



A Quantitative Approach to Determining Patentable Subject Matter

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A Quantitative Approach to Determining Patentable Subject Matter

Yuqing Cui*

Abstract

Although declared to be “only a threshold test”, what constitutes patentable subject matter is a difficult question that courts have been trying to answer for decades. This work develops a quantitative framework that addresses the question of patent-eligibility of a category of inventions from a fundamental level: whether the benefits outweigh the costs that arise from granting patents to the category of inventions. In evaluating each factor, the framework focuses on determining whether the goals of establishing the patent system in the first place are achieved by granting patents to these inventions. These goals include encouraging the creation, disclosure, and commercialization of the current and future inventions. The factors considered include the cost of research and development, cost of imitation, and the extent of taxing of future innovation. The results of this framework correlate well with the expected outcome of canonical cases and cases under debate. Finally, this paper proposes that the USPTO should be chosen as the institution administering the standard for patentable subject matter. This quantitative framework will hopefully change the current focus on construing statutory language and instead focus efforts on the big picture of achieving goals of having the patent system. It promises to bring in more consistency in future decisions by employing a quantitative analysis methodology which is already widely and successfully used in decision-making in many other fields.

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I. Introduction

The US patent statutes have historically adopted broad languages on the issue of patentable subject matter. §101 of the Patent Act states that “whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”¹ In the committee reports accompanying the 1952 Patent Act, Congress claimed it intended statutory subject matter of patents to “include anything under the sun that is made by man.”² In reality, however, there are three major and enduring exceptions carved out by the judicial system since the 19th century³: laws of nature, natural phenomena, and abstract ideas.⁴ Even though the court recites that patentable subject matter is “only a threshold test,”⁵ this mere “threshold test” has proved to be a long struggle for the judicial system, especially regarding the three exceptions. There are two major reasons leading to the struggle and the dissatisfaction among observers with respect to the courts’ decisions: a lack of consistent and enduring guidelines, and too close of a focus given to technicality of the languages.

¹ See 35 U.S.C. § 101.

² See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (citing S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952)).

³ See *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (citing 19th century cases in describing Court’s long-standing exclusions of certain patentable subject matter).

⁴ See, for example, *Diamond v. Diehr*, 450 U.S. 175, 185 (1981), in which the Court stated that it “has undoubtedly recognized limits to §101 and every discovery is not embraced within the statutory terms. Excluded from such patent protections are laws of nature, natural phenomena, and abstract ideas.” at 185 (citation omitted).

⁵ *Bilski*, 130 S. Ct. at 3225 (“The §101 patent-eligibility inquiry is only a threshold test.”)

Part II of this article shows how these problems manifest themselves in the “laws of nature” or “natural phenomena” exceptions represented by the *Myriad* case, and in the “abstract ideas” exception represented by its long and controversial judicial history.

No matter who makes the ultimate call of what constitutes patentable subject matter—be it the judicial system, Congress, or government agencies—ultimately some entity has to go through the cognitive process of choosing one policy among all alternatives, i.e., the process of decision making. Generally, there are five steps leading to a rational decision-making process (also known as Operational Research), and they are: (1) defining the problem; (2) identifying the alternatives; (3) determining the criteria; (4) evaluating the alternatives; (5) choosing an alternative.⁶ The problem definition is clear: we need to determine the types of subject matter that are patent-eligible. There are only two alternatives: a subject is either patent-eligible or it is not. The most difficult part then is step (3), which is to determine clear criteria and guidelines for selecting either alternative, and courts have not articulated such guidelines so far. The failure of establishing clear criteria makes the fourth step of evaluating the alternatives impossible, which calls the final decision into question.

When one finds oneself struggling to determine criteria for making a decision, it is often a good idea to take a step back and look at the bigger picture. There is a good reason why statutes and exceptions exist, and that is to serve the purposes of enacting the Patent Act in the first place. Therefore, when we find ourselves struggling to dig ourselves out of the dilemma of where to draw the line of the exceptions, we should ask the question of whether, by granting the patents to a certain category of inventions, we are achieving the goals of enacting the Patent Act. From the

⁶ D ANDERSON ET AL., AN INTRODUCTION TO MANAGEMENT SCIENCE: QUANTITATIVE APPROACHES TO DECISION MAKING (2015).

utilitarian point of view, the ultimate goal of having a patent system is to draw out and make available to the public new and useful inventions that would not have been invented absent the system. To achieve this ultimate goal, there are smaller objectives that the Patent Act tries to achieve: to encourage (1) creation of inventions, (2) disclosure of inventions, and (3) further development, dissemination and commercialization of inventions.⁷ On the other hand, the patent system tries to discourage overprotection that would stifle future innovation. Instead of devising standards that attempt to construe the literal language of laws, this work explores the approach of directly weighing the benefits that arise from granting patents to a category of inventions against the cost of doing so. When the benefits outweigh costs, patents should be granted; otherwise, they should not. This proposal is similar to that of the cost-benefit analysis of Kaplow.⁸ Part III of this article evaluates the factors that measure such benefits and costs, and formulates a framework based on a simple cost-benefit analysis.

This proposed method rests on the utilitarian theory, and this basis has its roots in the Constitution, which empowers the United States Congress “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁹ While it has been proposed before that patentable subject matter should be determined by applying strict utilitarian analysis on a category-by-category basis,¹⁰ a quantitative framework detailing what and how factors come into play has never been studied. As this paper points out earlier, the determination of patentable subject matter is ultimately a decision-making process. It has become increasingly clear in business,

⁷ John M. Golden, *Principles for Patent Remedies*, 88 TEX. LAW REV. (2009).

⁸ Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. LAW REV. 1813–1892 (1984).

⁹ U.S. Const. art. I, §8 (The Constitution grants Congress the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”)

¹⁰ David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, SSRN ELECTRON. J. (2009).

economics, science, psychology, and many other fields that quantitative analysis is one of the best methods for rational decision-making.¹¹ Policy-making, as a form of decision-making, should be no exception.

Part IV of the paper verifies this framework by testing its extremes and applying the framework to a canonical case. Following the verification, Part V uses this framework to determine the patent-eligibility of several categories of inventions under dispute. Finally, Part VI discusses the institutional choice for implementing the proposed framework on patentable subject matter.

II. The Judicial System’s Struggle with the Exceptions of Patentable Subject Matter

The three exceptions of patentable subject matter, i.e., laws of nature, natural phenomena and abstract idea, can be consolidated into two categories. One category is abstractness, where all steps could be performed mentally in theory.¹² The other category includes natural principles or entities that are simply discovered and not invented by humans¹³, as well as those that, after being stripped off the abstract steps, are left with only the natural principles or entities.¹⁴ This section will show that courts have struggled with both categories.

a. Laws of Nature / Natural Phenomena

i. Background of the *Myriad* Case

Breast cancer is one of the most common cancers affecting women and the principal cause of death from cancer among women globally.¹⁵ Breast cancer can be hereditary. In 1990, a group of

¹¹ ANDERSON ET AL., *supra* note 6, and Virginia Postrel, “Operations Everything,” *The Boston Globe*, June 27, 2004.

¹² *See, e.g., Bilski v. Kappos*, 130 S.Ct. 3218 (2010), *Research Corp. Techs v. Microsoft*, 627 F.3d 859 (Fed. Cir. 2010) and *Cybersource v. Retail Decisions*, 654 F.3d 1366 (Fed. Cir. 2011).

¹³ *See, e.g., Funk Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 76 U.S.P.Q. 280, 281 (1948).

¹⁴ *See, e.g., Mayo Collaborative Services v. Prometheus Labs, Inc.* 132 S.Ct. 1289 (2012)

¹⁵ Jacques Ferlay et al., *Global Burden of Breast Cancer*, in *BREAST CANCER EPIDEMIOLOGY* 1–19 (Christopher Li ed., 2010).

researchers at the University of California, Berkeley, published a paper that demonstrated, for the first time, a gene linked to breast cancer, known as Breast Cancer Susceptibility Gene 1 (*BRCA1*), located on a region of chromosome 17. Following this discovery, a group at Myriad Genetics along with researchers from various other institutions and companies sequenced the *BRCA1* gene and later discovered and sequenced a similar *BRCA2* gene. These genes are strong indicators of the likelihood a woman will develop breast cancers. An average American woman has approximately 12 percent of chance of developing breast cancer during her lifetime.¹⁶ By contrast, 55-65% of women who inherit a harmful *BRCA1* mutation and approximately 45% of women who inherited a harmful *BRCA2* mutation will develop breast cancer by the age 70 years.¹⁷

ii. Court Opinions on Patent-Eligibility of Isolated Genes

Following the sequencing of *BRCA1* and *BRCA2* genes, Myriad patented the discovery. In Myriad's patents, the challenged claims relate to isolated gene sequences, and the real debate is whether isolated genes fall under the "natural phenomena" exception of the patentable subject matter. Myriad argued that an isolated DNA molecule does not exist in nature in pure form.¹⁸ It is "a nonnaturally occurring composition of matter" with "a distinctive name, character, and use."¹⁹ Furthermore, isolated DNAs also have distinct functions compared to native DNAs.²⁰ For example, isolated DNAs can be used as primers and probes for diagnosis. Native DNAs cannot

¹⁶ Howlader N, Noone AM, Krapcho M, et al. (eds). SEER Cancer Statistics Review, 1975-2011, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2011/, based on November 2013 SEER data submission, posted to the SEER web site, April 2014.

¹⁷ A Antoniou et al., *Average risks of breast and ovarian cancer associated with BRCA1 or BRCA2 mutations detected in case Series unselected for family history: a combined analysis of 22 studies.*, 72 AM. J. HUM. GENET. 1117-30 (2003); Sining Chen & Giovanni Parmigiani, *Meta-analysis of BRCA1 and BRCA2 penetrance.*, 25 J. CLIN. ONCOL. 1329-33 (2007).

¹⁸ See *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 702 F.Supp.2d 181 (S.D.N.Y. 2010), at 224.

