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Intellectual Property and Public Health – A White Paper

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INTELLECTUAL PROPERTY AND PUBLIC HEALTH – A WHITE PAPER

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I. INTRODUCTION

On October 26, 2012, The University of Akron School of Law's Center for Intellectual Property and Technology hosted its Sixth Annual IP Scholars Forum. In attendance were thirteen legal scholars with expertise and an interest in IP and public health who met to discuss problems and potential solutions at the intersection of these fields. This report summarizes this discussion by describing the problems raised, areas of agreement and disagreement between the participants, suggestions and solutions made by participants, and the subsequent evaluations of these suggestions and solutions.

Led by the moderator, participants at the Forum focused generally on three broad questions. First, are there alternatives to the patent system or specific patent doctrines that can provide or help provide sufficient incentives for health-related innovation? Second, is health information being used proprietarily, and if so, is this use appropriate? Third, does IP conflict with other non-IP values that are important in health, and how does or how can IP law help resolve these conflicts? This report addresses each of these questions in turn.

II. THE PATENT SYSTEM AND ITS ALTERNATIVES

The IP Forum began by noting that although there are numerous problems with the patent system, such as high costs for prosecution¹ and litigation,² uncertainty as to patent validity,³ and nebulous terms and concepts like “non-obviousness,” “utility,” and “novelty,”⁴ many consider patent law the primary driver of health-related innovation in the United States.⁵ In fact, some have argued that patents are the best way to incentivize innovation and that the United States patent system is the

1. See Ted Sichelman & Stuart J.H. Graham, *Patenting by Entrepreneurs: An Empirical Study*, 17 MICH. TELECOMM. & TECH. L. REV. 111, 167-68 (2010).

2. See James Bessen & Michael J. Meurer, *Lessons for Patent Policy From Empirical Research on Patent Litigation*, 9 LEWIS & CLARK L. REV. 1, 2 (2005).

3. See Harry Surden, *Efficient Uncertainty in Patent Interpretation*, 68 WASH. & LEE L. REV. 1737, 1740-42 (2011).

4. See Tun-Jen Chiang, *A Cost-Benefit Approach to Patent Obviousness*, 82 ST. JOHN'S L. REV. 39, 40-41 (2008).

5. See Anna B. Laakmann, *An Explicit Policy Lever for Patent Scope*, 19 MICH. TELECOMM. & TECH. L. REV. 43, 93 (2012) (stating that “[p]atent law shapes biomedical innovation,” but noting that federal research funding also plays a role); see also Andrew W. Torrance, *Nothing Under the Sun that is Made of Man 31* (Oct. 24, 2012) (unpublished manuscript) (on file with reporter) (“Biotechnology owes much of its rapid progress to the availability of patent protection for genes and their polypeptide products.”).

best in the world.⁶ The underlying rationale is an oft-told story. We have a free market economy which ultimately lets consumers decide, *ex post*, which innovations were worthy investments of research and development.⁷ This may be superior to a grant system which, *ex ante*, puts the valuation decision in the hands of the government or other institutions and could squander limited resources on ineffective, inefficient, or impractical innovations.⁸ In short, the market can, and should, provide the incentives for innovation.

The discussion began by questioning this traditional premise. Is it true that markets are the best way to incentivize health-related innovation? Are there alternatives to the patent system that would work better? Or are there ways to improve the patent system so it works better?⁹

A. *Incentivizing What?*

An important and foundational issue to discerning how the patent system can be improved or what alternatives would be better is understanding what goals the patent system should seek to achieve and whether it actually achieves them. Apropos of the Forum's focus on health care, these same questions can be asked with respect to the role of patents driving innovation in health care. Nevertheless, strong reasons for market failure in health care innovation make asking these same questions particularly difficult.

For hundreds of years we have thought that the patent system is the best system for innovation, but we really have no idea whatsoever. Reference was made to a National Academy of Sciences study, which

6. See *United States v. Line Material Co.*, 333 U.S. 287, 335 n.12 (1948) (Burton, J., dissenting) (citing H.R. Doc. No. 78-239, available in National Patent Planning Commission, *The American Patent System*, 25 J. PAT. OFF. SOC'Y 455, 457 (1943) ("The strongest industrial nations have the most effective patent systems, and after a careful study, the Commission has reached the conclusion that the American system is the best in the world.")).

7. Jane M. Marciszyn, *What Has Happened Since Chakrabarty?*, 2 J.L. & HEALTH 141, 141-42 (1988) (quoting Arthur R. Whale, 7 APLA Q.J. 172 (1979)); see also SUZANNE SCOTCHMER, *INNOVATION AND INCENTIVES* 58 (2006) ("As an incentive mechanism, intellectual property has the following virtues: 1. The reward is linked to the social value of the invention, so that firms will, to some degree, compare social value and social cost when deciding whether to invest. 2. Users of the intellectual property voluntarily pay the costs, so no one objects to its development.").

8. See Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115, 194-95 (2003).

9. One such proposal for reforming patent law is included in Thomas C. Folsom, *Algorithm Methods and Their Biological Issue* (Oct. 20, 2012) (unpublished manuscript) (on file with reporter).

concluded that “we need a much more detailed understanding of how the patent system affects innovation in various sectors.”¹⁰ For example, patents could work wonderfully to incentivize innovation in the biotechnology sector, but could stifle innovation in the computer hardware sector. Other studies suggest that our patent system may not be incentivizing innovation at an optimal rate.¹¹ It could be that the patent system is the best system for promoting innovation. Perhaps it is not. But if we choose to rely on the patent system for so much, such as providing excellent innovations in health care, then we really should have a better idea rather than simply assuming this is the case. As mentioned earlier, the reasons for market failure make health care an especially difficult case.

