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# The Innovator's Dilemma

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## THE INNOVATOR'S DILEMMA

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#### INTRODUCTION

The United States patent system is designed to force innovators to make a choice: maintain their innovations as trade secrets or disclose them in exchange for patent protection.

Trade secret protection offers the prospect of perpetual protection, but it may be defeated by independent discovery of the secret. Conversely,

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<sup>1.</sup> Uniform Trade Secrets Act § 1 (1979) (amended 1985) (stating that a trade secret is "information that: (i) derives independent economic value... from not being generally known to, and not being readily ascertainable by proper means... and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its

patent protection offers protection against independent discovery, but it limits the term of protection.<sup>2</sup>

The patent system is often referred to in contract terms: the public obtains information which the innovator had the right to keep secret plus the right to use the innovation once the patent expires, while the innovator obtains enhanced protection for the innovation during the term of the patent. It is elementary contract law that there must be a "meeting of the minds"; ach party must know what they are giving up and what they are receiving.

Through the mid-twentieth century, innovators were able to make rational decisions between the two forms of protection; the decision did not need to be made until the terms of the patent on offer were finalized. Therefore, the innovator could compare known patent protection against known trade secret protection, fully understanding the bargain.

Four developments have made innovators' decisions more of a gamble and less of a contract: (1) patent office disclosure of innovations before reaching a decision on patentability, resulting from the introduction of pregrant publication;<sup>4</sup> (2) delay in processing patent applications resulting from increased volume of applications;<sup>5</sup> (3) restrictions and uncertainty as to what is patentable, resulting from Supreme Court decisions regarding statutory subject matter;<sup>6</sup> and (4) incentives to file patent applications early (and possibly prematurely), resulting from the change from a first-to-invent system to a first-to-file system.<sup>7</sup>

Combined, these developments force innovators to guess what might be on the other side of the bargain. They know that they must give up trade secret protection but they no longer know what, if any, patent protection they will get in exchange.

secrecy.") There is no fixed term—as long as the definitional requirements are met, trade secret rights continue. However, those rights only extend to prevention of "misappropriation"—acquisition or use of the trade secret by one who obtained it by "improper means." Thus, there is no protection against subsequent independent invention, since it does not meet the definition of misappropriation.

<sup>2. 35</sup> U.S.C. § 154(a)(2) (2011) ("Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States.").

<sup>3.</sup> Bowsher v. Merck & Co., 460 U.S. 824, 864 (1983) ("A contract, after all, is a meeting of the minds."); see also RESTATEMENT (SECOND) OF CONTRACTS § 17 (1981).

<sup>4. 35</sup> U.S.C. § 122 (stating in pertinent part that "each application for a patent shall be published . . . promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought under this title").

<sup>5.</sup> See infra p. 381.

<sup>6.</sup> See infra p. 385.

<sup>7.</sup> See infra p. 383.

This Article begins by describing the fundamental patent bargain: the federal government's offer of patent rights to an innovator in exchange for the innovator's trade secret rights. It then describes how the bargain was reached in "the good old days"—prior to the recent wave of patent reform. It then describes that wave of patent reform and how the modernization movement changed the nature of the bargain, with an emphasis on four changes: (1) the statutory revision that mandated publication of patent applications while they were still pending; (2) the administrative delays in deciding whether an innovation was patentable or not; (3) the statutory change to a first-to-file system and the resultant pressures on the patent office; and (4) Supreme Court decisions casting uncertainty on the likelihood of patentability of certain categories of innovation. It then catalogs and evaluates options for improving innovators' options.

### I. THE FUNDAMENTAL PATENT BARGAIN

All inventions start as trade secrets. The Uniform Trade Secrets Act defines a trade secret as information that—

(i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.<sup>8</sup>

Thus, until the inventor discloses the invention to someone else, it meets the definition of a trade secret because, prior to disclosure, there is no way other persons can learn it by proper means and the inventor is, by definition, taking reasonable steps to maintain its secrecy. A trade secret lasts as long as the definitional requirements are met; it has the theoretical potential to be a perpetual right. Publication of a patent destroys any trade secrets contained in the application by making them generally known. The inventor therefore must make a choice: keep the trade secret (perhaps forever) or give it up in exchange for a patent. More precisely, the exchange is not for a patent but rather for a possibility of a patent. It is this difference (possibility instead of certainty) that creates the dilemma facing innovators.

The owner of a trade secret can prevent misappropriation, which is generally defined as disclosure or use of a trade secret obtained by

<sup>8.</sup> Uniform Trade Secrets Act § 1(4) (1979) (amended 1985).

<sup>9.</sup> MPEP § 1309 (9th ed., Mar. 2014); see also id. § 1 (allowing publication would also destroy the trade secret as a failure to make reasonable efforts to maintain its secrecy).

<sup>10.</sup> See infra pp. 380-83.

improper means,<sup>11</sup> while the owner of a patent can prevent infringement, which is generally defined as the manufacture, use, sale or importation of a product incorporating a patented invention for a period starting on the date the patent is issued<sup>12</sup> and ending twenty years after the date the patent application was filed.<sup>13</sup>

While enforcement of a trade secret turns on whether the alleged infringer obtained the information from the trade secret owner, enforcement of a patent does not. 14 Thus, subsequent independent discovery is a defense against trade secret misappropriation but not against patent infringement. In addition, once a second party has independently discovered the trade secret information, that party is free to disclose it and thereby destroy the original trade secret owner's rights; a patent is not invalidated by subsequent independent discovery. 15 The patent system therefore provides motivation for holders of patent-eligible trade secrets to disclose them (and therefore surrender protection under trade secret law) in exchange for rights that are broader in scope but potentially shorter in duration. A patent has a fixed, but guaranteed, expiration date 16 while the term of a trade secret is uncertain and depends on events beyond the owner's control. 17

A patent represents a bargain between the federal government and an innovator, as envisioned by the Constitution.<sup>18</sup> The Constitution authorizes

<sup>11.</sup> Uniform Trade Secrets Act § 1(2).

<sup>12. 35</sup> U.S.C. § 154(a)(2) (2011).

<sup>13.</sup> Id. § 154 (stating that the patent expires twenty years after the date the earliest application was filed (i.e., if there are a series of related patent applications, referred to as "continuing applications," the term is measured from the date the first in the series was filed) and that it is subject to adjustment in certain circumstances related to delays in processing by the Patent Office).

<sup>14.</sup> Id. § 271(a) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.") (emphasis added).

<sup>15.</sup> Id. § 102 (providing that under the first-to-file system, a second inventor can destroy the first inventor's right to a patent by disclosing the invention before the first inventor discloses the invention (and files an application within a year from the disclosure) or files a patent application. The first inventor can minimize or eliminate this risk by filing a patent application as soon as an invention is made. A problem under the first-to-file system is the difficulty of determining just when an invention has been made.).

<sup>16.</sup> Id. § 154 (stating that it is subject to the owner's payment of periodic maintenance fees).

<sup>17.</sup> Uniform Trade Secrets Act § 1 (1979) (amended 1985).

<sup>18.</sup> U. S. CONST. art. I, § 8, cl. 8 ("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 [....]"); see also Congoleum Indus., Inc. v. Armstrong Cork Co., 366 F.Supp. 220 (E.D. Pa.1973) (explaining that the "Public

Congress to motivate scientific progress by granting 'limited term monopolies to inventors. Congress implemented this power early, 19 creating a system that promotes progress by motivating innovators to give up trade secret protection in exchange for a limited term, federally protected monopoly on the innovation. 20 The patent laws are not "primarily designed to provide a special private benefit .... [They are] intended to motivate the creative activity of authors and inventors ... and to allow the public access to the products of their genius after the limited period of exclusive control has expired." However, in order to motivate that creative activity, the statute offers inventors several benefits; in return, the public gets disclosure. 22

In theory, the disclosure required by the patent system benefits society more broadly than trade secret protection because broad disclosure provides the starting point for further research to a larger pool of researchers.<sup>23</sup>

policy of promoting the progress of the useful arts is achieved by granting a limited monopoly to an inventor who fully discloses his invention to the public in a United States patent"); Edward C. Walterscheid, *To Promote the Progress of Science and Useful Arts*, 2 J. INTELL. PROP. L. 1, 31-34 (1994) (detailing how the clause was adopted).

