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THE PROBLEM OF UNPATENTABLE INNOVATION IN PHARMACEUTICALS

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I. Introduction

As capital intensive public goods, pharmaceuticals are likely to receive inefficiently-low investment in the absence of government intervention. The patent system functions well to promote innovation in the pharmaceutical industry. However, because innovation in pharmaceuticals depends on patent protection, there is under-investment in unpatentable innovation. As a result, the public is deprived of potentially biologically plausible interventions, some of which are only unpatentable because of how the novelty requirement is applied to patent prosecution. To mitigate this unfortunate result, a complement to the federal patent law is needed. State law is one potential option, though such an approach would require modification of Supreme Court precedent or an advancement in technology. Otherwise, the solution is likely federal.

II. Pharmaceutical Innovation is a High-Risk Proposition

Public goods—nonrivalrous and nonexcludable goods with large social benefits—tend to be produced in inefficiently low quantities without government intervention.[1] This tendency is exacerbated when the goods are in a capital intensive industry, when efforts to create the goods carry high risk, or when the goods are easily replicable by competitors.[2] Conversely, this tendency is mitigated when lead times allow recoupment of the investment, when network externalities raise the barrier to entry for second-comers, or when self-help methods can prevent free-riding.[3]

Pharmaceuticals are a particular type of public good that has the exacerbating factors. Because of regulatory requirements (various human protections in place via FDA regulations and HIPPA, among other restrictions), pharmaceuticals are a capital intensive industry, with average clinical

[1] WILLIAM W. FISHER III & TALHA SYED, *Chapter 2: Institutions*, *in* INFECTION: THE HEALTH CRISIS IN THE DEVELOPING WORLD AND WHAT WE SHOULD DO ABOUT IT 1, 2 (Stanford University Press, forthcoming 2017), https://cyber.harvard.edu/people/tfisher/Infection_Institutions.pdf (Version 2.1, January 14, 2015).
[2] *Id.* at 3.
[3] *Id.*

testing costs estimated at over $450 million.[4] Further, marketing costs for new drugs are high because developers must essentially create the market for their good and must communicate certain advertising messages required by the FDA.[5] There is a high risk of failure—a mere 10 percent of drugs initially developed successfully pass from drug design and drug discovery through Phase III clinical testing and FDA approval.[6] Additionally, pharmaceuticals are easily copied through reverse engineering.[7]

Yet pharmaceuticals lack the mitigating factors. Because pharmaceuticals are easily copied through reverse engineering,[8] there is no lead time advantage; network externalities are not present because second-comers must only show bioequivalence and only in one indication;[9] the formulas of drugs cannot be protected from reverse engineering through encryption or secrecy.[10]

With all of these factors in play, there is little natural incentive to invest in research and development (R&D). The risk of losing one's investment to free-riders is too high. But

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[4] Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 510–11 n.22 (2009) (citing Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs,* 22 J. HEALTH ECON. 151, 165 (2003)).

[5] Examples of FDA regulations regarding direct-to-consumer advertising are available from the FDA's Guidance, Compliance & Regulatory Information webpage, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064956.htm (last visited March 18, 2018).

[6] *CLINICAL DEVELOPMENT SUCCESS RATES 2006–2015*, https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf (probability of progressing from Phase 1 to FDA approval is 9.6%).

[7] Alan Devlin, *Systemic Bias in Patent Law*, 61 DEPAUL L. REV. 57, 69 (2011) (explaining that generic drug manufacturers are adept at reverse engineering drugs, and the payoff from the process makes it a "no brainer.").

[8] *But see* FISHER & SYED, *supra* note 1, at 3 (explaining that reverse engineering and replication is more difficult for "biologics" than for traditional pharmaceuticals).

[9] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, informally known as the Hatch-Waxman Act, prevents the FDA from requiring more than a showing of bioequivalence in a generic manufacturer's Abbreviated New Drug Application (*see generally* 21 U.S.C. § 355 (2012)); Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 293, 301–02 (2015) (explaining Hatch-Waxman Act's bioequivalence requirements); Devlin, *supra* note 7, at 69 (same).