Perhaps a more fundamental issue is what patents, or any other systems, are supposed to incentivize. Are they supposed to incentivize invention, development (i.e. delivering inventions in tangible ways), or both? If both, to what extent? Although both invention and development relate to innovation, they are two distinct parts of the process. For example, it was noted that medical technologies often come out of research universities based on subsidies. It is after patents are applied for or obtained that pharmaceutical and medical device companies develop these technologies. This illustrates the importance of patents on the development side rather than the invention side. Yet, without the proper focus on invention and development, this may lead to less than optimal results. For example, having a lot of inventions that are never developed is undesirable. Likewise, fully developing the only existing invention is undesirable. It seems that the system we endorse should try to drive both invention and development.¹²

B. Overbroad and Overcomplex?

A potential problem with relying on the patent system to incentivize health-related innovation is the overbreadth and overcomplexity of the patent system. Jim Chen suggested that the problem with the Patent Act was its Swiss army knife characteristic – it tries to accomplish

10. NAT’L. RESEARCH COUNCIL OF THE NAT’L. ACADS., A PATENT SYSTEM FOR THE 21ST CENTURY 2 (Stephen A. Merrill et al. eds., 2004).

11. See, e.g., Andrew W. Torrance & Bill Tomlinson, *Patents and the Regress of Useful Arts*, 10 COLUM. SCI. & TECH. L. REV. 130, 167 (2009).

12. See Jay Dratler, Jr., *Invention is a Process, or Why the Electronics and Pharmaceutical Industries are at Loggerheads over Patents* (Univ. of Akron Sch. of Law Legal Studies Research Paper Series, Paper No. 06-13, 2006), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=899924.

everything by having been written with broad applicability and without being technology-specific. The Patent Act serves as an open charter for innovation much like the Sherman Act does for free enterprise and competition.¹³ The Patent Act can be considered overbroad at the formal statutory level because it is written as if it were a constitution.¹⁴ In fact, the core of the Patent Act is a few sections with short phrases replete with excessive generalities.¹⁵ It is unlike the Food, Drug, and Cosmetic Act, which is a classic regulatory statute with amazing specificity.¹⁶

Some Forum participants argued that overcomplexity results because of this broad, constitution-like language. Congress has, by using broad language, delegated innovation policy to the courts to develop common law-esque doctrines under the language of sections 101, 102, 103, and 112 of the Patent Act.¹⁷ Because of this delegation, the courts have created an extraordinarily complex system that appears ad hoc and devoid of any meaningful structure tied to the validity of science or its application to solving human problems.¹⁸

For several participants, one of the major flaws of the patent system is that it is too general and does not focus on separate technologies or industries. TRIPS now requires this uniform approach to patent law.¹⁹

13. Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 53 (2010) (asserting patent stakeholders should keep in mind that the patent code, much like the Sherman Act, is a common law enabling statute, leaving ample room for courts to fill in the interstices or to create doctrine emanating solely from Article III's province).

14. One explanation for this is that the first patent act, Act of April 10, 1790, ch. 7, 1 Stat. 109, which serves as the basis for the current patent act, was written nearly contemporaneously with the U.S. Constitution.

15. See, e.g., 35 U.S.C. § 101 (2012) (listing patentable subject matter as covering processes, machines, manufactures, or compositions of matter, or any new and useful improvement thereof); 35 U.S.C. § 103 (2012) ("A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.").

16. See 21 U.S.C. §§ 301-399d (2012).

17. Obviousness, inherent anticipation, and infringement under the doctrine of equivalents are all examples of vague, but key, concepts that courts have been forced to develop as a result of Congress's use of broad language in the Patent Act.

18. See Jay Dratler, Jr., *Fixing Our Broken Patent System*, 14 MARQ. INTELL. PROP. L. REV. 47, 66 n.60 (2010).

19. See Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS] ("Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, *in all fields of technology*, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this

But not all participants agreed this was problematic. There was a fairly even split on whether the Patent Act's one-size-fits-all approach was a good idea. Some detractors of TRIPS's uniformity principle viewed varied patent terms, stronger patentability requirements, and the need for actual reduction to practice as positive developments for invention and development.

To justify the TRIPS approach to a broad, non-discriminatory patent system, participants pointed out that when the U.S. patent system was first created, the United States was a least-developed country, and the hope for our patent system was from that perspective. We used this system to move from newly-released colony to world power. Perhaps this same approach can be useful to other developing nations and permit them to rapidly innovate like the United States has done.

With respect to the Patent Act bearing resemblance to a constitution, participants pointed out that that this broad language has served as an umbrella to more than one patent system. That is, our patent system has changed based on how the courts have interpreted the broad standards set forth in the Patent Act. And it is for this reason that we cannot answer the question of whether the patent system works; it is always changing due to changed circumstances. We have ratcheted up and down the standards for obviousness, patentable subject matter, utility, etcetera; and the one-size-fits-all approach has allowed this to happen.²⁰

Although courts have traditionally undertaken this "ratcheting" role, we should also ask what other institutions should play a role in shaping innovation policy. Sometimes courts shape policy in a way that includes other institutions, such as the U.S. Patent and Trademark Office (PTO), industry stakeholders, and the general public,²¹ but not always. Perhaps the PTO should be more involved in the process of establishing policy to incentivize innovation.²² Given its frequent interactions with innovators, the PTO may be well-situated to help determine if the rules we have established for promoting innovation actually reflect how innovation takes place. Alternatively, or perhaps additionally, we may

Article, patents shall be available and patent rights enjoyable *without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*") (emphasis added).

20. See Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1576-77 (2003).

21. See generally Ryan Vacca, *Acting Like an Administrative Agency: The Federal Circuit En Banc*, 76 MO. L. REV. 733 (2011).