- 19. Patent Act of 1790, 1 Stat. 109 (1790) (repealed 1793).
- 20. See U.S. CONST. art. I, § 8, cl. 8 ("The Congress shall have Power... [t]o 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."). Note that this particular exchange is Congress' invention—the Constitution does not require disclosure of the invention in order to obtain the exclusive rights conferred by a patent.
- 21. Sony Corp. v. Universal City Studios, 464 U.S. 417, 429 (1984). Sony is not a patent case. It involved alleged infringement of copyrights. However, both copyright and patent laws are authorized by the same clause of the Constitution, and the Sony copyright analysis relies in part on patent precedents.
- 22. The Constitution speaks of promoting "progress," not "disclosure." Professor Malla Pollack has analyzed the meaning of the term "progress" in the Constitution and has concluded that the best interpretation is that Congress was instructed to promote disclosure and dissemination of inventions and discoveries. Malla Pollack, What Is Congress Supposed to Promote?: Defining "Progress" in Article i, Section 8, Clause 8 of the United States Constitution, or Introducing the Progress Clause, 80 NEB. L. REV. 754 (2001) (noting that there are multiple possible interpretations of "progress" in Art. I Sec 8 Cl. 8: "quality improvement in the knowledge base, quantity improvement in the knowledge base (judged economically), and spread (distribution to the population)" but concluding that "progress means 'spread,' i.e. diffusion, distribution"); see also id. at 755 ("Disclosure and dissemination" is also the interpretation which supports the requirements of 35 USC §§ 112 and 122.").
- 23. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974); see also Peter Lee, Note, *Patents, Paradigm Shifts and Progress in Biomedical Science*, 114 YALE L.J. 659 (2004) (arguing that patents promote hypothesis generation).

#### II. THE GOOD OLD DAYS

The innovators ideal would be to have the exclusive right to sell products embodying their innovations forever. This would enable them to charge monopoly prices and maximize profits. This ideal cannot be achieved.

An innovator can choose to maintain the innovation as a trade secret. There is no time limit on the trade secret. However, there is an "event limit" on the term of trade secret protection. If a second innovator independently makes the same innovation, it is not a misappropriation, and therefore, the second innovator is free to make use of that innovation to compete. Thus, the holder of a trade secret risks competition from another innovator. Moreover, it is not a misappropriation, (and therefore, the second innovator is free) to make a public disclosure of the innovation. Thus, the holder of a trade secret risks destruction of the trade secret and the resulting competition from the general public, and he or she can do nothing to preclude this risk. (27)

This provides the motivation to seek a less fragile form of protection for innovation, and the consideration (in the form of a patent) that the public might provide in a contract to obtain disclosure of the trade secret information. In the normal contract situation, each party knows what it is giving up and what it is gaining.<sup>28</sup>

As initially contemplated, the patent system provided innovators with a clear understanding of what the contract bargain involved, allowing innovators to make reasoned decisions concerning whether to maintain their innovations as trade secrets (and take the chance that someone else might independently recreate the same innovation and thereby destroy their competitive invention) or to accept instead a patent whose terms were known at the time the choice was made.

In "the good old days," lasting roughly from 1793 until the wave of patent harmonization and modernization that began in the mid-twentieth century, patent applications were maintained in confidence until issued as

<sup>24.</sup> See supra p. 373.

<sup>25.</sup> See supra note 1.

<sup>26.</sup> See supra p. 374.

<sup>27.</sup> See supra p. 374 (explaining that in order to maintain a trade secret, the innovator must take reasonable steps to prevent disclosure of the secret information. While that is necessary, it is not sufficient.); see also supra note 8 (noting that an additional requirement for maintaining trade secrecy is that the information not become generally available by improper means. Therefore, even if the innovator is entirely successful in taking reasonable steps to prevent disclosure, there is still a risk that the trade secret will be lost.).

<sup>28.</sup> The consideration may depend on external factors (as do, for example, production contracts or requirements contracts) but not to the point that there is no consideration on one side of the contract.

patents. Therefore, the patent process did not destroy trade secrets until the patent actually issued.<sup>29</sup>

The process of patenting an innovation begins with the filing of a patent application, 30 which includes specific, one-sentence-long claims which define the invention and set forth what competitors may not use, sell, or import. 31 In considering whether to issue a patent, the U.S. Patent and Trademark Office ("PTO" or "Patent Office") examines the application 32 to determine whether it discloses and claims an invention that meets the statutory criteria: principally, that the claimed invention is patentable subject matter, 33 that it is novel, 34 that it is non-obvious, 35 and that it is adequately described in the application. 36 The PTO then advises the applicant which, if any, of the claims it is willing to allow. The applicant then has several options, including attempting to convince the PTO to allow additional claims, amending claims to overcome the PTO's concerns, or abandoning the application. Applicants are generally allowed at least six months to reply to an examiner's action regarding an application. 37

Patent applications used to be maintained in confidence until the patent

<sup>29.</sup> Other events could, of course, still destroy the trade secret during pendency of the patent application. For example, if a competitor independently discovered the trade secret information and decided to publish it, the trade secret would be destroyed. However, provided that this occurred after the patent application had been filed, it would have no effect on patentability. In this situation, the competitor would face infringement (for using its own independent invention) once the innovators patent issued.

<sup>30.</sup> There are two types of utility patent applications—provisional and non-provisional. Only Non-Provisional applications are examined. 35 U.S.C. § 111 (2011).

<sup>31. 35</sup> U.S.C. § 112 (2011).

<sup>32.</sup> Id. § 131.

<sup>33.</sup> Id. § 101.

<sup>34.</sup> Id. § 102.

<sup>35.</sup> Id. § 103.

<sup>36.</sup> Id. § 112 (requiring the application to contain a written description (and drawings, if necessary to understand the invention as per § 113) in sufficient detail to enable one of ordinary skill in the art to make and use the invention).

<sup>37. 35</sup> U.S.C. § 133 (2011) ("Upon failure of the applicant to prosecute the application within six months after any action therein... or within such shorter time... as fixed by the Director in such action, the application shall be regarded as abandoned."); see also 37 C.F.R. § 1.136(1) (2002) (noting that the Patent Office usually sets an administrative deadline of less than six months but its administrative rules provide that such deadlines can be extended up to the statutory six months by paying late fees); MPEP § 710.02(e) (9th ed., Mar. 2014) ("If an applicant is required to reply within a nonstatutory or shortened statutory time period, applicant may extend the time period for reply up to the earlier of the expiration of any maximum period set by statute or five months after the time period set for reply, if a petition for an extension of time and the fee set in § 1.17(a) are filed.").

issued.<sup>38</sup> Thus, at any point prior to issuance of the patent, the applicant could withdraw the application, and its contents would remain secret. As a result, there was a bargain in the contract sense.<sup>39</sup> The applicant traded a trade secret for a patent, and both parties knew exactly what they were giving up and what they were getting.<sup>40</sup>

Patents lasted for seventeen years from the date the patent issued. Therefore, delays in the patent office did not reduce the term of the patent.<sup>41</sup>

Thus, in "the good old days," the fundamental bargain – limited term monopoly in exchange for the disclosure of a trade secret – comported with standard contract notions. The owner of a trade secret made an informed decision to exchange that property for specific other property.<sup>42</sup>

The fundamental bargain began to become complicated, as the patent reform movement changed the date when that decision needed to be made, then provided strong incentives that increased the number of patent applications and so increased the pendency of applications, while the Supreme Court cast doubt on the reliability of predictions of patentability.