¹⁹ *Id.* at 228.

²⁰ *Id.* at 230.

achieve these functions because the strands are too long and the double-stranded nature renders them incapable of binding to any other gene targets.

Judge Sweet in the district court rejected Myriad's arguments and decided isolated DNAs are not patentable subject matter.²¹ The opinion states that the claimed isolated DNA has the same nucleotide sequence as native DNA, and thus is not "markedly different" from native DNA.²² Therefore, it falls into the exception of "laws of nature".

On appeal, the Court of Appeals for the Federal Circuit (CAFC) reversed the trial court.²³ Judge Lourie believes that since isolating DNAs necessarily requires cleaving covalent bonds that connect the piece of gene with the rest of the DNA strand, it technically creates a new molecule that has never existed alone in nature.²⁴ Responding to the argument that isolated DNA is not "markedly different" from native DNA, Judge Lourie wrote: "... it is the distinctive nature of DNA molecules as isolated compositions of matter that determines their patent eligibility rather than their physiological use or benefit."²⁵

Judge Moore concurred in part with this opinion, claiming if she were to decide on a blank canvas she might not have arrived at the same conclusion because although the literal chemical composition is different, the isolated gene does not have a new utility.²⁶ Judge Bryson dissented, arguing the structural differences between the isolated genes and the native forms are irrelevant to the functioning and utility of the genes. Furthermore, "the use to which the genetic material

²¹ *Id.*

²² *Id.* at 227.

²³ *See Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed.Cir. 2011)

²⁴ *Id.* at 1352.

²⁵ *Id.* at 1353.

²⁶ *Id.* at 1366-1367.

can be put, i.e., determining its sequence in a clinical setting, is not a new use; it is only a consequence of possession.”²⁷

Eventually the case made it to the Supreme Court. The Supreme Court decided the exact chemical composition is not the key dispute because although the isolated and native DNAs are not chemically identical, Myriad’s claim “is concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule”.²⁸ Rather, “Myriad’s principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13”²⁹. The Supreme Court thus decided “genes and the information they code are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material.”³⁰

iii. Issues with Court Rulings on the Laws of Nature Exception

From the court opinions described in the previous section, we can make several observations. First, the district court and the Federal Circuit put a lot of focus on the technicality of the language. The questions under dispute were what could almost be considered technicalities: when one chops off a part of an entity, does the new part technically become a new thing on its own? How different is this chopped off part from its original entity? How far does the definition of “nature” reach?

The second problem is the lack of long-term guidance on how to deal with the “law of nature” exception in the future. The Supreme Court ruling is fairly narrow in that it claims “there are no method claims before this Court”, “this case does not involve patents on new applications of

²⁷ *Id.* at 1373.

²⁸ Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al., 133 S.Ct. 2107, 2126 (2013)

²⁹ *Id.*

³⁰ *Id.* at 2129.

knowledge about the BRCA1 and BRCA2 genes”, and “nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered”.³¹ The Supreme Court merely ruled isolated genes are not patent-eligible, leaving the question open of what the standards are to determining what constitutes laws of nature or natural phenomena. In fact, some commentators observed that this ruling may not even be able to truly exclude gene-patenting since applicants can simply draft around simple isolated DNA molecules and around explicitly human sequences: “the very same sequences would likely still be the object of composition-of-matter claims, just claimed more obliquely, within the context of sufficiently, complex, nonnative genetic constructs, or with enhancing changes to the sequence, enough to make it a ‘synthetic’ or ‘artificial’ sequence, rather than a ‘natural’ sequence.”³²

Some may argue that the Supreme Court laid down some guidelines regarding laws of nature in the *Mayo* case³³. The guidelines, however, are not very helpful in guiding future cases: they focus on the question of whether the process adds anything specific or inventive to the laws of nature other than “what is well-understood, routine, conventional activity previously engaged in by researchers in the field”.³⁴ The *Myriad* case, which came after the guidelines for *Mayo* are issued, obviously did not deal with what was well-understood, routine or conventional, but was still classified as laws of nature. It shows there is still sufficient confusion surrounding what exactly constitutes laws of nature and/or natural phenomena. In the long run, inventors, businesses, and the lower court are still largely left in vagueness of what falls within these exceptions.

³¹ *Id.* at 2129.

³² Gregory D Graff et al., *Not quite a myriad of gene patents.*, 31 NAT. BIOTECHNOL. 404–10 (2013).

³³ *See Mayo Collaborative Services v. Prometheus Labs, Inc.* 132 S.Ct. 1289 (2012).

³⁴ *Id.* at 1292.

b. Abstract Ideas

Similar to its sister exceptions, the abstract ideas exception has a judicial history of uncertainties since Justice Story first raised the concern in the nineteenth century that “principles in the abstract” are not honored by our patent system.³⁵ Absent clear guidelines on what constitutes “abstract ideas”, the lower courts have come up with various rules of their own, most of which were eventually struck down or abandoned by the upper courts. In 1970, the Court of Customs and Patent Appeals developed the “technological arts” test, stating that to be patent-eligible, the invention needs to be “in the technological arts.”³⁶ While this interpretation seems fitting for the time, it did not really manage to limit the scope of patentable subject matter. To pass this test, the applicants simply have to carry out their invention on a computer. This test was struck down by USPTO’s administrative judges’ ruling that no such requirement existed in the law.³⁷

Another failed attempt to clarify the “abstract ideas” exception by the lower court is the “business method exception”, where the Second Circuit decided that “a system of transacting business disconnected from the means for carrying out the system is not [patent eligible subject matter].”³⁸ This exception was also doomed when the Court of Appeals for the Federal Circuit rejected the “so-called ‘business method’ exception to statutory [patentable] subject matter” once and for all.³⁹

³⁵ See *Stone v. Sprague*, 1 Story, 270 (D.R.I 1840).

³⁶ *In re Musgrave*, 431 F.2d 882, 893 (C.C.P.A. 1970).

³⁷ *Ex Parte Lundgren*, Appeal No. 2003-2088 (BPAI 2005)

³⁸ 160 F.467 (2nd Cir. 1908). at 469.

³⁹ See *State Street Bank & Trust Co.*, 149 F.3d at 1373-75.

Subsequently, the Federal Circuit adopted a test to determine subject matter eligibility that requires the claim to produce “a useful, concrete, and tangible result.”⁴⁰ This holding, however, was never explicitly adopted by the Supreme Court.⁴¹

The Federal Circuit then crafted another test called the “machine-or-transformation” test, which states that a process is patent-eligible under §101§ if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.⁴² In the *Bilski* case, the Supreme Court rejected this standard as the sole test governing §101 analyses for determining patent eligibility of a process under §101.⁴³ Many were frustrated that the Court “not only failed to offer clear guidance as to the boundaries of patentable subject matter, but also missed an opportunity to explain what patentable subject matter is about.”⁴⁴ Indeed, the Supreme Court offered so little guidance that the Federal Circuit continues using the machine-or-transformation test, paying lip service to the Supreme Court ruling by acknowledging that the machine-or-transformation test only offers an “important clue”⁴⁵.

The recent ruling by the Supreme Court on *Alice v. CLS Bank* sheds more light on the abstract idea exception. The Court affirmed a two-step analysis framework from *Mayo*⁴⁶ whereby the first step is to determine whether the invention is directed towards abstract ideas, and the second step is to search for an “inventive concept”.⁴⁷ Unfortunately, it remains unclear still what the “inventive concept” entails exactly.

⁴⁰ *Alappat*, 33F.3d at 1544

⁴¹ *See* *Lab. Corp. of Am. Holdings v. Metabolite Lab., Inc.*, 548 U.S. 124 (2006).

⁴² *Bilski*, 545 F.3d 961.

⁴³ *See* *Bilski v. Kappos*, 130 S.Ct. 3218 (2010) at 3226.

⁴⁴ Rebecca S. Eisenberg, *Wisdom of the Ages or Deadhand Control - Patentable Subject Matter for Diagnostic Methods after in Re Bilski*, 3 CASE WEST. RESERV. J. LAW, TECHNOL. INTERNET (2012).

⁴⁵ *In re Bilski*, 545 F.3d 954 (Fed. Cir. 2008) (en banc)

⁴⁶ *Supra* note 33.

⁴⁷ *See* *Alice Corp. Pty. Ltd. V. CLS Bank Int'l.*, 134 S.Ct. 2347, 2355 (2014)

Some commentators have pessimistically concluded the struggles by stating that “despite the hundreds, probably thousands of attempts in judicial opinions and academic commentaries over the last forty years to reconcile the Supreme Court’s opinions, it is time to admit that they cannot be reconciled.”⁴⁸ There is a great need for a more consistent guidance for these exceptions to patentable subject matter.

III. A Quantitative Framework to Determine Patentable Subject Matter

This section will first establish the factors that measure the benefits arising from granting patents to a certain category of inventions, and factors that measure the costs arising from doing so. A quantitative framework is then proposed to incorporate these factors into arriving at a final decision.

a. Research and Development (R&D) Cost Measures the Benefits Arising from Granting Patents

i. Creation of Inventions

Many useful inventions come at an immense price, cutting-edge research especially so. Not only do reagents and lab equipment cost tremendous amount of money, but research is done by skilled labor that commands a high salary too. Taking everything into account, it is not unusual to see research grant proposals that ask for hundreds of thousands of dollars for inventing a single brilliant product. In fact, the National Institutes of Health (NIH) calculated that the average size of one Research Project Grant (RPG) for the year 2014 is \$472,827.⁴⁹ Private sector investment

⁴⁸ Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence of Abstractions*, (2015) pp. 9.

⁴⁹ S. Rockey. “2014 By the Numbers”. *Extramural Nexus* by Office of Extramural Research of the National Institutes of Health. Dec. 2014. <https://nexus.od.nih.gov/all/2014/12/31/2014-by-the-numbers/>. Accessed April 18, 2015.

in research could be even more costly considering higher worker salaries and the absence of instrument discounts that are enjoyed in the academia.