22. See Melissa F. Wasserman, *The Changing Guard of Patent Law: Chevron Deference for the PTO*, 54 WM & MARY L. REV. 1959, 2007-18 (2013).

need some other administrative agency or non-governmental organization to give its input on innovation policy. Whatever form it takes, it could be helpful in developing a focused and particularized patent system or an effective, broad system, but at least it would be a more informed system.²³

Despite some participants' pushes for a more technology-specific approach to patent law, others were resistant. A comparison was made between this approach to patent law and copyright law. In contrast to the Patent Act, the Copyright Act has incredibly detailed provisions.²⁴ It was suggested that before adopting a detailed approach to patent law, we must ask ourselves whether the current patent system is worse than the copyright system. To some, it is not clear that it is worse.

C. Alternatives to the Patent System

Participants discussed many alternatives to the patent system. The list of possibilities that could incentivize innovation included Regulatory Competitive Shelters (RCSs),²⁵ such as the exclusive marketing periods for certain generic drugs, biologicals, and other innovations provided under the Hatch-Waxman Act and similar statutes;²⁶ prizes;²⁷ government subsidies and education;²⁸ other types of IP, such as copyright protection;²⁹ and open user and collaborative innovation systems.³⁰ RCSs and collectively governed systems received the most attention and are discussed in detail below.

Despite the variety of alternatives to patents, participants noted that the success of these alternatives depends on the industry and technology. One system may work very well for the medical industry, but not so well

23. If it turns out that a particularized, technology-specific system is optimal, then article 27 of TRIPS very much hampers our ability to use patent rights most effectively. See TRIPS, *supra* note 19.

24. See, e.g., 17 U.S.C. §§ 110(5), 111, 112, 114, 115 (2012).

25. See discussion *infra* Part II.C.1.

26. See generally Yaniv Heled, Regulatory Competitive Shelters – An Emerging Class of Administrative Properties (Oct. 17, 2012) (unpublished manuscript) (on file with reporter).

27. See, e.g., XPRIZE, <http://www.xprize.org> (last visited Aug. 20, 2014); see also Steven Shavell & Tanguy Van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525, 525-26 (2001).

28. See Paul M. Romer, *Endogenous Technological Change*, 98 J. POL. ECON. S71, S96-97 (1990).

29. See, e.g., Andrew W. Torrance, *DNA Copyright*, 46 VAL. U. L. REV. 1, 3 (2011); Dan L. Burk, *Copyrightability of Recombinant DNA Sequences*, 29 JURIMETRICS J. 469, 470-71 (1989).

30. See discussion *infra* Part II.C.2; see generally Katherine J. Strandburg, *User Innovator Community Norms: At the Boundary Between Academic and Industry Research*, 77 FORDHAM L. REV. 2237 (2009).

for the software industry. Even within a particular industry, optimal systems may vary. For example, within the medical industry, one alternative might work very well for pharmaceuticals, but not great for medical devices. Perhaps an alternative works well for diabetes drugs, but not very well for cancer drugs. This analysis can become fractured very quickly when discussing whether and to what extent these alternatives work.

Another suggested alternative to incentivizing innovation was not really an alternative system, but a rejection of all systems. Taken from Matt Ridley's work, one participant posited that innovation simply happens regardless of what we do to incentivize it.³¹ That is, innovation happens at an increasing trend because there are more and more ideas and more and more people to combine ideas – and it may not matter if we have patents, copyrights, prizes, regulations, or anything else for that matter.³² Innovation occurs whether we want it or not. This was a comforting thought to some who were convinced that it is impossible to design a system where moneyed-interests are not trying to get the best advantage and where the behemoths that developed the initial technology have driven innovators to work within that ecosystem rather than develop an entirely new one.³³

1. Regulatory Competitive Shelters

One solution proposed by Yaniv Heled was the further use of RCSs, which are specifically crafted shelters from competition afforded by the government to give competitive advantages to those who invest in bringing technology to the market.³⁴ An example of an RCS regime is the one instituted under the Hatch-Waxman Act whereby the U.S. Food and Drug Administration (FDA) affords a variety of exclusivity periods to drug developers who disclose clinical trial data about new chemical entities, new uses for old drugs (including in pediatric populations), and bioequivalence data.³⁵ A participant suggested that a system of RCSs

31. See generally MATT RIDLEY, *THE RATIONAL OPTIMIST: HOW PROSPERITY EVOLVES* (Harper Collins Publishers 2010).

32. *Id.*

33. See, e.g., FEDERAL TRADE COMMISSION, *TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY* 6-7 (2003) (“One panelist asserted that the time and money his software company spends on creating and filing these so-called defensive patents, which ‘have no . . . innovative value in and of themselves,’ could have been better spent on developing new technologies.”) (internal citations omitted).

34. See Heled, *supra* note 26.

35. 21 U.S.C. §§ 355(c)(3)(E), 355(a) (2012); see also *Pandemic and All-Hazards Preparedness Reauthorization Act of 2013*, Pub. L. No. 113-5, 127 Stat. 161, 191-92 (codified as

replace the difficult concepts of novelty and non-obviousness with experimental results on safety and efficacy,³⁶ which is what scientists in the health care industry really desire. In addition, an RCS system would not involve the costs of patent prosecution and the ensuing litigation, claim construction, or the difficult concept of non-obviousness which, it was noted, helps promote attorneys' fees, but not much innovation.

However, there was concern that if we used an RCS model instead of a patent model, then we would simply shift the costs and uncertainties of complications from the patent system to the FDA, which has its own institutional delays and inefficiencies. Perhaps the FDA's delays and inefficiencies are less pronounced than those in the PTO and in the patent litigation context, but it was agreed that an RCS model is not a panacea.

One comment made about RCSs was that the data submitted to the FDA are typically held in confidence. This concerned some participants. If exclusivity is given, then why the need for all of the secrecy?³⁷ Some participants argued that consumers should know more about clinical trial results so they can make more informed choices about whether they are willing to pay more for a new drug than an old one.