<sup>38. 35</sup> U.S.C. § 122(a).

<sup>39.</sup> RESTATEMENT (SECOND) OF CONTRACTS § 17 (1981) ("The formation of a contract requires a bargain in which there is a manifestation of mutual assent to the exchange and consideration.").

<sup>40.</sup> Even an issued patent can be invalidated, and the Commissioner can withdraw a patent (although that power is rarely exercised). Either of these situations deprives the applicant of nothing if the invalidation is based on prior art, but poses a problem if the invalidation is based on qualification as statutory subject matter.

<sup>41.</sup> While delays did not reduce the term of the patent, they did shift the term. One of the motivations for the shift from the seventeen year from date of issue term to the current twenty year from date of application term was the fear of an abuse known as the submarine patent - an application kept pending for a long period while competitors invested in product development and promotion, only to find that they could not market their products once the patent issued. An extreme example, U.S. Pat. 2,705,484 (Mechanism for Controlling the Starting and Operation of Internal Combustion Engines), was filed in 1932 and not issued until 1955. Jorgensen v. Kingsland, 83 F. Supp. 319 (D.D.C. 1949). Delay in issuing a patent does not always work to the innovator's advantage. Fad products, for example, may lose market value before the patent issues, and therefore, the patent has no value in constraining competition. Delays in gaining patent protection can also give competitors time to build market power before being constrained by the threat of patent infringement. For example, it took Texas Instruments nearly thirty years to obtain the Japanese patent on the integrated circuit, the key to the modern computer industry. Texas Instruments applied for the patent on February 6, 1960, and it did not receive conditional approval until 1986. Japanese companies filed objections which further delayed issue until 1989. Some thought the Japanese government acquiesced in the delay in order to help its domestic computer industry develop. John Burgess, Japan Gives U.S. Firm Circuit Patent, WASH. POST, Nov. 22, 1989, at E2.

<sup>42.</sup> Interesting contract issues, beyond the scope of this article, arise where the trade secret owner is a minor.

#### III. THE MODERNIZATION MOVEMENT

Beginning in the 1970s, patents began to play a larger role in business. The emergence of high technology industries—the semiconductors and the personal computer industry, which enabled computer software and biotechnology—focused public attention on the importance of patents. With that attention came proposals to modernize the patent statute and increased patent litigation (and with it opportunities for courts to modernize interpretations of the statute).

Four developments, in particular, complicated the innovator's decision whether to surrender trade secret protection in order to obtain patent protection: a statutory change which allowed publication of patent applications eighteen months after filing, whether the patent had issued or not; delays in patent office processing which pushed the average time before patents were issued well beyond the eighteen month period thus forcing a decision before the patentability of the innovation was known; a statutory change awarding patents based on filing date rather than date of invention, with the effect of motivating additional patent filings and therefore greater pressure on the patent office's backlog; and Supreme Court statutory interpretations that limit the categories of patentable innovations.

#### A. Pre-Grant Publication

In 1975, as part of an international harmonization effort, the statute was amended to provide for publication of pending patent applications. With certain exceptions, the new law provided that patent applications would be published eighteen months after their initial filing date. If the PTO reviews an application and issues a final decision within eighteen months, there is no problem. The innovator can make a decision whether to accept the offered patent before the PTO publishes the application and destroys its trade secrets. In the case where the PTO concludes that the innovation is not patentable (or the scope of protection offered by the PTO is not satisfactory to the innovator), the innovator can abandon the application, and the patent will not be published – the trade secrets will remain intact. If the PTO agrees to a scope of patent protection satisfactory to the innovator, the innovator can allow the patent to be issued, thereby destroying its trade secrets but obtaining an acceptable patent in return.

<sup>43. 35</sup> U.S.C. § 122(b) (stating that applications are published eighteen months after their priority date).

<sup>44.</sup> It is common to file patent applications which claim priority from earlier-filed patent applications. In many cases, there are advantages to establishing the earliest priority date possible. The publication rule measures the eighteen months from the date of the earliest filed application from which priority is claimed.

Thus, the fundamental contract bargain is maintained if the patent office disposes<sup>45</sup> of applications before publication. However, if the PTO has not reached a final decision on patentability before the eighteen-month date is reached, the innovator is faced with balancing not trade secret protection against determined patent protection but trade secret protection against a range of possibilities of patent protection. The innovator's dilemma is even more acute if the application has not even been reviewed substantively at the time the applicant must make the decision. In that case, not only does the applicant not know the final form of patent protection, the applicant does not even have information regarding the PTO's position on patentability. In other words, the decision is more a lottery than a traditional contractual bargain.

#### B. The Pendency Problem

In "the good old days," pendency was generally not an issue for applicants. Patentees could maintain trade secret protection for as long as the application remained pending, so there was no trade-secret-related cost of delay. With the introduction of publication at eighteen months after filing, pendency became important.

There are two pendency periods of interest. "First action pendency" is the time from the filing of a complete patent application until a patent examiner substantively reviews the application and issues a first action regarding patentability), and "disposition pendency" is the time from filing until the application is disposed of, either by allowance and issue as a patent or by abandonment). While the PTO measures both and both are of interest to an applicant, first action pendency is the applicant's first opportunity to gain insight into how the PTO views the application and therefore the applicant's first opportunity to make an informed evaluation of the chances of obtaining a patent and the likely scope of protection. 47

The ability of the applicant to make this evaluation is important because of the "trade secret disclosure in exchange for patent protection" trade.

<sup>45.</sup> Disposition - i.e., either allowance of claims or final denial of the application-would be ideal. A first substantive patent office evaluation of the application prior to publication would at least give the applicant an indication of the likelihood of obtaining patent protection before the irrevocable decision to surrender trade secret protection had to be made.

<sup>46. 2013</sup> USPTO PERFORMANCE AND ACCOUNTABILITY REP. 14.

<sup>47.</sup> The inventor still faces uncertainty, as the first substantive action is rarely the end of prosecution. The first action does, however, provide important information indicating how the Patent Office views the application. In particular, under the current system, this is the earliest date on which the inventor will learn whether the Patent Office perceives an issue regarding statutory subject matter. Of course, there is still uncertainty even if the Patent Office sees no such issue, as the issue can still be raised as a defense in an infringement action.

Under pre-1975 law, the problem did not arise because patent applications were maintained in confidence until the patent issued, <sup>48</sup> so at any point prior to issuance of the patent, the applicant could withdraw the application and its contents would remain secret. There was a bargain in the contract sense. The applicant traded a trade secret for a patent, and both parties knew exactly what they were giving up and what they were getting. <sup>49</sup> With the 1975 statutory amendment <sup>50</sup> that provided for publication of pending patent applications, <sup>51</sup> the fundamental contract bargain could still be maintained if the patent office disposed <sup>52</sup> of applications before publication. However, if the application has not even been reviewed substantively at the time the applicant must make the decision, the decision is more a lottery than a traditional contractual bargain.

The Patent Office faces a significantly different world today than it did in 1975. In 1975, roughly 100,000 utility patent applications were filed, and 72,000 were issued as patents. In 2013 (the latest year for which there is available data), nearly 575,000 applications were filed, and more than 275,000 patents were issued. Expectations are that the transition to first-to-file under the America Invents Act ("AIA") will result in even more applications being filed, as nervous inventors will be motivated to file multiple applications on the same invention in order to reduce the risk that an anticipatory prior art reference will be created while the inventor is perfecting the invention. Expectations of the same invention in order to reduce the risk that an anticipatory prior art reference will be created while the inventor is

While the Patent Office has made progress in the last five years, it has been unable to provide a first substantive review of most patent applications within eighteen months of their filing date, and the average

<sup>48. 35</sup> U.S.C. § 122(a).