Useful inventions are getting more costly now, as pointed out by the Ewing Marion Kauffman Foundation, a think-tank.⁵⁰ There is an ongoing trend that radical innovation is getting more complex with the low-hanging fruits mostly gone. Given such a trend, no rational market players are likely to invest large sums of money needed for useful innovation in the absence of awards, such as the promise of a 20-year monopoly offered by the patent system. Therefore, the higher the R&D cost is, the more such innovation needs the patent system to draw out the invention, which means granting patents for inventions with a high R&D cost accords more benefits to society, i.e., drawing out more useful invention, than granting patents to those with a low R&D cost.

This concept is easy to illustrate. The inventors of the Halloween lawn bags⁵¹ may well make such bags when the idea came to their mind, whether there is a promise of future market monopoly or not since it costs little to create such invention. On the other hand, absent an alternative government scheme for rewards or funding, no rational company would start looking for a drug target treating Alzheimer's without knowing once the target is discovered, the patent on the drug target will help recoup the original research cost.

ii. Disclosure of Inventions

The importance of granting patents to inventions with high R&D costs does not stop at encouraging inventions. Inventions that are kept to inventors themselves prevent cumulative

⁵⁰ J. Bell-Masterson. "Innovation Series: The Rising Costs of Invention". The Ewing Marion Kauffman Foundation. Mar. 24, 2015. <http://www.kauffman.org/blogs/growthology/2015/03/innovation-series-increasing-costs-of-invention>. Accessed Apr. 18, 2015

⁵¹ U.S. Patent D310,023 (filed Nov. 6, 1989).

advancement of science and technology. Thus, one of the goals of the patent system is to encourage the disclosure of inventions to the public.

There are two reasons why inventions with high R&D costs need the patent system more than their low cost counterparts to achieve the goal of public disclosure. First, as we discussed in the previous section, radical inventions are coming by at increasingly higher costs now with the low-hanging fruits picked up in the past already. Higher R&D costs often signal more valuable inventions now, and more valuable inventions are at higher risk of theft than less valuable ones. Second, theft of inventions with high R&D costs is more likely to deter the inventions from being created in the first place. This is because inventors who spend a hefty sum to create inventions have a much higher need of recouping the cost of research.

It is thus clear that once disclosed, inventions with high R&D costs are not only at higher risk of theft, but they are also susceptible to a more detrimental and catastrophic effect from such theft. Hence, inventions with high R&D costs have more urgent need of patent protection to draw out disclosure to the public, which means granting patents to them accords more benefits.

iii. Development and Commercialization of Inventions

The public will not enjoy the full benefits of an invention unless it is developed and commercialized. The scale-up and commercialization part can often be as expensive, if not more so, than the invention stage of the product. In the pharmaceutical industry for example, the identification of a drug target only composes a small fraction of the R&D process. Development of the target is the heavy work that commonly takes another 10 years⁵² and hundreds of millions

⁵² Hans-Jürgen Federsel, *Chemical Process Research and Development in the 21st Century: Challenges, Strategies, and Solutions from a Pharmaceutical Industry Perspective*, 42 ACC. CHEM. RES. 671–680 (2009).

of dollars⁵³ for the target to be fully commercialized into a marketable drug. See Figure 1 for an overview of the value chain in pharmaceutical R&D.⁵⁴

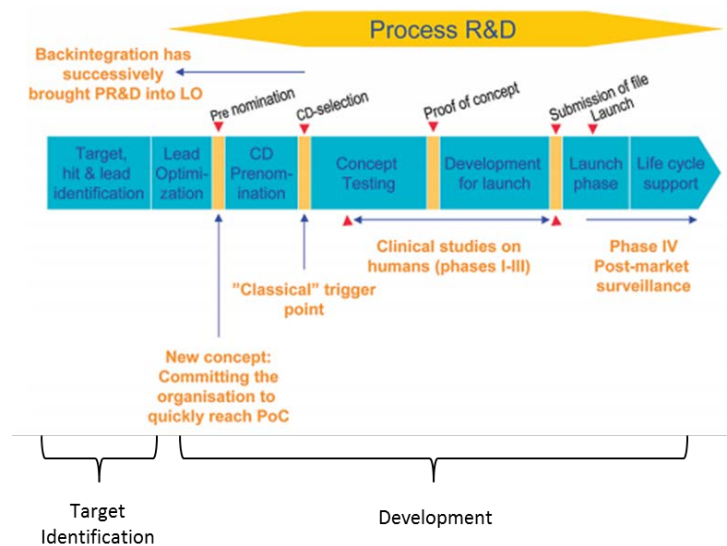


Figure 1. Timeline of target identification and development for the pharmaceutical industries. (Adapted from Federsel⁵⁵)

The patent system is designed to encourage these costly but important inventions by awarding a monopoly to the inventors for them to recoup the cost of development. Without this award, the public likely will never get this invention. Examples abound where an invention has been created but could not be commercialized because there is little promise that the development cost could be recouped. One such example is bexarotene (also known as its brand name Targretin), a cancer drug that was recently discovered also to be a promising target for Alzheimer's disease.⁵⁶ In this scenario, the target has already been identified by prior inventors, and the only cost involved to bring the drug to market for treatment of Alzheimer's disease is the development of the drug to go through clinical trial again and obtaining the Food and Drug Administration (FDA) approval

⁵³ Joseph A DiMasi et al., *Cost of innovation in the pharmaceutical industry*, 10 J. HEALTH ECON. 107–142 (1991).

⁵⁴ Federsel, *supra* note 52.

⁵⁵ *Id.*

⁵⁶ Paige E Cramer et al., *ApoE-directed therapeutics rapidly clear β -amyloid and reverse deficits in AD mouse models.*, 335 SCIENCE 1503–6 (2012).

for the new treatment. Despite its starkly positive results in laboratory research,⁵⁷ fund-raising to commercialize this drug was long and arduous. It took Cleveland Clinic’s team almost a year to gather the funding because “there has been little interest in developing a drug that will soon be available generically.”⁵⁸ The patent on Targretin began to expire in 2012⁵⁹, and one cannot obtain patent on the same molecule twice even if it is later found to have new uses.⁶⁰ Without the promise of patents, the development cost will be more difficult to recoup. The point of this example is not to argue whether new uses deserve a new patent, but to show that commercialization is more challenging for inventions with high development cost without the promise of recouping such cost.

One of the important goals of having the patent system is to encourage development and commercialization of inventions. The logic why R&D cost is an important measure in evaluating whether such a goal will be achieved through patenting is similar to the arguments for creation of inventions. That is, the higher the R&D cost is, the more such innovation needs the patent system to draw out the development of the invention, which means granting patents for inventions with high R&D cost accords more benefits than those with a low R&D cost.

Another, and perhaps still debatable, aspect of development and commercialization that concerns R&D cost is the coordination function served by the patent system. The aforementioned form of rewarding the inventors through market monopoly is an aspect described in the reward theory of

⁵⁷ *Id.*

⁵⁸ B. Zeltner. “Cleveland Clinic starts trial of cancer drug to treat Alzheimer’s disease”. Sept. 2013. http://www.cleveland.com/healthfit/index.ssf/2013/09/cleveland_clinic_starts_trial.html. Accessed Apr. 18, 2015.

⁵⁹ *Id.*

⁶⁰ Ted T Ashburn & Karl B Thor, *Drug repositioning: identifying and developing new uses for existing drugs.*, 3 NAT. REV. DRUG DISCOV. 673–83 (2004).

the patent system.⁶¹ Evaluating the R&D costs also helps achieve an important goal of the patent system according to Kitch's prospect theory:⁶² to promote coordination and to reduce the amount of duplicative investment in innovation. One can easily imagine that if multiple pharmaceutical companies invest billions of dollars on the same drug target at the same time, racing towards commercialization of the same drug, the cost to the public is devastating. On the other hand, if multiple people are simultaneously inventing pencils with erasers attached to the tips, it is not nearly as socially wasteful. In the former case, the coordination function of the patent system is much more valuable, if not critical, because of the tremendous R&D cost. This argument seems to make sense, but it should be taken with a grain of salt. As Merges and Nelson have suggested, "in many industries the efficiency gains from the pioneer's ability to coordinate are likely to be outweighed by the loss of competition for improvements to the basic invention."⁶³ Hence, a more in-depth study on the balance of the gain from coordination and the loss from the absence of competition is needed to assert this argument with confidence. This uncertainty, however, does not affect the overall argument for development and commercialization since coordination is only a small aspect of it.

iv. Remarks on Using R&D Cost as a Measure of Benefits Arising from Granting Patents

This section of the paper so far has argued that inventions with high R&D costs need the patent system more than their low cost counterpart to draw out the creation, disclosure and

⁶¹ WILLIAM D NORDHAUS & WILLIAM D NORDHAUS, INVENTION, GROWTH, AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE (1969). F. M. Scherer, NORDHAUS' THEORY OF OPTIMAL PATENT LIFE: A GEOMETRIC REINTERPRETATION THE AMERICAN ECONOMIC REVIEW, VOL. 62, NO. 3 422-427 (1972); Pankaj Tandon, OPTIMAL PATENTS WITH COMPULSORY LICENSING JOURNAL OF POLITICAL ECONOMY, VOL. 90, NO. 3 470-486 (1982).

⁶² Edmund W Kitch, *The Nature and Function of the Patent System*, 20 J. LAW ECON. 265-290 CR – Copyright © 1977 The University (1977).

⁶³ Robert P Merges & Richard R Nelson, *On the Complex Economics of Patent Scope*, 90 COLUMBIA LAW REV. 839-916 CR – Copyright © 1990 Columbia Law R (1990).

commercialization of the inventions. Meanwhile, the more costly inventions are at higher risk of creating social waste by promoting competitors racing against each other at launching products, and the patent system can prevent such waste by serving the coordination function. Therefore, R&D cost is an accurate indicator of how much the society will benefit from granting patents to a certain class of inventions. It suggests whether granting patents to this class of inventions would serve the goals of having a patent system in the first place.