Other participants further noted that just because it may be desirable to have different solutions for different areas of technology, this does not mean that immediately regulating every emerging technology or industry is advisable. In fact, someone suggested that the patent system is probably a good default system until a certain industry or technology gets its own regulatory system. But once regulation of a certain area starts, RCSs are a good method of incentivizing innovation. Of course, RCSs are not perfect, but they do take scientists and consumers down to real world utility that is important. In addition to the concerns expressed above, some problems with RCSs are: (1) they are subject to abuse; (2) rarely is there an effective advocate for the public as a whole; and (3) an agency serves as a gatekeeper, and sometimes agencies get captured. Of course, patents may suffer from the same problems. Despite these potential problems, RCSs may solve some industries' problems, and it may be advisable to require innovators to opt

amended in scattered sections of 21 U.S.C. and 42 U.S.C.).

36. This can be thought of as a more meaningful form of the utility requirement of patentability.

37. See Rebecca S. Eisenberg, *Data Secrecy in the Age of Regulatory Exclusivity*, in *THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH* 467-91 (Rochelle C. Dreyfuss & Katherine J. Strandburg eds., 2012).

for either patent rights or an RCS.³⁸

2. Collectively Governed Systems

Another alternative to the patent system that was discussed in depth was collectively governed systems for innovation that do not rely on exclusive legal rights. Professional norms and open source software are examples. Such systems are not true alternatives to patents, but instead, are systems that can coexist with patents. That is, the patent system and specific doctrines often have a big impact on the viability of those other systems, which affects not only the amount of innovation but also what innovation we get.³⁹

These other institutions and how they interact with the patent system can partly determine at what point in the innovation process we should have patent rights. For example, with respect to pharmaceuticals, patent doctrine has pushed exclusivity up the chain of generality so that utility has ceased to be a requirement and is more like an exception. That is, to get a patent on a new drug, one does not need to show that it works at all; all that needs to be shown is that it *might* work.⁴⁰ Of course, although patent law does not require efficacy, pre-marketing regulation does require proof of efficacy and safety.⁴¹

One explanation for the lack of new drugs in the pharmaceutical industry is that the amount of exclusivity given is insufficient. As a result, there is a lot of talk that the pharmaceutical companies are interested in engaging in open innovation and public-private partnerships. It is unclear whether this is a real attempt to change the

38. See generally Yaniv Heled, *Why Primary Patents Covering Biologics Should be Unenforceable Against Generic Applicants Under the Biologics Price Competition and Innovation Act*, 21 ANNALS HEALTH L. 211 (2012).

39. See, e.g., Katherine J. Strandburg, *Legal But Acceptable: Pallin v. Singer and Physician Patenting Norms*, in INTELLECTUAL PROPERTY AT THE EDGE: THE CONTESTED CONTOURS OF IP 321, 336-37 (R. Dreyfuss & J. Ginsburg eds., Cambridge Univ. Press 2014) (describing section 287(c) of the Patent Act and how this provision interacts well with physicians' norms).

40. See *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995).

41. 21 U.S.C. § 355(a) (2012); see generally Katharine Van Tassel, *Regulating in Uncertainty: Animating the Product Public Health Safety Net to Capture Consumer Products that Use Innovative Technologies such as Nanotechnology, Genetically Modified Food and Cloned Meat*, 2013 U. OF CHI. LEGAL F. 433 (describing the burden of proof that manufacturers bear to establish both safety and effectiveness for drugs through the premarket approval process under the Food, Drug, & Cosmetic Act); see also Jay Dratler, Jr., *IP and Health Care: New Drugs Pricing and Medical Mistakes*, 7 AKRON INTELL. PROP. J. 1, 5 (2014) ("Not only do drug innovators have to create something new, safe, and effective, they also have to prove it is safe and effective in large-scale clinical trials that are among the most complex, tricky, and expensive things that any industry does.").

institutional structure for innovation or whether it is just another road to move invention and development towards subsidies rather than exclusivities.⁴² Nonetheless, it exemplifies the interplay between these institutions.⁴³

Reputational credit and other non-pecuniary interests may also incentivize innovation. Several participants thought these could play an enormous and important role as there are situations where economically motivated people use collaborative innovation.⁴⁴ Early in the development of some industries, there are periods where everyone shares everything.⁴⁵ To fully take advantage of these alternative motivating forces we must engage in more research to understand when and why this happens and what the pros and cons are when compared to the market-based patent system.

Another suggested modification to the patent system was doing more with exemptions to infringement. The basic idea is to have a fair use doctrine in patent law, but unlike that in copyright law.⁴⁶ Such a doctrine accounts for these alternative innovation systems and considers their vitality in light of the existence of patents.⁴⁷ For example, if we have an alternative system for promoting innovation in research, such as

42. Another explanation for the lack of new drug development is that too many early-stage patents are hindering or actually blocking follow-on innovation. See Jay Dratler, Jr., *Combinatorial Mathematics and the Problem of Early-Stage Patents in Biotechnology* (Univ. of Akron Sch. of Law Legal Studies Research Paper Series, Paper No. 06-13, 2007), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=959462. Because of these patent “thickets,” pharmaceutical companies may be searching for alternatives.

43. Another example of this is taking place at The University of Akron, where the Timken Company has partnered with the University and is engaging in open innovation with its core technology to help foster further innovation in other industries where this technology may be useful (e.g., biomedical products and devices) and to further develop the technology so it can be useful to Timken. See *New University Lab Promotes Idea-Sharing and Innovation*, THE UNIVERSITY OF AKRON (Oct. 19, 2012), http://www.uakron.edu/im/online-newsroom/news_details.dot?newsId=31b16504-04a9-48d0-92fd489a94dfbfbf&pageTitle=Top%20Story%20Headline&crumbTitle=New%20University%20lab%20promotes%20idea-sharing%20and%20innovation.

44. See, e.g., Strandburg, *supra* note 39, at 336-37 (describing ophthalmologists rejecting patents on surgical techniques because they have always documented originality by publication and place information sharing and patient care as a higher priority).

