/03/article_0005.html.
Nonetheless the SARS pool experience suggests a few practical steps. As circumstances will inevitably demand urgency, advance development of a legal blueprint for formation of similar patent pools would be useful. The blueprint should consider inter alia, the fact that influenza virus pools are likely to consist in part or entirely of patent applications.\(^{118}\) The risk of non-issuance would therefore have to be neutralized.\(^{119}\) Further, because of the lengthy R&D process, the commercial endpoint is often not clear until the development process is concluded.\(^{120}\) Determinations of essentiality and substitutability at the stage of formation are therefore virtually impossible. Arguments regarding the pool’s legality under antitrust laws should be part of the blueprint.\(^{121}\) Along the lines suggested by Lerner and Tirole\(^{122}\) and Gilbert,\(^{123}\) the pool should provide for independent licensing.

Assuming an influenza-based patent pool can successfully overcome these hurdles and address the requisite antitrust problems,\(^{124}\) it would provide considerable benefits over individual licensing in that it would promote participation of multiple players in the market,\(^{125}\) stimulate innovation by granting access for research purposes and allow more efficient pricing.\(^{126}\) Pooling of patents derived from the influenza virus would defuse the tension among the recipient/patentees who compete for a share of the market, by forcing them to cross-license in a situation in which they might have denied licenses to each other. The number of players in a position to bring products to market would therefore be increased.

\(^{118}\) Levy, et al, supra note 11, at 91.

\(^{119}\) Id.

\(^{120}\) In the SARS context, the relationship between the patents and specific commercial products that might incorporate the patents’ teachings differed from the historical precedents. In the SARS case, as for genomics in general, commercial therapeutic and prophylactic products can be placed on the market only after a lengthy research and development process, and the range of possible commercial endpoints remains only partially defined until well into the development process. Levy, et al. supra note 11, at 92.

\(^{121}\) See supra text accompanying notes 133 et seq.

\(^{122}\) Lerner and Tirole, supra note 96.

\(^{123}\) Gilbert, supra note 107.

\(^{124}\) Some commentators suggest that patent pools are mostly appropriate in mature industries, in particular surrounding industry standards. Krattiger, supra note 59, at 141; Rimmer, supra note 111, at 358.

\(^{125}\) The usefulness of a patent pool increases with the number of patents required for assembling a product, and the number of individual transactions required to do so. Merges, supra note 64, at 1341.

\(^{126}\) Greene, supra note 25, at 117.
In short, it appears that a patent pool could serve as a beneficial IP governance model for the Framework.

12. Enforcing the Pooling Agreement

This leads to a final consideration, namely the vulnerability of the proposed structure to reluctant recipients. A recipient of virus samples, required by the SMTA to participate in a patent pool, can too easily prevent the pool’s formation by stalling negotiations. The entire structure would then become illusory. The SMTA could be given “teeth,” by providing that failure to form a pool would trigger default to a pre-established fixed royalty. The royalty could be a percentage of revenue from products based on the virus samples, which the recipient/patentee would become obligated to pay in the event a patent pool is not established. The critical element for this structure to be successful, is the level at which the royalty rate is set. If the rate is too low, the default may become preferable to the patent pool. It would allow parties to “buy” their exclusivity in the market by way of a low royalty and avoid sharing technologies with potential competitors. The result would in effect be a compensatory liability type regime, which, as discussed above, is not equipped to deal with patent thickets.127 If, on the other hand, the default rate is too high, it may be a deal breaker ab initio, in that parties might not enter the SMTA. The default rate would have to be just high enough to make a patent pool a more attractive option, and deter parties from electing the default. Therefore, if calibrated correctly, a default royalty rate can operate as safety mechanism to ensure that a patent pool is in fact formed.

CONCLUSION

The PIP Framework does not provide for an IP governance regime for inventions based on H5N1 virus samples released by WHO Centers to private parties under the Framework. The resulting unrestricted patenting does, contrary to conventional acceptance, not result in broad-based availability of products. Examination of the conditions along the downstream path of the virus samples reveals that the cumulative effect of a number of conditions causes the patent system to function sub-optimally. These conditions include the fact that all recipient/inventors rely on the same biological resource, that they seek to patent largely similar functionalities, that gene patents are sought early upstream and that patents in the field are narrow and fragmented. As a result, each developer must license-in multiple patents in order to obtain freedom to operate. These conditions give rise to patent thickets and

127 See supra text accompanying notes 86-88.
render development of products difficult or impossible. Furthermore, many of the licenses must be secured from competitors for the same market, a situation that is prone to hold-outs. When it comes to commercialization, the strong risk of a “single player” or a “no player” scenario exists, a scenario that does not support the Framework’s overall goal of providing broad-based availability of affordable medicines.

Based on the data points generated by the analysis, this paper considers an IP governance model that better meets the Framework’s goal of availability and affordability. The proposal is a cross-licensing arrangement in the nature of a patent pool. Its conceptual premise is to re-allocate IP rights among the recipient/inventors, so that each has freedom to operate from a patent perspective. This would reduce the players’ profit potential, but, on the other hand, would also reduce their risk of not being able to commercialize. A larger number of players would bring product to market. Overall, the proposed model would better meet the objectives of broader availability and affordability of influenza-related medicines.