It is worth noting that the above arguments do not suggest inventions produced at low costs are useless. On the contrary, many low-cost inventions are brilliant and useful. Take *Rubber Tip Pencil Co. v. Howard*, where the invention was adding a piece of eraser to the tip of a pencil.⁶⁴ Throughout my grade-school years, I have found this product very handy. However, a low R&D cost does suggest the invention could be obtained more easily. Kitch once pointed out that it is important to separate “those inventions that would have been made absent the incentives of the patent system from those that would not,” and there is a good reason for it.⁶⁵ Granting a monopoly should not be taken lightly. In fact, Adam Smith found that a monopoly in trade is “necessarily hurtful to the society in which it takes place.”⁶⁶ Adam Smith does concede that a temporary monopoly granted to the inventor of a new machine could be justified as a means of rewarding risk and expense. However, this exception should be reserved for inventions that truly have large expenses to reward. If an invention does not cost very much to come up with or to commercialize, then someone may well have done so in the absence of the lure of the monopoly granted by the patent system. Comparing the invention of a pencil with an eraser attached to its tip to the pharmaceutical industry where each product costs hundreds of millions of dollars to

⁶⁴ 20 Wall. 498 (1874)

⁶⁵ Edmund W Kitch, *Graham v. John Deere Co.: New Standards for Patents*, 1966 SUPREME COURT REV. 293–346 CR – Copyright © 1966 The University (1966).

⁶⁶ Adam Smith, *Wealth of Nations* (“World’s Classics”; London: Oxford University Press, 1928), Bk. IV, chap. vii, Part III, 244 (first published, 1776).

develop, the patent is needed much more desperately for the latter product to get into the public domain.

v. Quantification of R&D Costs

Now that it is established R&D cost is a key factor to evaluate, we proceed to the quantification of this factor. Most industries publish the average cost of R&D. One approach is to directly normalize the R&D cost of each industry. This may be a tricky task since it is difficult to define the maximum R&D cost against which this factor should be normalized. Some industries also use accounting tricks to artificially inflate R&D costs for tax purposes.⁶⁷ Rather, one can use a broad-stroke approach and bin R&D cost on a scale of 1 to 5 against benchmarks. There are numerous methods to do that including various industry reports, social science research and etc. Here, I use Standard & Poor's Industry Surveys to illustrate one of the many ways this quantification can be done. On the high end of R&D cost is the pharmaceutical industry. In its report for the pharmaceutical industry, the Standard & Poor's survey says:⁶⁸

As new drugs represent the lifeblood of the pharmaceutical industry, the percentage of a company's sales that it devotes to R&D can have an important impact on future trends in sales and earnings. For the drug industry overall, this percentage in the aggregate is *higher than for any other industry*. Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade group, reported that R&D spending by members, both in the

⁶⁷ Donald W Light & Rebecca Warburton, *Demythologizing the high costs of pharmaceutical research*, 6 BIOSOCIETIES 34–50 (2011).

⁶⁸ JEFFREY LOO, INDUSTRY SURVEYS, HEALTHCARE: PHARMACEUTICALS (2014).

US and abroad, totaled an estimated \$51.1 billion in 2013, up from \$49.6 billion in 2012. (emphasis added)

From the report, it is clear that the research and development is not only critical for the future of the entire pharmaceutical industry, but its cost is higher than any other industry. Thus, I benchmark the R&D cost of the pharmaceutical industry to have a value of “5” on the R&D cost scale.

The next level down on the R&D scale includes industries where research and development has strategic importance and the costs are relatively high. An example is the software industry. In this industry, spending on research and development provides critical support for new product pipeline, and in the digital age, revenue is directly related to fancy new products. The Standard and Poor’s industry survey notes:⁶⁹

In software, as in many other industries, research and development (R&D) programs are important. Given the computer industry’s rapid technological change, R&D is especially crucial. To remain competitive, software vendors must support consistently high levels of R&D spending, which are necessary to develop new products and to upgrade and enhance existing ones. Thus, it is not unusual to see computer industry R&D costs of 10% to 20% of revenues, a considerably *higher percentage than for most other industries*. (Emphasis added)

⁶⁹ SCOTT KESSLER, INDUSTRY SUREYS, COMPUTERS: SOFTWARE (2014).

For these industries where R&D cost is higher than most others, they receive a value of “4” on the R&D cost scale.

A value of “3” is given to industries with average R&D cost. The commodity chemical operations industry is one such example. The Standard & Poor industry survey reports that this industry is “characterized by limited research and development (R&D) spending and a strong emphasis on reducing feedstock, energy requirements, and labor costs through engineering process improvements.”⁷⁰

A value of “2” is assigned to industries where research and development does not play an important role and is not part of the core business model. For example, the Standard and Poor’s industry reports on the property-casualty insurance industry⁷¹ and on the investment services⁷² industry do not mention research and development cost or the importance of innovation at all. This is not surprising since these are not innovation-driven industries. While some may argue that some very substantial innovation has taken place in the last couple of decades, these inventions, such as the idea of hedging risks,⁷³ simply do not cost all that much to come up with or to warrant mentioning in industry reports. Indeed, the development cost of such invention could hardly compare to that of even the commodity chemical operations industry. Thus, the R&D cost of this class of inventions is categorized as low and benchmarked to have a value of “2” on the R&D cost scale.

Finally, a value of “1” on the R&D cost scale is reserved for categories of inventions with absolutely trivial R&D cost—inventions that essentially cost nothing to make. These categories

⁷⁰ CHRISTOPHER B. MUIR, *INDUSTRY SURVEYS: CHEMICALS* (2014).

⁷¹ CATHERINE A. SEIFERT, *INDUSTRY SURVEYS, INSURANCE: PROPERTY-CASUALTY* (2014).

⁷² KENNETH LEON, *INDUSTRY SURVEYS: INVESTMENT SERVICES* (2014).

⁷³ U.S. Patent Application 13/567,426. (Filed Aug. 6, 2012).

are rare, but one potential category is inventions that most children can come up with easily, such as swinging a swing sideways⁷⁴ or exercising your cats with a laser pen.⁷⁵ This category of inventions cost next to nothing to research and develop.

To summarize, the quantification of R&D cost can be presented in the following figure.

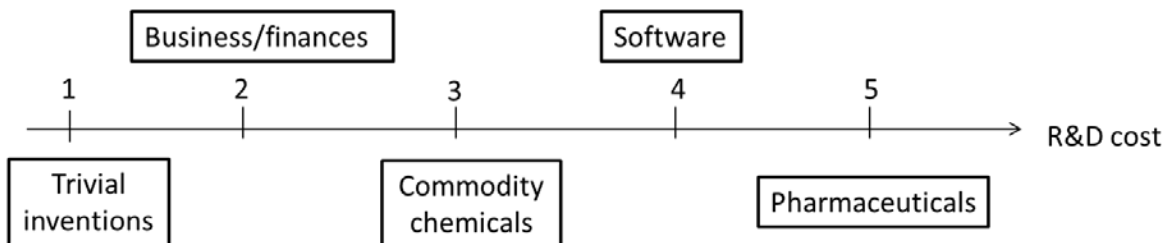


Figure 2. R&D Cost Quantification Scheme

b. Cost of Imitation Measures Benefits Arising from Granting Patents

i. Inventions with Low Cost of Imitation Need Patent Protection to Fend Off Copycats

One key aspect of promoting commercialization of a new technology and realizing the full benefits of the patent system is the prohibition of copycats. After all, an inventor would be reluctant to mass produce or even discuss her invention with potential investors if fear lingers that someone else can easily steal her idea that she invested so much effort and expenses in. Just as Willard Phillips wrote in his Law of Patents for Inventions:⁷⁶

[W]ithout some encouragement and hope of indemnity for expenses, held out by the law, many inventions, after being made, would not be rendered practically useful... Now without the

⁷⁴ U.S. Patent No. 6,368,227 (filed Nov. 17, 2000).

⁷⁵ U.S. Patent No. 5,443,036 (filed Nov. 2, 1993).

⁷⁶ Phillips, The Law of Patents for Inventions 12-14 (1837)

encouragement of a patent, how is any man to engage in a novel and expensive process, if the moment he succeeds, at the cost of all this outlay, he must be sure that his neighbors, who were cautious enough to shun all chances of loss, will come into competition with him, and make the remuneration of all this outlay impossible?

One of the most intuitive defenses against such imitation is to keep the manufacturing process a trade secret. However, the effectiveness of such defense largely depends on the nature of the invention, i.e., how easy it is for competitors to imitate the product. Reverse engineering, one of the most common methods of imitation, is a standard industry practice in the traditional manufacturing,⁷⁷ semiconductor industries,⁷⁸ and computer software industry.⁷⁹ With the development of ever more powerful analytical instruments, what could have been kept as a secret in the past might now be reverse-engineered without much effort. For example, the composition of various grades of steel used to be difficult to crack. Now with the help of infrared spectroscopy, Raman spectroscopy, scanning electron microscopy, and many other analytical techniques, a person skilled in the art can reverse engineer the invention by obtaining a small sample.

In light of these new trends, more and more inventions beg for the protection offered by the patent system. For inventions with low imitation cost, patents are much needed to encourage commercialization, because it would allow inventors to freely disclose their inventions to potential investors without fear that the fruits of their invention may be appropriated. It also

⁷⁷ Pamela Samuelson & Suzanne Scotchmer, *The Law and Economics of Reverse Engineering*, 111 YALE LAW J. 1575–1663.