45. See Robert C. Allen, *Collective Invention*, 4 J. ECON. BEHAV. & ORG. 1 *passim* (1983); see also Peter B. Meyer, *Episodes of Collective Invention* (U.S. Dept. of Labor, Bureau of Labor Statistics, Working Paper No. 368, 2003), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=466880.

46. See generally Katherine J. Strandburg, *Patent Fair Use 2.0*, 1 U.C. IRVINE L. REV. 265 (2011).

47. *Id.* at 299. This exemption is broader than the already existing, but limited, experimental use exemption. See generally Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81 (2004).

reputational interests, and this system does not use patents, then the exemption should consider the fact that the alternative system may be vulnerable to attacks from the outside (via patent infringement) because it does not have blocking patents to assert as leverage. Although not dispositive, this factor would weigh in favor of an exemption.⁴⁸

More concretely, if we think medical doctors are basically the only people doing important innovative work in medical procedures and they have a system in place that rewards innovation in medical procedure without the use of patents, then we may want to sacrifice the occasional electrical engineer who comes up with a great medical procedure because allowing an outsider to have patent rights and enforce them against the medical doctors would threaten the whole alternative system.⁴⁹ This is the rationale behind section 287(c) of the Patent Act.⁵⁰ Section 287(c) extinguishes the remedy against infringing physicians performing a patented medical procedure and effectively deals with the inventor from outside the physician system as well as those inside the system who want to defect and take their innovation to the market-based patent system.⁵¹ Such an exemption protects the alternative system.⁵²

As an institutional matter, we should really ask if we think the best innovation will occur within one or more of these alternative systems. If so, we should be willing to sacrifice a particular inventor so as to preserve the alternative systems. Such a view of fair use could be used to protect the alternative systems and could be narrowly tailored.⁵³

In sum, we must continue to consider what the patent system should encourage and whether the Patent Act's current structure achieves those ends. Despite these fundamental inquiries, policymakers and health care stakeholders should closely consider the suggested alternatives to patent law as they may spur innovation without the same deadweight loss generated by patents.

48. See Strandburg, *supra* note 46, at 300-01.

49. See generally Strandburg, *supra* note 39, at 341-42.

50. See 35 U.S.C. § 287(c) (2012).

51. See *id.*

52. *Id.* Section 287(c) does not apply to drugs and medical products. 35 U.S.C. § 287(c)(2)(A) (2012) (“‘[M]edical activity’ means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.”).

53. Of course, such a proposal raises other questions, including whether such a system would increase uncertainty and litigation costs and how the norms of the physicians would be established in the courtroom.

III. PROPRIETARY HEALTH INFORMATION

During the next portion of the Forum, the participants shifted their focus to data about health care and health-related innovations. This discussion was comprised of two parts. The first part dealt with data related to pricing, costs, and value of health care. The second part dealt with personal data and privacy.

A. Pricing, Costs, and Value

As illustrated by the interest in the use of RCSs, which provide shelters from competition for disclosing, *inter alia*, clinical trial data,⁵⁴ there is an emphasis on IP protection not just for how products are made, but also for information about products. What is needed is a way to incentivize the creation of information about products and to incentivize using the information in the health care system via comparative effectiveness research about the products. Doing so will better equip consumers and the government to understand how we pay for drugs. For example, if a drug gives marginally better treatments for a disease, then perhaps we should only pay marginally more for it. In essence, the system should incentivize not just information creation, but also disclosure of the information, including information about prices and effectiveness. Disclosure of this type of information is distinct from disclosures about safety and efficacy that already take place for regulatory approval.

An underlying problem with respect to the use of data is the free market economy does not work very well with respect to medical care. The prices negotiated between the insurance companies and providers are secret to everyone outside of the negotiation, such as other providers, patients, and insurance companies.⁵⁵ This, in effect, creates a black box.⁵⁶ Participants suggested that if more price information was disclosed, then this may lead to more competition between health care providers on quality rather than negotiating the best set of prices. This is because patients could easily compare the prices and take them into account, along with other information such as quality outcomes, when deciding on a course of care. In short, the hope is for less innovation on complex multivariate pricing formulas, which is a symptom of financialization in certain areas, and a move towards good indicators of

54. See discussion *supra* Part II.C.1.

55. See Frank Pasquale, *Cultivating, Complementing, & Curbing IP Protections for Health Care Data*, (Oct. 22, 2012) (unpublished manuscript) (on file with reporter).

56. *Id.*

quality and what is actually effective.

For example, in a study of pricing data for chest x-rays at California hospitals, some hospitals charged patients close to \$200 while another charged approximately \$1,500.⁵⁷ Likewise, in Boston, a study showed that Massachusetts General Hospital (MGH) charged \$51,000 for coronary bypass procedures whereas the Boston Medical Center charged \$34,000 for the same procedure.⁵⁸ It may be that MGH provides better services, obtains better results, or receives the more difficult cases. But if consumers have access to the data, then they can analyze it to see if the different pricing is based on quality differentials or differential pricing power. It was noted, however, that some services are easy to compare between providers, such as taking an x-ray. Nearly every provider does this the same way, making it easy to compare. But diagnosis is completely different. The unique circumstances of each patient complicate this comparison between providers. As a result, disclosure of pricing data may effectively create competition on quality of care in some circumstances, but may be less helpful in others.

Assuming disclosure of pricing data results in a net gain, an important question is how we use certain levers in health law to reveal how certain things are priced. Small steps have been made toward getting inside the black box.⁵⁹ Some participants hope that implementing health care reform will provide easier access to this data because there will be more of an emphasis on revealing it.⁶⁰

The black box nature of health care data distinguishes its pricing from other markets – no one goes in knowing the price. Patients' inability to negotiate further distinguishes the health care market. If you go to the hospital with a kidney stone, you are not going to negotiate a price – you are paying whatever it costs to fix the problem. As stated by one participant, "health economics is the poster child for market failure." We cannot have a pure free market system for health care in the United States because there are so many built-in exceptions to the neoclassical

57. Lucette Lagnado, *California Hospitals Open Books, Showing Huge Price Differences*, WALL ST. J. (Dec. 27, 2004, 12:01 AM) <http://online.wsj.com/article/SB110410465492809649.html>.