<sup>49.</sup> See supra note 40.

<sup>50.</sup> Pub. L. No. 93-596, 88 Stat. 1949 (1975).

<sup>51. 35</sup> U.S.C. § 122(b) (stating that applications are published eighteen months after their priority date).

<sup>52.</sup> Disposition - i.e., either allowance of claims or final denial of the application-would be ideal. A first substantive patent office evaluation of the application prior to publication would at least give the applicant an indication of the likelihood of obtaining patent protection before the irrevocable decision to surrender trade secret protection had to be made.

<sup>53.</sup> U.S. PATENT STATISTICS CHART CALENDAR YEARS 1963-2013, http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us\_stat.htm (showing that the exact numbers were 101,014 applications filed and 72,000 issued. Of course, the issued patents were unlikely to have been filed in the same year they were issued because of the time taken to examine an application. The numbers, however, are representative. Between 1970 and 1980, applications ranged from 99,298 to 104,329, and issued patents ranged from 48,854 to 78,317.).

<sup>54.</sup> Id.

<sup>55.</sup> Sean T. Carnathan, Patent Priority Disputes-A Proposed Re-Definition of "First-to-Invent", 49 ALA. L. REV. 755, 796 (1998).

time to reach a final decision on patentability approaches two and a half years.<sup>56</sup> Assuming that two weeks would be sufficient time for an inventor to receive a first substantive action, evaluate it, and make a decision whether to continue with the application or abandon it, the average pendency to first action would need to be reduced to sixteen-and-a-half months in order to allow for a decision to abandon the application to be communicated to the PTO in time to withdraw the application from publication.<sup>57</sup>

In part, the pendency problem can be traced to a PTO policy known as "compact prosecution," i.e., the identification of all issues related to patentability in the first substantive response to the applicant.<sup>58</sup> Patent Office guidance to its examiners cautions against "piecemeal prosecution":

Piecemeal examination should be avoided as much as possible. The examiner ordinarily should reject each claim on all valid grounds available.... Rejections on grounds such as lack of proper disclosure, lack of enablement, indefiniteness and res judicata should be applied where appropriate even though there may be a seemingly sufficient rejection on the basis of prior art. 59

On the positive side, compact prosecution gives the applicant as complete a picture as possible of the hurdles (if any) to patentability. There is, however, also a negative side because compact prosecution requires more work and therefore extends the time from filing until an application is even examined, delaying the point at which the applicant gets initial insight into the Patent Office's position on patentability.<sup>60</sup>

Prior to the adoption of pre-grant publication, this delay would have had no adverse impact on the innovator, as trade secret rights remained intact during the delay. Therefore, prior to issue (and surrender of the trade

<sup>56.</sup> USPTO PERFORMANCE AND ACCOUNTABILITY REP., supra note 46, at 16 (revealing that average pendency to first action was 18.2 months and to disposition 29.1 months in 2010. Five years ago, the average time to first action was 26.9 months, and the average time to disposition was 34.7 months.).

<sup>57. 37</sup> C.F.R § 1.138(c) (2002) (stating that an applicant can avoid publication by filing an express abandonment of an application under). *Cf.* MPEP § 1120 (9th ed., Mar. 2014) ("The Office cannot discontinue the pre-grant publication process during the last two to four weeks of the publication process.") It would therefore appear that the Patent Office must receive notice of abandonment no later than (and possibly earlier than) seventeen months from the effective application date.

<sup>58. 37</sup> C.F.R § 1.104(b) ("The examiner's action will be complete as to all matters, except that in appropriate circumstances, such as misjoinder of invention, fundamental defects in the application, and the like, the action of the examiner may be limited to such matters before further action is made."); MPEP § 706.03.

<sup>59.</sup> MPEP § 707.07(g).

<sup>60.</sup> An administrative decision to relax the rules of compact prosecution would benefit innovators. See Max S. Oppenheimer, Rethinking Compact Prosecution, 25 ALB. L.J. SCI. & TECH. 257 (2015).

secrets disclosed by the patent), the innovator would have received (and approved) the exact language reflecting what the patent claims would cover (and therefore deny to competitors). The patent bargain reflected a fully informed choice by the innovator, made at a time when both options (trade secrecy or defined patent protection) were available.<sup>61</sup>

However, with the publication clock ticking, a policy which delays the time at which the innovator can make an informed evaluation of what the Patent Office might offer in exchange for the innovator's trade secrets is a negative.

## C. The Redefinition of Inventorship: First-to-File

The move from the historical first-to-invent system to a first-to-file system was highly contentious. During that debate, proponents of the historical system worried about the impact of the change on the quality and pendency of patent applications. Under the historical first-to-invent system, the first inventor was entitled to a patent if an application was filed within a year of the first public disclosure or offer of sale of the invention. Under a first-to-file system, if the technology claimed in a patent application is already in the prior art at 64 as of the date the application is filed, the application will be rejected. Critics of the first-to-file system were therefore concerned that such a system would force inventors to file multiple premature and sketchy disclosures for fear of losing out to a later inventor who managed to draft an application more quickly. This, critics

<sup>61.</sup> Even an issued patent is, of course, subject to subsequent challenge. A patent owner also has options for dealing with errors in an issued patent, provided the errors were not made with deceptive intent.

<sup>62.</sup> President's Commission on the Patent System, To Promote the Progress of . . . Useful Arts in an Age of Exploding Technology at 5 (1966) (The proposed change was formally aired in the 1966 recommendation by President Johnson's Commission on the Patent System.); see also Statement of Donald J. Quigg, Assistant Sec'y & Comm'r of Patents & Trademarks (Mar. 16, 1987), available at http://www.uspto.gov/go/og/con/files/cons123.htm (supporting the 1987 move by the Clinton Administration); Max S. Oppenheimer, Harmonization Through Condemnation: Is New London the Key to World Patent Harmony?, 40 VAND. J. TRANSNAT'L L. 445 (2006) (noting arguments for and against the two systems).

<sup>63. 35</sup> U.S.C. § 102 (2012).

<sup>64.</sup> Id. § 102(a)(1)-(2) (explaining that "prior art" refers to information which is relevant to a determination of patentability: information which was available to the public through a printed publication, through public use, through an offer of sale, "or otherwise available to the public," expanded by the legal fiction that issued patents and published patent applications are treated as though they were published on their filing date, not the date on which the public has access to them).

<sup>65. 35</sup> U.S.C. § 101; see also id. § 102 (defining prior art which may be used as the basis for rejecting claims as not novel and also as the basis for rejecting claims as obvious under 35 U.S.C. § 103).

<sup>66.</sup> See, e.g., MAURICE H. KLITZMANN, PATENT INTERFERENCE LAW AND PRACTICE

worried, would lead to an increased burden on the Patent Office, which would need to respond either by lowering examination quality or tolerating increased application pendency.<sup>67</sup> Former Patent Commissioner, Donald W. Banner, noted that the negative impact of the system would fall disproportionately on inventors with limited resources.<sup>68</sup>

On March 15, 2013, the debate ended, and the first-to-file system went into full effect.<sup>69</sup>

While it is too soon for definitive data, one commentator pointed to Japan as a first-to-file country whose experience was predictive: over five times as many applications are filed in Japan than in the United States, and many of the 600,000 Japanese applications are "scraps of papers written by the inventors and submitted for a priority date."