⁷⁸ *Id.*

⁷⁹ Andrew Johnson-Laird, *Reverse Engineering of Software: Separating Legal Mythology from Actual Technology*, 5 SOFTW. LAW J. (1992).

lowers the cost for the owners of the invention because it allows them to contract with other firms possessing complementary information and technology fear-free. These are important goals of the patent system as outlined in Kitch's prospect theory.⁸⁰ It is clear that inventions with low cost of imitation need the patent system much more to allow the full-realization of the benefits of the invention.

ii. Inventions with High Cost of Imitation Need Patents to Draw Out the Disclosure of Inventions

While owners of inventions with high cost of imitation have fewer worries of their inventions being stolen by copycats, when this cost becomes prohibitively high, they have a strong incentive to simply keep their inventions as trade secrets to enjoy longer period of monopoly. When inventors opt for the path of trade secret, the social cost could be detrimentally high. The reason is three-fold: first, the inventors could potentially enjoy a monopoly not just for 20 years, but infinitely. While there are risks to keeping an invention a trade secret, there are plenty of companies that managed to keep their secrets for longer than 20 years, Coca Cola being one prominent example.⁸¹ Second, for a valuable invention, keeping it a trade secret encourages reverse engineering, which is socially wasteful. Third, keeping an invention a trade secret prevents the public from building upon the invention until the trade secret is breached. Given the cumulative nature of science and technology, even a delay in access of information could be harmful to the social goods.

⁸⁰ Kitch, *supra* note 62.

⁸¹ FREDERICK ALLEN, SECRET FORMULA (1994).

Take for example, Myriad Genetics' discovery of *BRCA1* and *BRCA2* gene sequences. In its opinion, the Federal Circuit pointed out the difficulty of locating the exact sequence of these two genes:⁸²

...the *BRCA1* gene in its native state resides on chromosome 17, a DNA molecule of around eight million nucleotides. Similarly, *BRCA2* in its native state is located on chromosome 13, a DNA of approximately 114 million nucleotides. In contrast, isolated *BRCA1* and *BRCA2*, with introns, each consists of just 80,000 or so nucleotides....

Myriad does not sell its *BRCA* gene primers and patients have to send to Myriad their DNA samples. Thus, reverse engineering the *BRCA* genes is not only technically challenging but socially wasteful. Had Myriad Genetics kept the gene sequence in secret and kept the testing method proprietary, it would take competitors a great amount of time and resources to find out the sequences of these genes.

The danger is real, but it can be mitigated by the patent system. Granting patents to inventions with high costs of imitation discourages inventors from keeping them trade secrets by offering a 20-year guaranteed monopoly, offsetting the risk of trade secrecy. Thus, counterintuitive as it might be, inventions with high costs of imitation also need the patent system to fully-realize the benefits of granting patents. This point is illustrated by the reaction to the Supreme Court's ruling on the *Myriad* case. After the ruling, the National Cancer Institute hosted the Ethical and Regulatory Issues in Cancer Research (ENRICH)

⁸² *Supra* note 23.

Forum in November 2013, entitled “the Myriad mire: patents and trade secrets in the age of the genome.” One of the leaders of the forum, Eleonore Pauwels, a public policy scholar at the Woodrow Wilson International Center for Scholars (Washington, D.C.), pointed out that the Supreme Court decision on *Myriad* could make the trade-secret route look more attractive to the biotech industry, including Myriad itself.⁸³ Her comments echoed a 2011 *New York Times* piece in which Myriad’s chief executive, Peter Meldrum, said “if I had my druthers, I would not want to go into a new market in a heavy-handed fashion, trying to enforce patents.”⁸⁴

To realize the full benefits of an invention, those with high imitation cost should be granted patents to encourage disclosure of the technology and facilitate coordination among competitors. Of course there might be exceptions in some areas where most people would rather choose trade secrets over disclosing their inventions even in the presence of the patent system. If it proves to be the case, less weight could be given to imitation cost for these areas when accounting for benefits of granting patents.

In general, the importance of granting patent as a function of cost of imitation can be loosely illustrated below:

⁸³ C. Palmer, “The Myriad Decision: A Move toward Trade Secrets?” *The NIH Catalyst Newsletter*. Vol. 22, Issue 2. March-April 2014

⁸⁴ A. Pollack. “Ruling Upholds Gene Patent in Cancer Test”. *The New York Times*. July 29, 2011

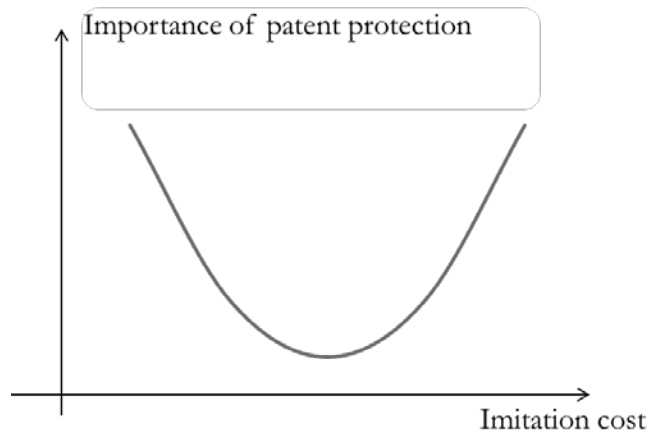


Figure 3. Importance of patent protection as a function of imitation cost

iii. Quantification of Cost of Imitation

There are many methods to quantify the cost of imitation. An obvious approach is to survey such cost among companies working on reverse engineering. Without the data in hand, this paper proposes an alternative method that determines cost of imitation by borrowing the person-having-ordinary-skill-in-the-art (PHOSITA) standard used to determine obviousness.⁸⁵

The standard is straightforward: if a PHOSITA can identify the route of imitation fairly easily using standard laboratory equipment, this cost of imitation is benchmarked to be a value of “2.” Take for example the small-molecule pharmaceutical industry. Since there is only one small molecule that needs to be identified, a PHOSITA will easily point out that reverse engineering can be done by using a combination of high-performance liquid chromatography (HPLC), nuclear magnetic resonance (NMR) and mass spectroscopy (MS),

⁸⁵ Michael Abramowicz & John F Duffy, *The Inducement Standard of Patentability*, 120 YALE LAW J. 1590–1680 (2011).

and Power X-Ray Diffraction (PXRD), all of which are standard instruments that can be found in the laboratory of a pharmaceutical company.

On the other hand, if a PHOSITA finds it cumbersome to identify the route of imitation or the imitation requires extraordinary equipment that a typical laboratory does not possess, this cost of imitation is benchmarked to be a value of “4.” This represents a category of innovation that is technically challenging and financially costly to imitate.

Based on the benchmark for values of “2” and “4,” it is reasonable to assign a value of “1” to be trivially easy to copy—one can look at the invention and replicate it. A value of “3” represents an imitation cost that is intermediate according to PHOSITA. A value of “5” is designated to be extremely difficult to copy. Take as an example the device used to wrap cable for a tire’s inner thread manufactured by Goodyear Tire & Rubber. The rival company had to engage in corporate espionage to get the technology.⁸⁶

To summarize, the quantification of cost of imitation can be presented in the following figure.

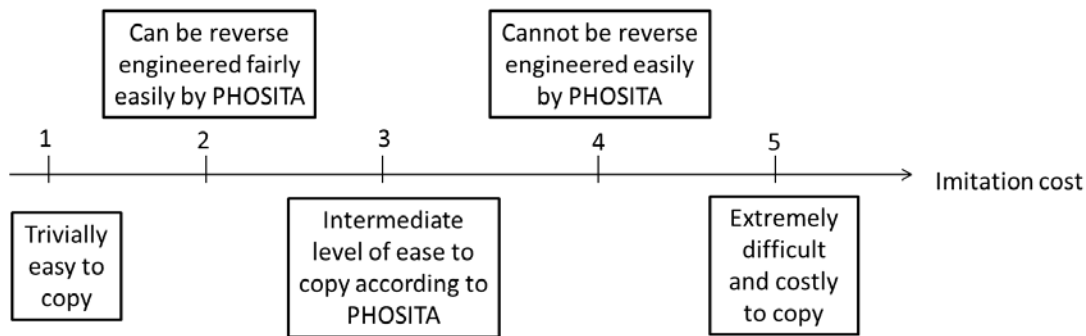


Figure 4. Cost of Imitation Quantification Scheme

⁸⁶ NORTON PALEY, HOW TO OUTTHINK, OUTMANEUVER, AND OUTPERFORM YOUR COMPETITORS: LESSONS FROM THE MASTERS OF STRATEGY (2013), pp 73.

c. Taxation on Future Innovation Measures the Cost Arising from Granting Patents

i. Taxation on Future Innovation Can Impose a Heavy Cost

In recent decades, a phenomenon starts to emerge that patents in certain areas are becoming increasingly taxing on future innovations. Heller and Eisenberg pointed out the danger in the biomedical research where competing patent rights in upstream research overlap and may prevent useful and affordable products from reaching the market place.⁸⁷ It is under debate to what extent the prediction of the tragedy of anticommons has come true. Ten years after the publication of the Heller and Eisenberg article on anticommons, Eisenberg herself did a review of the current status of biomedical research. She concluded that the phenomenon did arise and some researchers have abandoned their original projects because of existing blocking patents. However, the percentage of such occurrences is small and many of the anticommons fears have not been realized—at least not in more extreme forms. Shiu reviewed the biotechnology area and observed that an anticommons in biomedical research has not arisen because of powerful public actors and some private actors.⁸⁸ Merges further argued about the prominent role private parties and individuals have played in preempting or undermining the potential property rights of the economic adversaries that might have prevented the tragedy of the anticommons from disrupting the biomedical market.⁸⁹

Concern about anticommons is not unique to biomedical research, and could extend to any area where either of the two conditions are met, as outlined by Heller and Eisenberg: “creating too

⁸⁷ M. A. Heller, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* (80-.). 698–701 (1998).

⁸⁸ Chester J. Shiu, *Of Mice and Men: Why an Anticommons Has Not Emerged in the Biotechnology Realm*, 17 *TEXAS INTELLECT. PROP. LAW J.* (2008).