58. Aaron Atencio, *Comparable Quality, Different Prices*, BOSTON GLOBE, Nov. 16, 2008, <http://www.boston.com/news/health/articles/2008/11/16/differentprices>.

59. See generally Uwe E. Reinhardt, *The Pricing of U.S. Hospital Services: Chaos Behind a Veil of Secrecy*, 25 HEALTH AFF. 57 (2006).

60. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2718, 124 Stat. 119, 136-37 (codified as amended in scattered sections of 26 U.S.C., 31 U.S.C., and 42 U.S.C.) (2010); see also *How to Research Health Care Prices*, WALL ST. J. (Dec. 4, 2009), <http://guides.wsj.com/health/health-costs/how-to-research-health-care-prices>.

free market, such as information asymmetry, lack of choice, and lack of transparency.⁶¹ Third-party payment further complicates this situation, as the person paying (the insurer) is not the person receiving the benefit (the patient). Given this difference in market structure, why do we allow a black box system to exist? Protection of this type of data makes it so there is no rational relationship between the price that is billed and the service provided.⁶²

With this skepticism about health care markets, what should be done about them? Rhetorically, one participant questioned if we were proposing a public utilities commission model for health care. Participants suggested several possible solutions or improvements to the market problem. First, it was noted that some areas had a system where all insurers paid the same price to the same hospital (a most favored nation type system).⁶³ If the provider charged \$850 to an insurer for a particular procedure, then it must charge \$850 to all insurers for the same procedure. A different provider could charge a different price, however. These most favored nation clauses could help the market distortion problem at least between insurers and providers.

A second suggestion was administered pricing, which is a system with a formula that takes into consideration multiple factors, such as the skill of the doctor, how much effort is required, how much concentration is needed, how much time the procedure takes, etcetera.⁶⁴ Despite the attraction of administered pricing, it is very slow to change. For example, we may have a procedure at time zero and it is very laborious. But later we have a change in technology that makes the procedure much easier to perform. Until the inputs to the formula are updated, the providers are still paid at the higher rate. It oftentimes takes a long period of time for the change in price to take effect.

A third suggestion was using the data available from other countries

61. This is not necessarily the case for all medical procedures, however. Elective procedures appear to be the exception. Lasik surgery is a great example. The cost of Lasik was pretty high, but now it is fairly cheap because consumers have the ability to shop around and get the best combination of quality and price.

62. Compare this with the market-based system underlying patent law discussed *supra* Part II.

63. James C. DeChane, *Preferred Provider Organization Structures and Agreements*, 4 ANNALS HEALTH L. 35, 59-62 (1995); Anthony J. Dennis, *Most Favored Nation Contract Clauses Under the Antitrust Laws*, 20 U. DAYTON L. REV. 821, 822-24 (1995); Arnold Celnicker, *A Competitive Analysis of Most Favored Nations Clauses in Contracts Between Health Care Providers and Insurers*, 69 N.C. L. REV. 863, 868-69 (1991).

64. Timothy Stoltzfus Jost, *The Most Important Health Care Legislation of the Millennium (So Far): The Medicare Modernization Act*, 5 YALE J. HEALTH POL'Y L. & ETHICS 437, 439 n.14 (2005).

as a guide for health care pricing in the United States. These countries permit use of the same procedures and equipment as the United States and they make their data available.⁶⁵ These countries allow one price to be charged for procedure *X*, and the price is public. Of course, it may not be the “right” price for the United States, but it could be used as a good baseline to compare the American prices to and to ask why providers here are charging so much more.⁶⁶

A fourth suggestion for an alternative to the current market structure is Accountable Care Organizations (ACOs). “An ACO generally is defined as a local organization comprised of and controlled by primary care physicians, specialists, and other providers that are jointly accountable for the cost and quality of the full continuum of care delivered to a patient population.”⁶⁷ Right now, chronic illness accounts for a large portion of the total cost of health care.⁶⁸ By some estimates, 20% of patients make up 80% of the costs.⁶⁹ ACOs are tasked with reducing what they spend while maintaining quality over a given population.⁷⁰ If they are successful, then the ACOs receive additional money.⁷¹

Despite focusing on solutions that using data could provide, it was pointed out that data will not answer all of the questions. There are still value judgments to be made behind the data. For example, we may have a more effective pill that can be taken once per week instead of daily. Because of this, the pill generates an increased rate of compliance, but the weekly pill costs more than the daily pill. How do we value the patient’s convenience? Do we take the attitude that if people cannot be bothered to take their medicine once a day, then we should not be willing to pay an extra \$100 for their convenience? No consensus was

65. See, e.g., Alberta Health Care Insurance Plan (2012), available at <http://www.health.alberta.ca/documents/SOMB-Medical-Prices-2012-04.pdf>; Ontario Ministry of Health and Long-Term Care, Schedule of Benefits for Physician Services Under the Health Insurance Act (2013), available at http://www.health.gov.on.ca/english/providers/program/ohip/sob/physerv/physerv_mn.html.

66. One commentator points out that many variables affect pricing across national boundaries, such as customs, exchange rates, and standards of living, and queries whether it would be better to study the effect of secrecy and regulation on pricing.

67. Jessica L. Mantel, *Accountable Care Organizations: Can We Have Our Cake and Eat it Too?*, 42 SETON HALL L. REV. 1393, 1410 (2012).

68. Mark W. Stanton, *The High Concentration of U.S. Health Care Expenditures*, RESEARCH IN ACTION, June 2006, at 3, available at <http://www.ahrq.gov/research/findings/factsheets/costs/expriach/expendria.pdf>.