United States standards would penalize such cursory applications because the Patent Act sets a higher standard of disclosure, one sufficient to enable those of ordinary skill in the field to make and use the invention. <sup>71</sup> If the United States continues to maintain its standards of enablement, United States inventors will face a disadvantage since they are required to file their applications in the United States, <sup>72</sup> and the higher standards

<sup>24 (1984) (</sup>noting that first-to-file would encourage a race to the patent office with "hasty application drafting with limited experimental exemplification or support"); Sean T. Carnathan, Patent Priority Disputes--A Proposed Re-Definition of "First-to-Invent", 49 ALA. L. REV. 755, 755, 796 (1998) (arguing that applicants may be "forced to file continuation-in-part applications in increased numbers" under a first-to-file system); Gregory J. Wrenn, What Should Be Our Priority: Protection for the First to File or the First to Invent?, 72 J. PAT. & TRADEMARK OFF. SOC'Y 872, 885 (1990) (cautioning that "there are significant risks that result from over-encouraging early filing").

<sup>67.</sup> See, e.g., Vito J. DeBari, International Harmonization of Patent Law: a Proposed Solution to the United States' First-to-file Debate, 16 FORDHAM INT'L L.J. 687, 704 (1993).

<sup>68.</sup> Donald W. Banner, *Patent Law Harmonization*, 1 U. Baltimore Intell. Prop. L. J. 9 (1992).

<sup>69.</sup> America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (prior to 2013 amendment) (technical corrections amendments); see also 35 U.S.C. § 100.

<sup>70.</sup> Charles R. Macedo, First-to-File: Is American Adoption of the International Standard in Patent Law Worth the Price?, 8 COLUM. BUS. L. REV. 543, 573 (1988) (noting the major part of a Japanese application contains marketing and sales promotion aspects of an invention. The actual detailed description of the invention itself is typically done in a very general manner [and] . . . the detail of black boxes is generally left undescribed even though the specific contents may not be readily available on the market.). See also Samson Helfgott, Differences Between U.S. and Japanese Patent Applications, 1 U. BALT. INTELL. PROP. L.J. 1, 3 (1992) (stating that, in the United States, "black boxes" would fail the disclosure requirements of 35 U.S.C. § 112).

<sup>71. 35</sup> U.S.C. § 112.

<sup>72.</sup> Id. § 184 (requiring United States inventors to file in the United States and wait six months before filing abroad or to obtain a foreign filing license).

translate into longer time to prepare the application (and therefore a later priority date). Therefore, a prudent United States inventor, unable to take advantage of more relaxed filing requirements abroad, would need to file at least two applications per invention: a minimal application to protect against lower-standard foreign filings and a fully-enabled application to meet United States standards. Therefore, even if inventive activity does not increase, it would be expected that filings would increase. These additional filings would increase the burden on the PTO and would be expected to increase pendency times.

## D. Supreme Court Activism

Adding even greater complexity, the Supreme Court's evolving definition of patentable subject matter has made it harder to predict whether an innovation will be patentable or not,<sup>73</sup> even if it represents a dramatic breakthrough.

Patents are only granted for certain types of inventions, known as "statutory subject matter" and defined in 35 U.S.C. § 101 as machines, manufactures, compositions of matter and processes.<sup>74</sup> The list of patentable subject matter, though broad,<sup>75</sup> is exclusive.<sup>76</sup>

More than 250 years ago, the Supreme Court held that Congress has "plenary" power to decide how to implement the Constitutional power to promote progress through the patent system, 77 and more recently, the Court

<sup>73.</sup> See infra pp. 391-92 (stating that there is always uncertainty in predicting patentability of an invention. Under 35 U.S.C. §§ 102 and 103, a patent will be denied if the claimed invention was already known or is merely an obvious extension of what was already known. Because it is impossible to fully characterize the prior art (some of which may be contained in patent applications which have been pending less than eighteen months and are therefore inaccessible), there is always an element of uncertainty around a patentability opinion. This is an unavoidable aspect of the priority system and one that is not even fully removed upon grant of the patent. Even an issued patent is subject to invalidation based on prior art that was not before the Patent Office during examination. However, the issue of patentable subject matter is a different (and solvable) uncertainty.).

<sup>74. 35</sup> U.S.C. § 101.

<sup>75.</sup> S. REP. No. 82-1979, at 5 (1952); H.R. REP. No. 82-1923, at 6 (1952) (stating that manufacture includes "anything under the sun that is made by man"); see also Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (rejecting the argument that a genetically engineered bacterium was implicitly excluded from statutory subject matter because, although a "composition of matter" it was alive).

<sup>76.</sup> Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 483 (1974) ("[N]o patent is available for a discovery, however useful, novel, and nonobvious, unless it falls within one of the express categories of patentable subject matter of 35 U.S.C. § 101 . . . . ").

<sup>77.</sup> McClurg v. Kingsland, 42 U.S. 202, 206 (1843) ("[T]he powers of Congress to legislate upon the subject of patents is plenary by the terms of the Constitution, and . . . there are no restraints on its exercise . . . . "); see also Evans v. Jordan, 13 U.S. 199 (1815); Bloomer v. McQuewan, 55 U.S. 539 (1852); Bloomer v. Millinger, 68 U.S. 340

warned lower courts not to read words into the patent statute.<sup>78</sup> This has not stopped the Court from creating exceptions to the categories of statutory subject matter<sup>79</sup> that are established by the clear words of the statute.

While the statutory language chosen by Congress is broad and has remained largely unchanged since first enacted in 1790, the Supreme Court has engrafted limitations on what otherwise appears to be a clear statement of Congressional intent. Moreover, the Court has revised its interpretation several times, leaving researchers uncertain as to what can be protected (and therefore what research might be justified economically). 80

While the statute authorizes four categories of statutory subject matter, the Supreme Court has excluded "laws of nature, natural phenomena, and ideas" from patent protection (even if they fall within one of the four categories) because "[p]henomena of nature... mental processes, and abstract intellectual concepts are... the basic tools of scientific and technological work." This matters, not only because the Court's definition is narrower than the statute's, but more importantly because the Court's definition is less predictable than the statute's. The unpredictability of the Supreme Court's definition is clearly shown by the difficulty the Federal Circuit has had in applying it; in every recent statutory subject matter case reaching the Supreme Court, it has reversed the Federal Circuit. In dealing with these reversals, the Federal Circuit has noted the difficulty of fathoming the Supreme Court's instructions. Its frustration is evident in passages such as the following:

The Supreme Court has not been clear... as to whether such subject matter is excluded from the scope of Sec. 101 because it represents laws of nature, natural phenomena, or abstract ideas. The Supreme Court also has not been clear as to exactly what kind of mathematical subject matter

<sup>(1864);</sup> Eunson v. Dodge, 85 U.S. 414 (1873).

<sup>78.</sup> Diamond v. Diehr, 450 U.S. 175 (1981).

<sup>79.</sup> *Id.*; see also Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63 (1972).

<sup>80.</sup> Max S. Oppenheimer, Patents 101: Patentable Subject Matter and Separation of Powers, 15 VAND. J. ENT. & TECH. L. 1 (2012).

<sup>81.</sup> Diamond, 450 U.S. at 185 ("Laws of nature, natural phenomena, and abstract ideas are . . . unpatentable."); Gottschalk, 409 U.S. at 71-72 ("Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable as they are the basic tools of scientific and technological work."); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) ("Laws of nature . . . are part of the storehouse of knowledge . . . free to all men and reserved exclusively to none.").

<sup>82.</sup> Gottschalk, 409 U.S. at 67.