⁸⁹ Robert P Merges, *A New Dynamism in the Public Domain*, 71 *UNIV. CHICAGO LAW REV.* 183–203 (2004).

many concurrent fragments of intellectual property rights in potential future products,” or “permitting too many upstream patent owners to stack licenses on top of the future discoveries of downstream users.”⁹⁰ The software realm has increasingly been fulfilling the first condition where many concurrent fragments of codes are patented: software patents have relatively long patent life in contrast to the fast-changing software market. The situation is worsened by the fact that a new software product often encompasses hundreds or even thousands of smaller components of code that might be patented already. Not only is obtaining licensing deals with each individual inventor an ominous task, but in many situations, a new product inventor may not even be aware of the existence of patents that cover a minor function of his or her product. One infamous example of a small component patent taxing future software is *Lucent v. Gateway*.⁹¹ Lucent accused Microsoft’s Outlook, Money and Windows Mobile software of using the “date picker” feature, which was patented by Lucent. For anyone who has used any one of these Microsoft products, it is clear there are many more components than just a date picker function. Nonetheless, the jury initially awarded Lucent a lump-sum royalty payment of approximately 358 million dollars,⁹² although this case was eventually settled between the two parties after courts revisited and the payment was brought down to a much lower value.

ii. Quantification of Taxation on Future Innovation

One indicator of whether an area is over-taxing intellectual property rights is to look into the likelihood of litigation. The fact that certain industries see higher patent litigation percentages than average suggests heightened conflicts between existing intellectual property rights and new technology. In fact, the empirical evidence collected by Allison *et al* seems to support this

⁹⁰ Heller, *supra* note 87.

⁹¹ See *Lucent Technologies, Inc. v. Gateway, Inc.* 580 F.3d 1301, 1338-39 (Fed. Cir. 2009)

⁹² *Id.* at 1325

argument. To study how litigation patterns differed by industry, Allison *et al.* examined data on every patent issued between 1963 and 1999 and every patent lawsuit terminated during 1999-2000.⁹³ They then hand-coded the patents in the sample study into 14 different technology categories and calculated percentage of patents litigated among all 14 industries.⁹⁴ Their results suggest 33.3% of the software patents in the sample study were litigated, compared with 21.9% of the non-software patents.⁹⁵ This result echoes discussions in the previous section that the software industry sees patents as more taxing than others. The pharmaceuticals industry, by comparison, only sees 16.8% of the patents in the sample litigated.⁹⁶

While the approach of evaluating taxation based on patent litigation rate is viable, there are criticisms that the litigation pattern is heavily dependent on the licensing tradition of each industry and thus could be unreliable. This paper thus proposes an alternative method of quantification, which is based on the nature of the technology. For those inventions that are somewhat discrete, such as those in the small-molecule pharmaceutical industry,⁹⁷ the taxation factor is benchmarked to be a value of “2.” On the other hand, for those inventions already showing signs of notable taxation, such as the software industry as discussed before, they are benchmarked to have a taxation value of “4.” Consequently, a value of “1” is assigned to be not taxing at all on future technology, “3” to be intermediate level of taxing, and “5” to be broadly and fundamentally preempting (such as a fundamental natural law).

The benchmark scheme can be represented below.

⁹³ John R. Allison et al., *Valuable Patents*, 92 GEORGETOWN LAW J. (2003). p. 437.

⁹⁴ *Id.* at 472

⁹⁵ *Id.* at 473

⁹⁶ *Id.*

⁹⁷ Robert P Merges & Richard R Nelson, *On the Complex Economics of Patent Scope*, 90 COLUMBIA LAW REV. 839–916 CR – Copyright © 1990 Columbia Law R (1990).

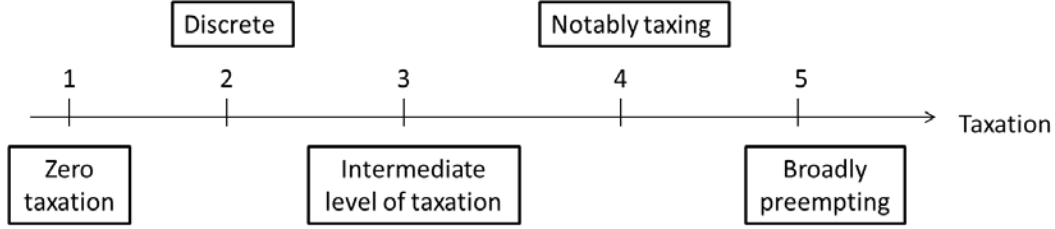


Figure 5. Taxation on Future Innovation Quantification Scheme

d. Framework Formulation

The basic framework to determining patentable subject matter for each category of inventions can be characterized as follows:

$$D = \frac{B}{C} \quad (1)$$

where D is the determination number, B is the benefits arising from granting patents for a category of inventions, and C is the costs of doing so. When $D > 1$, benefits outweigh costs, and the category of inventions should be patent-eligible; otherwise it should not. Further, let R denote R&D costs, I denote cost of imitation, and T denote taxation. Based on the discussions in previous sections, D can be expressed as:

$$D = \frac{B(R,I)}{C(T)} \quad (2)$$

The exact functional form of B as a function of R and I , and C as a function of T can vary depending on what in-depth research suggests the relationship between these factors should be. For demonstration purpose, this paper proposes that the benefit linearly correlates with R&D costs, and is a quadratic function of cost of imitation. We propose linear relationship between benefit and R&D costs because as discussed in previous sections, inventions with higher R&D costs tend to be more radically innovative. Benefit is proposed to be a quadratic function of

imitation cost because firstly the functional form reflects reality that the importance of granting patents is the highest for both extremes of the imitation cost and lowest for the middle imitation cost, and secondly squaring gives heightened effects to the extremes. Finally, it is assumed that cost is linearly correlated with taxation. Based on these assumptions, a sample model can be represented as below:

$$D = \frac{\alpha R + \beta [(I-3)^2 + 1]}{T} \quad (3)$$

where α and β are weights assigned to R&D cost and imitation cost. For demonstration purposes, in the rest of the paper, α and β take on values of 2/3 and 1/3, as R&D cost is often believed to be a more important factor to be considered. These weights, however, can be adjusted based on the judgments of policy-makers. Note that cost of imitation is subtracted by 3, which is the medium imitation cost. The quadratic term is added by 1 to shift the parabola such that the entire factor of $(I - 3)^2 + 1$ falls in the range of 1 to 5—just as for the factors R and T .

e. Remarks on the Framework

It is important to point out that the framework developed in this paper is not intended to evaluate the patentability of individual patents. Rather, this standard is intended to evaluate whether a class of inventions should be patent-eligible in light of the goal of enacting patent law. Problems may arise if this framework is applied to individual patents, as applicants may start to fiddle with research cost of the invention to enhance the chance of being patent-eligible. This would be socially wasteful and costly. This framework is also not suited for brand new industries or innovative activities that are not yet associated with any well-recognized categories, since the factors needed for the framework might not be available yet. However, the judicial system is

already confronted with a backlog of patentable subject matter cases to be sorted out, and this framework is intended to serve those inventions.

The model proposed here does not calculate all the benefits and costs of patenting, but it does encompass the major benefits and costs typically discussed in literature.⁹⁸ The model thus captures the main picture. The purpose of this work is to show that even a relatively crude model within the proposed framework shows a surprising level of consistency and robustness, as Part IV and V will show. This is a characteristic trait of quantitative analysis and demonstrates how powerful it can be when applied in policy-making. Thus the model is not definitive, but the framework it is built upon could serve as a starting point inviting more quantitative analysis in judicial decision-making process.

Finally, some commentators have argued that the system would be better off by simply abandoning the patentable subject matter inquiry as a whole, and instead heightening the standards of utility, novelty and nonobviousness already required by the Patent Act.⁹⁹ The invitation to substitute §102, 103 and 112 inquiries for the better established inquiry under §101 has not only been rejected by the Supreme Court in *Mayo*,¹⁰⁰ but it is also shown with rigorous economic model in Olson's study¹⁰¹ that this is not the most efficient method to determine patentable subject matter. Rather the patent system should start by determining initially on a category-by-category basis, whether classes of inventions should be patentable.¹⁰² Only after it is determined that a class of inventions is patent-eligible should one start applying other standards.

⁹⁸ Golden, *supra* note 7.

⁹⁹ 35 U.S.C. §102, 103 and 112 (2006).

¹⁰⁰ *Supra* note 33.

¹⁰¹ Olson, *supra* note 10.

¹⁰² *Id.* at 201

IV. Verification of the Framework

a. Limit-Testing

One way of testing robustness of a model is to take extreme values and see whether the outcome aligns with expectation. To do that, we first take value $T = 1$, which corresponds to the scenario where the invention does not tax any future inventions. This is a hypothetical scenario since all useful technologies are cumulative by definition. In this scenario, the determination number surface as a function of R&D cost and imitation cost looks as follows:

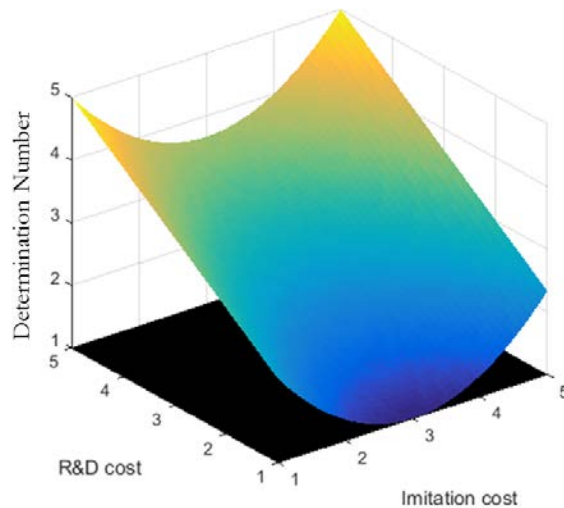


Figure 6. Determination number as a function of R&D cost and imitation cost when $T=1$

The black surface represents the patent-eligible threshold of 1. It can be seen that the model suggests when a class of inventions does not tax on any future innovation at all, it should be patent-eligible regardless of its R&D cost or imitation cost. This is reasonable since an invention that none of the future innovation will build upon likely is either a useless or trivial invention. In the case that it is useless, it does not hurt to grant the invention a patent since the only effect it

has is to increase revenue for the USPTO; in the case that the invention is trivial, the patent will likely be denied on the grounds of novelty or obviousness.