69. *Id.*

70. Mantel, *supra* note 67, at 1410-11.

71. *Id.*

reached among the participants on how to make these value judgments, but everyone agreed that they can and should play an important role.

Most participants agreed that the health care market is in failure and is replete with problems caused, in part, by a lack of access to pricing and quality data. The suggestions discussed at the Forum aimed to reduce the opacity of health care and to explore the few advances that have been made. Nonetheless, a tremendous amount of reform is still required.

B. Personal Data and Privacy

Not all health care data are the same.⁷² The discussion up to this point focused on pricing and value data. But personal and genetic data could be very helpful in providing better health care. However, laws such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA)⁷³ and the Genetic Information Nondiscrimination Act of 2008 (GINA)⁷⁴ may protect this type of data from disclosure and complicate efforts to obtain it. For example, one research organization reported that HIPAA (1) reduced patient recruitment; (2) increased selection bias; (3) increased the costs of research by requiring additional paperwork and complicating Institutional Review Board (IRB) processes; (4) increased errors when de-identified information was used; and (5) caused project abandonment.⁷⁵ The difficulties created by privacy laws raised the following questions: whether protection for personal health data is important, and whether these privacy laws create obstacles to the medical profession using digital technology to share such data.

Some participants argued that some patients are not very concerned about their personal health data because they do not suffer from any illness or condition that would cause them to be embarrassed, ridiculed, or discriminated against. The argument continued that because many (or perhaps most) patients are not concerned about their personal health data, the laws protecting such data create needless inefficiencies and

72. See Timothy S. Hall, *The Quantified Self Movement: Legal Challenges and Benefits of Personal Biometric Data Tracking*, 7 AKRON INTELL. PROP. J. 27, 27-28 (2014) (describing purchasing data predicting influenza outbreaks and the use of biometric data from pedometers and nutritional tracking apps to improve health outcomes of individuals).

73. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended in scattered sections of 18, 26, 29, & 42 U.S.C.).

74. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (2008) (codified as amended in scattered sections of 26, 29, & 42 U.S.C.).

75. Fred H. Cate, *Protecting Privacy in Health Research: The Limits of Individual Choice*, 98 CALIF. L. REV. 1765, 1795-96 (2010) (quoting Subcomm. on Privacy and Confidentiality, National Comm. on Vital and Health Statistics (Nov. 19, 2003)).

make using the personal health data more difficult.

Several participants took issue with this argument. One participant argued that what prevents the medical profession from using technology that would support the interchange of data is the lack of standards and the interchangeability of file formats.⁷⁶ Another participant noted that the American Recovery and Reinvestment Act of 2009 provides incentives to make meaningful use of health records, so steps are being made to solve this problem.⁷⁷

Another response to the needless inefficiency argument was that we should not think about privacy in a choice paradigm (i.e., that privacy is wholly about whether one thinks his or her information is private). The problem with this model is that for any particular topic, an overwhelming majority of people do not care about protecting their information.⁷⁸ Therefore, if a vote on any one particular issue were held, the result would always be to share the information.

So privacy is really a minority protective device and a social concept. It is not good enough to say that we can let people decide, and if someone has a special reason to keep his or her information private, then he or she can ask for it to be kept private. The problem with this is that if one asks for his or her information to be kept private, then those seeking the information know the person has the condition, disease, etcetera. Others echoed this belief and stated that an opt-out system is not necessarily the best path for health data.

In short, privacy is more complicated than the choice paradigm makes it seem, and this makes the conceptual framework for privacy very important. Despite its importance, the large problem that exists in discussions about health privacy is that there is no clear conceptual framework for what we are worried about. This makes it very difficult to create a system tailored to research and privacy.

IV. CONFLICTS WITH NON-IP VALUES

The final topic of discussion at the IP Forum revolved around IP values conflicting with non-IP values. The conversation began by recognizing that patents are frequently justified on efficient innovation-

76. See Pasquale, *supra* note 55, at 18. (“But to integrate and to port data, all systems need to be able to translate symptoms, diagnoses, interventions, and outcomes into commonly recognized coding.”).

77. See American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 13101, 123 Stat. 115, 234-38 (2009) (codified at 42 U.S.C. § 300jj-12 (2009)).

78. PRISCILLA M. REGAN, LEGISLATING PRIVACY: TECHNOLOGY, SOCIAL VALUES, AND PUBLIC POLICY 233 (Univ. North Carolina Press 1995).

incentivizing grounds, but other interests, such as human rights, morality, ethics, and *ordre public* may also play an important role.⁷⁹ If these conflicts exist, how can they be resolved? The predominate focus of the discussion revolved around health care and the lack of pharmaceuticals in developing countries.

One participant suggested that it is impossible to put off talking about these competing values. These values are part and parcel of every aspect of our patent system. Because we have values other than efficiently incentivizing innovation, we should not think of these various values as destroying and undermining the IP system. Instead, we should think of the IP system as a flexible one that allows for accommodation when there is a conflict. To this end, international activists are working through the political process to push for recognition of these values and to create more flexibility within TRIPS.⁸⁰

International patent law, it was argued, needs modification to allow these other values to flourish. TRIPS “hardened” the patent system by creating a floor of strong intellectual property rights;⁸¹ thus, it has become more difficult to craft national laws that incorporate other values. As such, although pharmaceutical companies have the choices to be green, be humane, or prioritize other values at the expensive of their bottom lines, TRIPS does little to promote these choices. Importantly, under an exclusive rights regime, the pharmaceutical companies’ choices are all but final. The grassroots pushback for a humanitarian or human-rights-based model is to focus on implementation of statutory schemes in developing countries that maximize TRIPS-compliant flexibilities rather

79. See, e.g., KARA W. SWANSON, *Patents, Politics, and Abortion*, in INTELLECTUAL PROPERTY LAW IN CONTEXT: LAW AND SOCIETY PERSPECTIVES ON IP 6 (William T. Gallagher & Debora J. Halbert eds., Cambridge Univ. Press, forthcoming 2014) (describing the PTO as choosing the less-controversial option to defend a rule against patenting life given the politics focused on life in the 1970s); see also Jeffrey M. Samuels, Up In Smoke Down Under 1 (Oct. 29, 2012) (unpublished manuscript) (on file with reporter) (describing the conflict between trademark rights and public health *vis à vis* the Australian High Court’s decision regarding The Tobacco Plain Packaging Act); James Ming Chen, *Bioprospect Theory*, 7 AKRON INTELL. PROP. J. 19, 26 (2014) (recommending the use of bioprospect theory as a means for humanity to “eschew the remote prospect of wealth . . . and focus on how it might better manage anthropogenic ecological disasters before they become full-blown, irreversible cataclysms of global proportions”).