<sup>83.</sup> Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).

may not be patented.... The Supreme Court has not set forth, however, any consistent or clear explanation.... 84

Given this uncertainty at the nation's specialized patent court, it is understandable that patent applicants would face difficulty in evaluating this aspect of patentability of their inventions - and therefore in evaluating the wisdom of surrendering trade secret protection. This uncertainty as to property rights is a disincentive for inventors to spend the time on fundamental research and for investors to provide the necessary funding.<sup>85</sup>

The clearest explanation of the theoretical underpinnings of these judicial exclusions may be found in Justice Breyer's dissent from the dismissal of certiorari in Laboratory Corp. of America v. Metabolite.<sup>86</sup>

The relevant principle of law "[e]xclude[s] from ... patent protection ... laws of nature, natural phenomena, and ideas." The justification for the principle does not lie in any claim that "laws of nature" are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race. Rather, the reason for the exclusion is that sometimes too much patent protection can impede rather than "promote the Progress of Science and useful Arts," the constitutional objective of patent and copyright protection. U.S. Const., Art. I, § 8, cl. 8. The problem arises from the fact that patents do not only encourage research by providing monetary incentives for invention. Sometimes their presence can discourage research by impeding the free exchange of information . . . . 88

As noted by Federal Circuit Judge Newman in 1994 "[t]he boundary between patentable and unpatentable subject matter is not always a bright line." Matters have not improved in the interim. The definition of

<sup>84.</sup> In re Alappat, 33 F.3d 1526 (Fed. Cir. 1994).

<sup>85.</sup> At a minimum, uncertainty results in higher costs of investment capital.

<sup>86.</sup> Lab. Corp. of Am. Holdings v. Metabolite Labs. Inc., 548 U.S. 124 (2006).

<sup>87.</sup> Diamond v. Diehr, 450 U.S. 175, 185 (1981).

<sup>88.</sup> Lab. Corp. of Am. Holdings, 548 U.S. at 126-27.

<sup>89.</sup> Alappat, 33 F.3d at 1568 n.19 ("The Supreme Court has not been clear, however, as to whether such subject matter is excluded from the scope of § 101 because it represents laws of nature, natural phenomena, or abstract ideas."); see also Diehr, 450 U.S. at 186 (viewing mathematical algorithm as a law of nature); Gottschalk, 409 U.S. 63, 71-72 (1972) (treating mathematical algorithm as an 'idea'). The Supreme Court also has not been clear as to exactly what kind of mathematical subject matter may not be patented. The Supreme Court has used, among others, the terms 'mathematical algorithm,' 'mathematical formula,' and 'mathematical equation' to describe types of mathematical subject matter not entitled to patent protection standing alone. The Supreme Court has not set forth, however, any consistent or clear explanation of what it intended by such terms or how these terms are related, if at all.

statutory subject matter has puzzled the Federal Circuit<sup>90</sup> and commentators.<sup>91</sup>

The Supreme Court itself noted that the "line between a patentable process and an unpatentable principle is not always clear." The PTO and Federal Circuit, in trying to implement the Supreme Court's evolving definition of statutory subject matter, have announced and then abandoned (or had overruled), a series of patentable subject matter rubrics: the "technological arts" test<sup>93</sup>; the "Freeman-Walter-Abele test" the "mental step" test<sup>95</sup>; the mathematical algorithm test<sup>96</sup>; the "machine implemented"

<sup>90.</sup> See infra pp. 388-89.

<sup>91.</sup> Joshua D. Sarnoff, Patent-Eligible Inventions after Bilski: History and Theory, 63 HASTINGS L.J. 53 (2011); Aaron J. Zakem, Note, Rethinking Patentable Subject Matter: Are Statutory Categories Useful?, 30 CARDOZO L. REV. 2983, 2988 (2009) ("[I]t has proven difficult to draw an exclusionary line which disallows inhibitive patents without prejudicing claims on novel and non-obvious technology..."; see also Max S. Oppenheimer, Patents 101: Patentable Subject Matter and Separation of Powers, 15 VAND. J. ENT. & TECH. L. 1 (2012).

<sup>92.</sup> Parker v. Flook, 437 U.S. 584, 589 (1978)

<sup>93.</sup> *In re* Musgrave, 431 F.2d 882 (CCPA 1970) (announcing the test); *Gottschalk*, 409 U.S. at 63 (rejecting the "technological arts" test).

<sup>94.</sup> Developed in three patent office decisions (*Freeman*, *Walter*, and *Abele*), the test essentially consisted of first determining whether a mathematical algorithm was recited directly or indirectly in the claim and, if so, next determining whether the claimed invention as a whole is no more than the algorithm itself or is applied to or limited by physical elements or process steps. See AT&T Corp. v. Excel Commc'ns, Inc., 172 F.3d 1352 (Fed. Cir. 1999) (rejecting the Freeman-Walter-Abele test) abrogated by *In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008) (rejecting the same test for it was too restrictive a formulation).

<sup>95.</sup> In re Musgrave, 431 F.2d 882, 893 (CCPA 1970) ("We cannot agree... that these claims... are directed to non-statutory processes merely because some or all the steps therein can also be carried out in or with the aid of the human mind or because it may be necessary for one performing the processes to think.").

<sup>96.</sup> Parker v. Flook, 437 U.S. 584, 593 (1978) (finding that a claim to a method of updating "alarm limits" was not covered by 35 U.S.C. § 101 since it amounted to the discovery of a mathematical formula which, although novel and since it was "not the kind of 'discovery' that the statute was enacted to protect"); Gottschalk, 409 U.S. at 71 (stating a claim to a method of converting binary-coded decimal numbers into decimal numbers was not an "invention or discovery" under § 101, even though the claimed method was to be performed by a computer, since the method had "no substantial practical application except in connection with a digital computer"); cf. Diamond v. Diehr, 450 U.S. 175, 185 (1981) (holding that a claim to a process for operating a rubber-molding press was within "101, even though one element of the claim was the calculation of the appropriate time to open the press. The Court distinguished Flook as not containing any disclosure relating to the chemical processes at work, the monitoring of process variables, or the means of setting off an alarm system" and noted "excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas . . . . Our recent holdings in Gottschalk v. Benson and Parker v. Flook, both of which are computer-related, stand for no more than these long-established principles.").

test<sup>97</sup>; and the "transformation" test.<sup>98</sup>

The two industries most affected by the narrowing of the statutory language are computer software and medical technology – two of the most important industries in the U.S. economy.

The early cases of *Gottschalk*, <sup>99</sup> *Flook*, <sup>100</sup> and *Diehr* <sup>101</sup> seemingly settled the question for the computer industry, but *Bilski* <sup>102</sup> and *Alice* <sup>103</sup> have reopened it. Most recently, the Supreme Court has held that certain types of medical treatment inventions, although within the meaning of "process," are nevertheless excluded from the definition of "statutory subject matter" and therefore cannot be patented because they represent no more than observing a correlation between a biological datum and a preferred method of treatment. <sup>104</sup> Further, it held that other types of inventions, although within the meaning of "composition of matter," are nevertheless excluded from the definition of "statutory subject matter" and therefore cannot be patented because they represent no more than extracting something which previously existed in nature. <sup>105</sup>

At a minimum, these cases complicate the innovator's decision concerning whether to seek patent protection for computer implementations or medical discoveries in general. Complication and uncertainty have two important consequences. They tend to favor trade secrecy in two fields where trade secret protection is a viable option, <sup>106</sup> and they increase the cost of financing innovation in two fields where innovation is economically important. For example, while Congress would certainly have the power to exclude the provision of medical services from the type of progress the

<sup>97.</sup> In re Grams, 888 F.2d 835, 841 (1989) ("The fact that a nonstatutory method is carried out on a programmed computer does not make the process claim statutory.").

<sup>98.</sup> Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014); Bilski v. Kappos, 561 U.S. 593 (2010).

<sup>99.</sup> Gottschalk, 409 U.S. 63 (1972).

<sup>100.</sup> Flook, 437 U.S. 584.

<sup>101.</sup> Diamond v. Diehr, 450 U.S. 175 (1981).

<sup>102.</sup> Bilski, 561 U.S. 593 (holding that although not all business methods were "categorically outside of '101'" the computer implemented method of "hedging risk and the application of that concept to energy markets" were not patentable as processes "because they are attempts to patent abstract ideas").