Now we test the other extreme, i.e., $T = 5$. This taxation value corresponds to the scenario that a class of invention is so taxing that granting patents to it would effectively stunt any future development of the field for the life of the patent. The determination number surface is represented in the following figure:

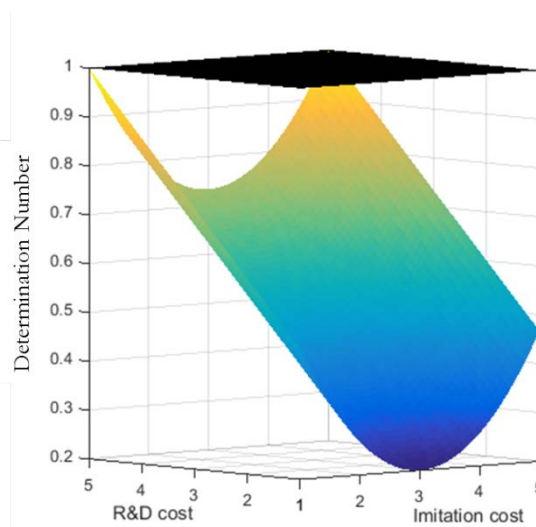


Figure 7. Determination number as a function of R&D cost and imitation cost when $T=5$

As can be seen from the figure, in the scenario of a class of inventions that is so taxing that development of the field is in danger of being stunted for the life of the patent, the model suggests no patents should be granted. This is reasonable since this effectively corresponds to the scenario of patenting plain physical principles or mathematical equations, such as $E = mc^2$. As courts have long realized, this category of inventions should not be patent-eligible because of its grave pre-empting effect.¹⁰³

¹⁰³ See e.g., *Parker v. Flook*, 437 U.S. 584 (1978) at 593.

b. A Canonical Case

The pharmaceutical industry has long been recognized as one area that needs and deserves patent protection.¹⁰⁴ Thus, we apply the model to the pharmaceutical industry to verify the outcome.

As discussed in Part III, the pharmaceutical industry has a high R&D cost, low imitation cost and low taxation. Therefore, the value of each factor is assigned to be $R = 5, I = 2, T = 2$.

Substituting these values into equation (3), and $D = 2 > 1$, which means pharmaceutical inventions should be considered patentable subject matter. This case is shown on the surface plot as follows:

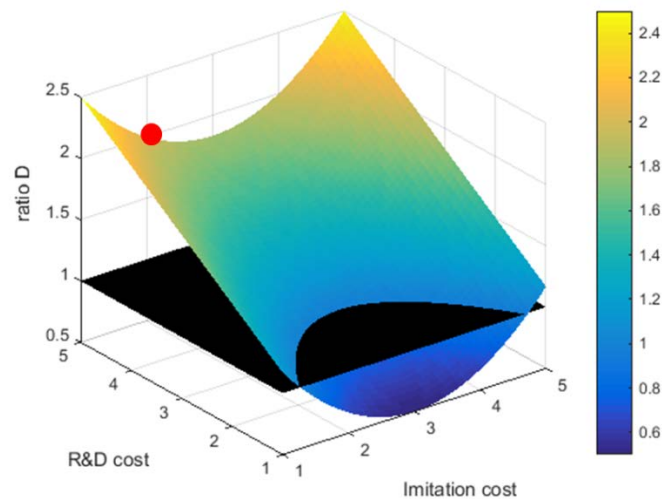


Figure 8. Determination Number of Pharmaceutical Inventions

It can be seen that the bar of patent-eligibility is fairly low because of the low-taxing nature of pharmaceutical inventions. Combined with high R&D cost and relatively low imitation cost, pharmaceutical inventions cross the threshold of patentability according to the model. This outcome aligns with our expectation.

¹⁰⁴ Gerald J. Mossinghoff, *Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide*, 2 J. LAW TECHNOL. (1987).

V. Applications

a. Isolated Human Genes

As the *Myriad* case illustrated, courts have struggled with the patent-eligibility of isolated human gene sequences. Applying the model proposed in this paper, we first need to decide the values of R , I and T . As we have discussed before, the R&D cost to discover these genes was high (but probably not as high as pharmaceuticals since no clinical trials are needed), the imitation cost could be so extremely high that it incentivizes inventors to keep a trade secret of it, and the invention is fairly taxing. Thus, the factors are assigned to be $R = 4, I = 5$ and $T = 4$. Substituting these values into the model, and we obtain a determination number of 1.083 (see the following figure), which suggests isolated human genes should be patent-eligible, but barely.

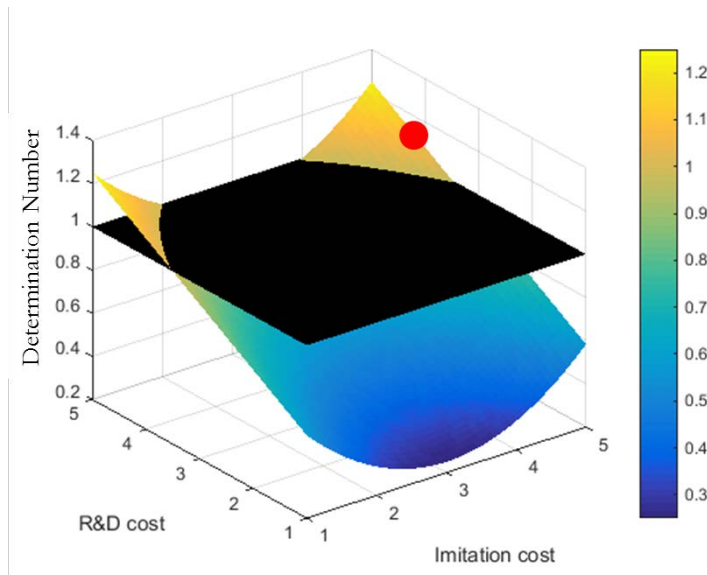


Figure 9 Isolated human gene patent-eligibility

As can be seen from the figure, the taxing nature of this class of inventions sets a high bar for patent-eligibility, and it only crossed the threshold because of a combination of high R&D cost and high imitation cost. The fact that the determination number comes out to be very close to the

threshold suggests the patent-eligibility of this class of invention is not as clear-cut as the case of pharmaceutical inventions. This correlates well with the actual current scenario where a lot of debates occurred surrounding the *Myriad* case.

b. Software

Software has been a controversial subject matter because it is inherently an algorithm, which means each step could technically be performed in someone's mind, although in reality that may take close to eternity to obtain any useful result.

Applying the formulation in section II, we first evaluate the R&D cost of software inventions. It is benchmarked to have a value of 4. The imitation cost of software is relatively high. Most software remains proprietary, such as Google's search algorithm. Therefore, the imitation cost factor I receives a value of 4. As discussed in section II(b), software patents are very taxing on future innovation. In fact, it is so taxing that many companies forbid their employees from reviewing patents for fear of being used for willful infringement of others' patents,¹⁰⁵ even though the infringement could be accidental. This is clearly contradictory to the intent of the patent system, and therefore software inventions receive a T value of 4.

Substituting the values of R and T into equation (3) and we obtain a determination number to be 0.833, which means software is not patent-eligible based on the proposed model, as shown in the following figure.

¹⁰⁵ Mark A. Lemley & Ragesh K. Tangri, *Ending Patent Law's Willfulness Game*, 18 BERKELEY TECHNOL. LAW J. (2003).

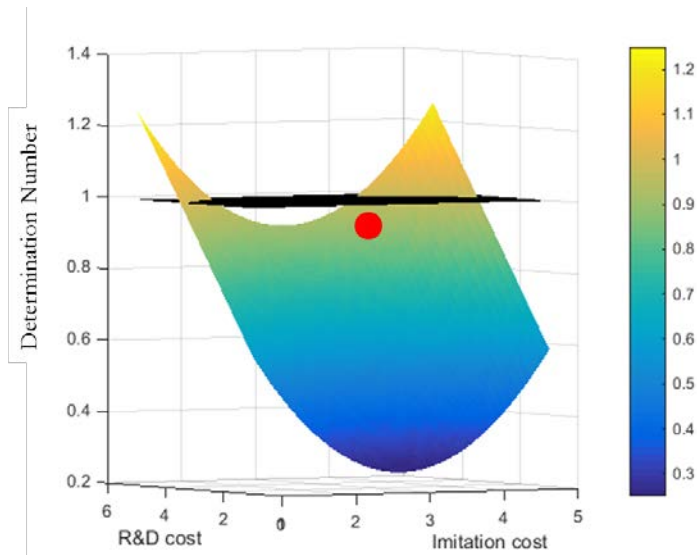


Figure 10. Software patent-eligibility

Although R&D cost and imitation cost are both high for software, the highly-taxing nature of software industry sets a high bar for patent-eligibility. This outcome suggests something should be done to alleviate the problem of existing patents taxing on future innovation. Many solutions have been proposed by scholars, such as shortening patent life¹⁰⁶ or creating a compulsory licensing scheme.¹⁰⁷ If these schemes are implemented, software inventions could become patentable subject matter.

c. Business Method

Business method patents have traditionally been allowed in the US. However, the idea of patenting abstract business methods is troubling on many levels. Intuitively, people are not used

¹⁰⁶ William D. Nordhaus, *The Optimal Life of a Patent*, COWLES FOUND. DISCUSS. PAP..