80. Some examples of international activist organizations include: Doctors without Borders; Access to Medicines Campaign; Oxfam; Health Global Access Projects; Knowledge Ecology International; Public Citizens Global Access to Medicines Program; Treatment Action Campaign (South Africa); and Lawyers’ Collective (India).

81. Sean A. Pager, *Patents on a Shoestring: Making Patent Protection Work for Developing Countries*, 23 GA. ST. U. L. REV. 755, 755-57 (2007); Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector*, 97 CALIF. L. REV. 1571, 1571-72 (2009).

than further “hardening” patent law with TRIPS-plus IP protections and enforcement measures.⁸² Preserving and promoting TRIPS’s flexibility would allow implementation to be done differently in one country if it chose to do so.

In response, an argument was made that if patents encourage drug development, then the current generation disregarding patent rights for an immediate benefit may result in fewer new drugs for subsequent generations. This effect flows from the unwillingness of future potential innovators to take the risk of ignored and unenforced patents. In reply to this concern, some participants argued that pharmaceutical companies could continue to price discriminate, but should not be allowed to cut off access to massive parts of the world and keep data secret. Although not economically beneficial for consumers in higher-paying countries, price discrimination does open up access to medicine for citizens of poorer countries.⁸³

Some participants focused on the economics behind the drug industry and pointed out that the real goal should be to sell the drug at a rate that is not so high that the citizens of these less developed countries cannot afford the care they need. The problem, from the drug companies’ perspectives, is arbitrage.⁸⁴ To help solve the arbitrage problem, one participant suggested creating audit trails on supply chains. That is, we already have systems that watch us as individuals, so why not have a similar system for drugs that indicates, for example, that drugs with codes stating “Made for Botswana” are illegal in the United States? By engaging in this type of price discrimination, the pharmaceutical companies can charge market-appropriate amounts for their products, while still providing the drugs to those in less developed countries. This system would help pharmaceutical companies contain arbitrage. We do this with importation restrictions in developed countries.⁸⁵ Similarly, pharmaceutical companies might also use technological means of avoiding international arbitrage, as was done with DVD country codes,⁸⁶ by a method of required color-coding or the

82. Kapczynski, *supra* note 81, at 1573.

83. Dratler, *supra* note 41, at 13 (describing how pricing drugs below cost in less developed countries “could save millions of lives around the world and still give the [pharmaceutical company’s] investors a satisfactory rate of return”).

84. See Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL’Y, L. & ETHICS 193, 195-96 (2005).

85. See, e.g., 21 U.S.C. § 331(t) (2012).

86. Robert C. Denicola, *Fair’s Fair: An Argument for Mandatory Disclosure of Technological Protection Measures*, 11 MICH. TELECOMM. & TECH. L. REV. 1, 12 (2004) (“DVDs

like.

A different model of resolving the conflicts between IP values and other values was illustrated by the example of the Medicines Patent Pool.⁸⁷ This group uses transparency in the negotiation process to put together a patent pool for producing HIV/AIDS drugs in less developed countries.⁸⁸ It negotiates licenses with pharmaceutical companies and puts on its web site the licenses it has executed and the status of the negotiations it is having with different pharmaceutical companies.⁸⁹ Although it is too early to know how effective it will be, this organization appears to put pressure on pharmaceutical companies that care about their reputation to expand their markets for life-saving medicines to countries that need it most.⁹⁰

The conflict between values certainly creates a tough problem. Resolving these conflicts requires an appreciation of both short-term and long-term consequences, an understanding of different cultures and economies, and compassion. It also requires an understanding of economics, so as to avoid killing the goose of research that lays the golden egg of new drugs. There are no easy answers, but interesting work is beginning to achieve a result that strikes an appropriate balance between competing values.

V. CONCLUSION

As illustrated above, participants at the Sixth Annual Forum raised and exhaustively discussed a number of current issues. The intersection of IP and public health raises issues dealing with economic theories, human and corporate motivation, the process of innovation, privacy, and human rights. Unfortunately, but not surprisingly, the participants did not resolve the conflicts between these thorny issues. Nonetheless, the discussion that took place contributed greatly towards exploring the problems and consequences from and the solutions and alternatives to

have included copy protection since their inception; they also contain embedded regional codes designed to limit play to DVD players coded for a particular geographic region.”).

87. See generally MEDICINES PATENT POOL, <http://www.medicinespatentpool.org> (last visited Aug. 20, 2014).

88. *Id.*

89. See *Company Engagement*, MEDICINES PATENT POOL, <http://www.medicinespatentpool.org/licensing/company-engagement> (last visited Aug. 20, 2014).

90. Krista L. Cox, *The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses*, 4 HASTINGS SCI. & TECH. L.J. 291, 301 (2012) (noting that “[p]harmaceutical companies should commit to the corporate social responsibility they claim to exercise and ensure life-saving medicines are accessible to those living in developing countries by licensing to the patent pool.”).

these issues. It is the hope of all the IP Scholars Forum participants that this White Paper will help steer future discussions about IP and public health and serve as a starting point for future analysis and just resolution of these problems.