<sup>103.</sup> Alice Corp., 134 S. Ct. at 2347 (holding that the claims did not "do more than simply instruct the practitioner to implement the abstract idea of intermediated settlement on a generic computer" and were therefore not patentable).

<sup>104.</sup> Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012).

<sup>105.</sup> Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

<sup>106.</sup> Computer programs can be maintained in secret while offering "Software As Service." Diagnostic test companies can maintain processes and evaluation criteria in secret and insist that samples be sent to them for analysis.

nation wants to encourage, <sup>107</sup> it would be astonishing if it chose to do so, given the recent emphasis on the importance of improving access to medical care and cost containment and the hope that better data management will help reach those goals.

#### IV. IMPROVING INNOVATORS' OPTIONS

Innovators have three categories of options for dealing with the dilemma: (1) lobby for statutory change or challenge the constitutionality of the statute, (2) lobby for regulatory reform, or (3) work within the system.

### A. Statutory Reform and Constitutional Challenge

Both the eighteen-month publication and the transition to first-to-file were part of a movement to harmonize United States patent law with international standards. Both were the result of lengthy lobbying and negotiation, <sup>108</sup> and it seems unlikely that lobbying could reverse the trend, absent a major problem in implementation.

It is tempting to argue that the publication of trade secrets before a patent is granted is, in effect, a taking of property (the trade secrets) without compensation in violation of the Fifth Amendment. However, the rule has been in effect for more than forty years without challenge, and success seems unlikely. As discussed *infra*, an applicant can opt out of the eighteen-month publication requirement if the application is not also being filed in another country which publishes after eighteen months. Thus, it could be argued that the trade secret would be lost in any event, so nothing is being taken.

The transition to first-to-file is more recent than the eighteen-month publication amendment, and it is also more open to constitutional challenge. 110 Commentators have noted the practical problems created by a

<sup>107.</sup> It has done so in several areas. Nuclear weapons technology and tax strategy patents and claims "directed to or encompassing a human organism" are specifically excluded from patentability. 42 U.S.C. § 2181(a) (2010) ("No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon."); America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011). Although theoretically patentable, medical procedures are, in effect, not worth patenting as Congress has denied remedies for infringement. See also 35 U.S.C. § 287(c)(1) (2002).

<sup>108.</sup> See generally Oppenheimer, supra note 62.

<sup>109.</sup> U.S. CONST. amend. V ("[N]or shall private property be taken for public use, without just compensation." To constitute an unconstitutional taking, it would need to be shown that the applicant had a trade secret at the time it was "taken" by government publication.).

<sup>110.</sup> See Oppenheimer, supra note 62, at 470-88 (discussing the arguments for and against constitutionality).

first-to-file system and its negative impact on innovators. <sup>111</sup> Congress, however, has the power to make laws that hurt innovators. The basic argument that the first-to-file system exceeds congressional power revolves around the constitutional authorization to offer limited term monopolies to "authors" and "inventors" <sup>112</sup> and the contemporary definition of inventor, <sup>113</sup> as reflected in every patent statute <sup>114</sup> prior to the AIA amendments. <sup>115</sup> All focus turns on an inventor being the first person to make a discovery, not the first person to reach the patent office. As the Constitution only authorizes rewards to "inventors," the first-to-file system is beyond constitutional authorization.

## B. Regulatory Reform

One of the factors contributing to the delay in the PTO is its administrative requirement of "compact prosecution" under which, when a patent application is examined substantively, the PTO examiner is instructed that the review is to be "complete as to all matters" and that "piecemeal examination should be avoided." While this may be a theoretically efficient way to examine applications, it results in delaying the time when an applicant receives a first substantive response to the application. 118

This system could be modified by administrative action, a process which is much easier to achieve than statutory reform. Especially given the uncertainty created by recent Supreme Court decisions on statutory subject matter, modifying the system to allow applicants to opt out, or to at least request an early determination as to statutory subject matter, would provide

<sup>111.</sup> See supra note 67.

<sup>112.</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>113.</sup> JOHNSON'S DICTIONARY OF THE ENGLISH LANGUAGE 1123 (1st ed. 1755) (defining inventor as "a finder of something new"); see also WILLIAM C. ROBINSON, THE LAW OF PATENTS AND USEFUL INVENTIONS, 211 n.2 (1890).

<sup>114.</sup> Burrow-Giles Lithographic Co. v. Sarony, 111 U.S. 53, 57 (1884) (noting the first two patent statutes were adopted in early sessions of Congress. "The construction of the Constitution by the first act of 1790... by the men who were contemporary with its formation, many of whom were members of the convention which framed it, is of itself entitled to very great weight, and when it is remembered that the rights thus established have not been disputed during a period of nearly a century, it is almost conclusive.").

<sup>115.</sup> See Patent Act of 1790 §§ 1, 5, 1 Stat. 109, 109-10, 111 (1790); Patent Act of 1793 §§ 3, 6, 1 Stat. 318, 321-22 (1793); Patent Act of 1836 § 9, 5 Stat. 117, 121 (1836).

<sup>116. 37</sup> C.F.R. § 1.104(b) (2002).

<sup>117.</sup> MPEP § 707.07 (9th ed., Mar. 2014).

<sup>118.</sup> See generally Oppenheimer, supra note 60 (detailing compact prosecution and a proposal for modifying the system).

significantly greater certainty at the time when the decision must be made whether to surrender trade secret protection by allowing publication of the application.

From the perspective of the constitutional bargain, the requirements of 35 U.S.C. § 101 are qualitatively different from the Section 102 and 103 requirements that a patent be issued only for new, non-obvious inventions. If an application is rejected because the claimed invention fails to satisfy Section 102 or 103, it means there is already publicly available information describing the claimed invention 119 or rendering it obvious, 120 and therefore, since the information was publicly available, there was no trade secret to protect. A Section 101 rejection, however, can apply even if the public does not have access to the information disclosed in the application (meaning that the applicant is, in fact, surrendering a trade secret.)

There is precedent for preliminary determinations, even under compact prosecution. Even before an application receives a filing date, it is examined for compliance with certain requirements of the statute: whether the application appears to be complete, whether it includes any required drawings, whether it contains claims if a non-provisional application, whether it identifies the inventor, and whether the appropriate fees have been paid. These examinations are carried out quickly, typically within a month of filing the application.

In addition, there is at least one instance in which, even under the current system of compact prosecution, there is a preliminary examination for compliance with the requirements of 35 U.S.C. § 101: where disclosure is directed to perpetual motion. <sup>123</sup> If the patent examiner believes the claims are directed to perpetual motion, the examiner is instructed to challenge the claims under 35 U.S.C. § 101 without also conducting a prior art search or

<sup>119. 35</sup> U.S.C. § 102 (2011).

<sup>120.</sup> Id. § 103.

<sup>121.</sup> Uniform Trade Secrets Act § 1 (1979) (amended 1985) (defining a trade secret as "information that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy"). Thus, for at least three reasons there can be no trade secret. By definition, a trade secret must be information which the applicant's competitors do not know. If publicly available, competitors can gain access through proper means, negating trade secret status. Finally, if publicly available, there is no way the applicant can take reasonable steps to protect it.

<sup>122.</sup> MPEP § 503 (9th ed., Mar. 2014).

<sup>123.</sup> MPEP § 707.07g(D) (instructing that "the best prior art readily available should be cited and its pertinency pointed out without specifically applying it to the claims"); see also Newman v. Quigg, 877 F.2d 1575, 1581 (Fed. Cir. 1989) (upholding a rejection of claims to an "Energy Generation System Having Higher Energy Output Than Input" as unpatentable for lack of 35 U.S.C. § 101 utility).

engaging in any of the other usual steps in examination.