¹⁰⁷ Catherine Parrish, *Unilateral Refusals to License Software: Limitations on the Right to Exclude and the Need for Compulsory Licensing*, 68 BROOKLYN LAW REV. (2002).

to the idea that a business strategy could be granted a temporary monopoly. As Dreyfuss pointed out:¹⁰⁸

Think how the airline industry might now be structured if the first company to offer frequent flyer miles had enjoyed the sole right to award them or how differently mergers and acquisitions would be financed (and how rich Michael Milken might have become) if the use of junk bonds had been protected by a patent. The trend toward expanding protection deserves attention, with the advent of business method patenting deserving the most attention of all.

Applying the formulation in section II, we first evaluate the R&D cost of coming up with an innovative business method. As mentioned in section II(a), there is generally little research and development cost related to business and trading in general, as they are not research-driven industries. The industry surveys on banks, insurance and investment conducted by Standard & Poor did not even mention research and development in these areas. This is not to say business methods are never innovative. The examples given by Dreyfuss are very creative business methods, but they did not take teams of highly skilled workers ten years to come up with. Compared with other industries, the R&D cost for business method is low, and thus the value of R is assigned to be 2.

Business methods have extremely low imitation cost. Just imagine when the first company rolls out the frequent flyer miles, its competitors could copy the scheme and roll out the same plan the next day. Thus, the cost of imitation is assigned a value of 1.

¹⁰⁸ Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?* 16 SANTA CLARA COMPUT. HIGH. TECHNOL. LAW J. (2000).

There is some evidence that business method patents are somewhat taxing. Some have pointed out that the claims of business method patents often tend to be overly broad.¹⁰⁹ Others come to the opposite conclusion.¹¹⁰ Thus, this industry is determined to be intermediate taxing on future inventions, with a T value of 3.

Substituting R , I and T values into equation (3), and we get a determination number of exactly 1 (shown in the following figure), which means under this specific set of parameters of this model, the patent-eligibility of business method is a real nail-biter, as it is in real life.

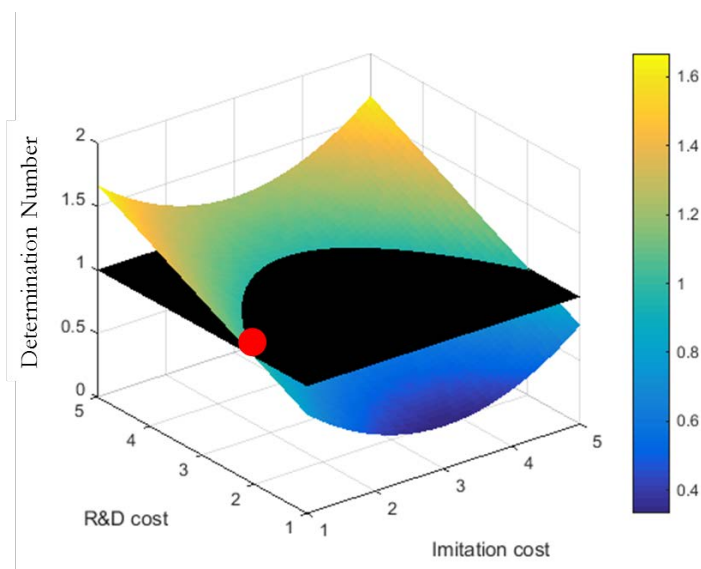


Figure 11. Business method patent-eligibility

The model suggests that the main reason why business method could be considered patent-eligible is because of the intermediate level of taxation on future business. If future studies come

¹⁰⁹ Lemley, Mark A. and Risch, Michael and Sichelman, Ted M. and Wagner, R. Polk, Life after Bilski (December 13, 2010). Stanford Law Review, Vol. 63, pp. 1315-1347, 2011; Stanford Public Law Working Paper No. 1725009; San Diego Legal Studies Paper No. 11-046; U of Penn, Inst for Law & Econ Research Paper No. 11-02; U of Penn Law School, Public Law Research Paper No. 11-05; Villanova Law/Public Policy Research Paper No. 2012-2003. Available at SSRN: <http://ssrn.com/abstract=1725009>

¹¹⁰ John R. Allison & Emerson H. Tiller, *The Business Method Patent Myth*, 18 BERKELEY TECHNOL. LAW J. (2003).

to a consensus that this class of inventions has overly-broad claims, the outcome will not tilt to the favor of business method.

VI. Institutional Choice

Professor Golden has investigated the institutional choice for patentable subject matter in great depth.¹¹¹ Presented with the choices of courts, Congress and the USPTO, Golden argues for giving rulemaking authority with respect to subject-matter eligibility to the USPTO. This section shows that the rationales outlined in Golden's article also apply to the framework proposed in this paper. Furthermore, the unique feature of this framework alleviates the usual concerns of capture for administrative agencies.

The first option to be evaluated is the courts. This paper and many other scholars have argued that courts' performance in adjudicating patentable subject matter has been fairly poor.¹¹² Courts are also ill-suited to apply the framework proposed in this paper for several reasons. First, the court system is dedicated to resolving individualized disputes, although it does take into some account *amici curiae*. Courts are not in a position to make policy decisions or to address matters in a way that takes proper account of a host of corollary scientific, economic and policy issues.¹¹³ Second, the framework proposed in this work may call for continual updating of the factors under consideration, methods of calculation and weights given to each factor. Courts lack the resources to do such industry and policy monitoring. Third, courts have limited power to implement a framework such as the one proposed in this paper since courts cannot apply the standard until a case is brought in front of the court, and not many cases make it to the court. The

¹¹¹ John M. Golden, *Patentable Subject Matter and Institutional Choice*, (2011).

¹¹² John F. Duffy, *Rules and Standards on the Forefront of Patentability*; Golden, *Id.*

¹¹³ *Supra* note 2 at 317.

decision period could be lengthy, adding uncertainties to the situation. Finally, this framework calls for flexibility to accommodate changes in technology and economics. Courts typically stick to prior rulings by the higher courts,¹¹⁴ thus removing one of the most important advantages of the framework.

The second option is Congress. As Golden pointed out in his work, Congress has been slow at providing useful instructions on patentable subject matter despite calls to do so from the court and commentators.¹¹⁵ The framework proposed here also deals with each industry/category of inventions individually, and Congress is unlikely to go into such details in legislation. As Burk and Lemley noted: “the prospect of the legislature continually revisiting the circumstances of each industry and passing appropriate new legislation for each situation is...bleak.”¹¹⁶

The last option is a government agency, and this paper agrees with Golden’s proposal to use the USPTO to implement patentable subject matter standards for three reasons. First, the USPTO has the most incentive and interest in administering the standard for patentable subject matter, especially considering its current situation of being flooded with patent applications. Proper application of patentable subject matter can act as a gatekeeper and weed out applications that do not need to be considered at all. Second, the USPTO already houses patent examiners who are experts in a variety of industries who are at the forefront of technological development. It is therefore in a good position to properly evaluate the factors that should be included in the proposed framework and the weight that should be given to each factor. It also can respond to new trends in technology in a timelier manner. Finally, granting the USPTO the power to implement the proposed framework raises less worry about agency-capture—one of the usual

¹¹⁴ See, Bowen, 448 U.S. at 221 (Scalia, J., concurring) (“Adjudication deals with what the law was; rulemaking deals with what the law will be.”)

¹¹⁵ *Id.* at 51-55.

¹¹⁶ DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT (2009), p 105.

concerns with government agencies. This is because “recent history suggests that concerns of USPTO capture and bias are overstated with respect to issues of patentable subject matter”¹¹⁷ to start with, and also the wholesome approach of the proposed framework that uses industry-wide data makes it less prone to individual lobbying effort. Furthermore, different industries would likely lobby towards different directions due to their diverse interests, and thus their efforts would cancel each other out.

VII. Conclusion

Current controversies regarding patentable subject matter in courts present substantial opportunities to make sensible standards to determine which class of inventions should be patent-eligible. Standards and rules are designed to ultimately serve the goal of enacting the law in the first place. Therefore, the framework developed here first considers the factor of research and development cost of a certain class of inventions: those with high research and development costs can only be invented and developed with the promise of a temporary monopoly granted by the patent system, without which the public may never get the invention because the inventors could not justify the cost and benefit of making such invention. Inventions with high R&D cost also need a larger sum of investment which means higher risk for investors. Absent the promise of a temporary market monopoly, investment crucial for the commercialization of costly inventions could be difficult to solicit. Finally, the coordination function served by the patent system is more important for inventions with a high R&D cost, because duplicative effort researching costly inventions is especially wasteful.

¹¹⁷ Golden, *supra* note 111.

The second factor considered is imitation cost. Those with low imitation cost could easily be copied and its market stolen by competitors that would necessarily have an edge since they did not invest in the invention of the product. Patent protection is therefore important for inventions with low imitation cost. However, when the imitation cost is high, the invention is at danger of being kept as a trade secret and the knowledge may theoretically never fall into the public domain. Thus the patent system is needed to encourage disclosure of the invention when the imitation cost is high. Therefore, inventions with imitation costs on both extremes call for patent protection, while those with intermediate imitation cost not as much.

After considering the two factors measuring the benefits of granting patents, the cost factor is then considered, i.e., taxation of future innovation. The goal of establishing the patent system is to encourage innovation. However, some categories of inventions are especially prone to the “tragedy of the anticommons” when there are too many concurrent fragments of intellectual property rights or when permitting too many upstream patent owners to stack licenses on top of the future discoveries of downstream users. When patents get too much in the way of future inventions, they should not be granted at all.

Monopoly, even a temporary one, is generally considered to have an adverse effect on the market, and therefore should not be generously handed out unless there is genuine need for it. Ultimately determining what constitutes patentable subject matter is a decision-making process. As many other fields have shown, quantitative analysis is often the most logical method to make rational decisions. Policy-making and judicial system should be no exception. The framework proposed here employs quantitative analysis of several important factors that parses out inventions that genuinely need patent protection to be invented, developed and commercialized, and at the same time the need is so great that it overcomes the potential taxation effect on future innovation by

granting patents to the current invention. This framework is robust, flexible and dynamic. It could be useful for government agencies when deciding which category of inventions should constitute patentable subject matter.