A determination of qualification as statutory subject matter is closely analogous to these types of determinations. It is an essentially legal analysis and does not require comparison of the claimed invention with prior art.<sup>124</sup>

Authorizing a preliminary evaluation of statutory subject matter eligibility should therefore be within the PTO's authority to manage the prosecution process. Moreover, such a preliminary determination might well save costs by terminating some applications early in light of a negative view of patentable subject matter eligibility. This would benefit the PTO by saving examination costs, and it should also help reduce overall pendency times by reducing the need for examiners to conduct prior art searches<sup>125</sup> and would preserve the innovator's option to maintain trade secrets by abandoning an application where the PTO concludes that the subject matter is not patentable.

The biotech and computer software industries would likely be the principal beneficiaries of this change. They are the industries that are front and center in the Supreme Court's definitional cases. They are enormously important to the U.S. economy, and they are industries which rely heavily on patent protection and suffer from above-average pendency times<sup>126</sup> because of their reliance on patents to protect their massive investments in research and development.<sup>127</sup>

In many cases the availability of patent protection for corporations engaging in biotechnology R&D is essential to their survival... [b]ecause it generally takes so much investment to develop and get approval for a new therapeutic....

Besides the argument for enhanced industry security, allowing patent protection would stimulate this and related business sectors by creating jobs and contributing to a positive balance of trade that the United States generally enjoys within the intellectual property marketplace. 129

<sup>124.</sup> AT&T Corp. v. Excel Commc'ns, 172 F.3d 1352, 1355 (Fed. Cir. 1999) (holding that statutory subject matter is a legal issue and is reviewed by courts without deference).

<sup>125.</sup> As an indication of the relative complexity of statutory subject matter determinations and prior art evaluations, the MPEP covers the former in four pages, while the latter requires more than 100 pages.

<sup>126.</sup> Thus, even if the Patent Office reaches its goal of reducing average pendency below eighteen months, it is unlikely that the average in these art units will reach that level.

<sup>127.</sup> See infra note 129 (noting that estimates vary widely but put the cost to bring a new drug to market in the billions).

<sup>128.</sup> Byron V. Olsen, The Biotechnology Balancing Act: Patents for Gene Fragments, and Licensing the "Useful Arts", 7 Alb. L.J. Sci. & Tech. 295, 321 (1997).

<sup>129.</sup> Id. 321-22 (positing that today's development costs for a new drug are in the

Even Justice Breyer's argument against patent protection for basic discoveries acknowledges the difficulty and value of these discoveries. 130

There is thus a reasonable case to be made for the PTO to revise its rules, at least to permit early determination of whether a claimed invention satisfies the statutory subject matter requirement.

#### C. Interim Options

In the absence of statutory change or regulatory reform, innovators have other options for mitigating the dilemma posed by the need to decide to surrender trade secrets before being assured of acceptable patent protection. The options are limited and imperfect. In some circumstances, an applicant can opt out of pre-grant publication. In other circumstances, an applicant can request expedited examination, and an applicant can use the Provisional Application option and a strategy of multiple filings to increase options (but at significant cost and without entirely eliminating the dilemma).

#### 1. Non-Publication Requests

Current rules allow an applicant to affirmatively opt out of the pre-grant publication program. <sup>131</sup> In order to do so, the applicant must represent that the application will not be filed in any country that publishes applications before the grant of a patent, including under the Patent Cooperation Treaty. <sup>132</sup> While this solution technically avoids the dilemma presented by the need to decide whether to surrender a trade secret in the absence of critical information, it exacts a significant price. In effect, it merely transfers the dilemma from "surrender trade secret or not" to "surrender international protection or not."

billions of dollars. The Tufts Center for the Study of Drug Development Annual estimate places the cost of developing a drug at \$2.558 billion.); see also Matthew Herper, The Cost Of Creating A New Drug Now \$5 Billion, Pushing Big Pharma To Change, FORBES (Aug. 11, 2013), http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/ (putting the cost of creating a new drug at \$5 billion).

<sup>130.</sup> Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 127 (2006) (Breyer, J., dissenting) ("The justification for the principle does not lie in any claim that "laws of nature" are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming... and that research may prove of great benefit to the human race.") (internal citations omitted).

<sup>131. 35</sup> U.S.C. § 122(b)(2) (2011); see also 37 C.F.R. § 1.213 (2002); MPEP § 1122 (9th ed., Mar. 2014).

<sup>132.</sup> MPEP § 1122.

#### 2. Expedited Processing Requests

Current rules also allow an applicant to request expedited examination under certain conditions and upon payment of an extra fee. The scope of the expedited examination does not differ from the scope of regular examination. The application is simply placed in a separate queue, ahead of those in the regular examination queue, and there is therefore no guarantee that the examination will take place ahead of the eighteen-month publication date.

### 3. Provisional Filings

Provisional Patent Applications are not published, but they may be used to establish a priority date for a subsequent Non-Provisional Patent Application.<sup>134</sup> However, if a Provisional Application is used to establish priority, then the publication calculation runs from the date the Provisional Application was filed.

A strategy can be used, however, to expand the applicant's options by filing multiple provisional applications.

For example, an innovator could file a Provisional Application, then refile it three months later, then refile it again in another three months, and then refile it again in another three months and so on. Shortly before one year after the initial filing, the innovator must make a decision whether to proceed with a Non-Provisional Application or not. If so, then the application will be published eighteen months after the initial Provisional filing (or, roughly six months after the Non-Provisional filing). If the applicant is confident, however, that no one else is developing the same invention, the first Provisional Application can be abandoned. In that case, another decision must be made shortly before the one-year anniversary of the second Provisional filing. The process is then repeated.

It is not without risk. Another inventor may be working on the same innovation but not have made any public disclosure. If that inventor files first, they will get the patent.

A variation, then, involves filing multiple Provisional applications and filing multiple Non-Provisional applications at the one-year anniversary of each Provisional application. This allows the innovator to review the competitive landscape near the eighteen-month anniversary of each Provisional filing, and make a determination at that time whether to proceed or not. The strategy is expensive and risky, only providing

<sup>133.</sup> Id. § 708.02.

<sup>134. 35</sup> U.S.C. § 122.

<sup>135.</sup> *Id.* (providing that provisional applications expire after twelve months so the decision cannot be postponed beyond that point).

periodic backstops rather than certainty that the innovation is being protected as well as possible, but it does expand the options for maintaining trade secrecy longer if this is a tolerable risk. However, the riskiness and expense of this strategy is itself evidence of the need for reform.

#### CONCLUSION

Given the current system of pre-grant publication, <sup>136</sup> the pressures of a first-to-file system, <sup>137</sup> and the uncertainty as to the scope of statutory subject matter, <sup>138</sup> innovators face a dilemma: they must make an irrevocable decision to sacrifice trade secret protection before knowing whether they will get anything in return. Strategies exist to reduce the problem, but all come at a price and none are perfect.

The Constitution authorized creation of the patent laws "to motivate the creative activity of authors and inventors . . . and to allow the public access to the products of their genius after the limited period of exclusive control has expired. Assuring inventors that their innovations will not be taken from them unfairly is a step toward motivating creativity and, more importantly, the disclosure that is the goal of the system.

<sup>136.</sup> America Inventors Protection Act, Pub. L. No. 106-113, § 4502, 113 Stat. 1501, 501A-561 (1999) (providing for publication of most patent applications eighteen months after their initial filing date, whether the application had been allowed as a patent or not). Prior to 1999, patent applications were maintained in secrecy until issued as patents. Under that system, the problem of pendency did not arise. See also 35 U.S.C. § 122(b)(1)(a) (stating that patent applications are treated as confidential by the Patent Office until the eighteen-month publication date (or until the application is issued as a patent if the applicant certifies that international applications will not be filed)).

<sup>137.</sup> See supra p. 383.

<sup>138.</sup> See supra p. 385.

<sup>139.</sup> Id.