[10] FISHER & SYED, *supra* note 1, at 3 ("The ease with which most pharmaceutical innovations can be deciphered and copied, and the low marginal costs of producing copies, increase the likelihood that innovators will be unable to recover their up-front costs. For much the same reason, the lead time enjoyed by the creator of new drug is usually short. Increasing excludability through self-help is typically impracticable; pills can't be encrypted.").

investment in more R&D in pharmaceuticals is better for society,[11] so some type of government intervention is necessary.

III. Pharmaceutical Innovation Depends on Patent Protection (And in Some Cases Additional Prizes)

In the pharmaceutical industry, patents provide the incentive to innovate.[12] Patents give drug developers the exclusive right to make and sell their drugs for a period of 20 years from the date of the patent application.[13] By artificially increasing the lead time, which typically is around 11 years of market exclusivity,[14] patent law's exclusivity neutralizes the replicability factor and ensures that high marketing costs for the new drugs will benefit the initial investor.[15] If new uses are discovered for the medical intervention, patent protection can essentially be extended through a "new use" patent.[16] There is still high risk, but it is mitigated by the potential of monopoly profits. The profits need to be substantial, because the developers must recoup not only the costs of investment in that particular drug—which may be as much as $2.6 billion per drug,[17] but also the sunk costs of the 90% of drugs developed that did not make it to market. Where the investment incentive would still be limited by the fact that a targeted disease or condition only affects a small number of patients, federal statutes offer prizes to supplement the patent system.[18]

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[11] *Id.* ("The benefits arising out of a discovery of the medicinal benefits of a particular compound can be enjoyed by an unlimited number of persons . . . "); Roin, *supra* note 4, at 513 ("[T]he available evidence indicates that society's investment in pharmaceutical R&D continues to generate substantial positive returns.").

[12] FISHER & SYED, *supra* note 1, at 3; Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1588 (2003) (citing studies finding that increasing patent protection gives a significant boost to pharmaceutical R&D), 1589 n.37 (same).

[13] *See* 35 U.S.C. § 154 (2012).

[14] FISHER & SYED, *supra* note 1, at 5 (After adjustments to restore some of the patent term lost to the research and approval process, "the patent is likely to expire roughly 11 years after the drug is first marketed.").

[15] Note, however, that the patent term begins at the date of filing, which typically is during pre-trial research. *See* Roin, *supra* note 4, at 568 n.342. The longer the testing period, then, the shorter the effective patent term on the drug's market period. Up to five years of this term can be restored based on the period of human trial testing. *See* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 190 (1999) (explaining calculation of patent restoration term); Fisher & Syed, *supra* note 1, at 4–5 (same).

[16] FISHER & SYED, *supra* note 1, at 5.

[17] Rick Mullin, *Tufts Study Finds Big Rise in Cost of Drug Development*, AMERICAN CHEMICAL SOCIETY: CHEMICAL & ENGINEERING NEWS (Nov. 20, 2014), https://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html (citing a 2014 report by the Tufts Center for the Study of Drug Development). In the years 2003–2007, this estimate was closer to $800 million. *See* Burk and Lemley, *supra* note 12, at 1616; Roin, *supra* note 4, at 510 n.21 (citing studies).

[18] For example, the Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049, offered grants, longer market exclusivity, and fee reductions for drugs developed to fight orphan diseases, defined as diseases affecting fewer than 200,000 people (*see* 21 U.S.C. § 360bb(a)(2) (2012)).

These laws and the patent system have been sufficient to promote pharmaceutical innovation at its current rate.

IV. Some Unpatentable Pharmaceutical Innovation is Valuable

To qualify for patent protection, a pharmaceutical product (whether a candidate for a chemical or a biotechnological patent) must be novel[19] and non-obvious.[20] Traditional remedies and drugs, such as traditional medicines or home remedies,[21] are unpatentable: They are unpatentable because they are not novel (failing § 102); even if they are novel, they are obvious (failing § 103). Some of these interventions may show biological plausibility, but because there is no possibility of a patent, there is no incentive to invest in R&D to determine whether there is potential for new drug development.[22]

Patent law is an all-or-nothing proposition: If a drug does not qualify for patent protection, it gets zero protection. But development of unpatentable interventions would still have the same human protection requirements even in the absence of patents. Additionally, the exacerbating factors that had been mitigated by patent law return. Lead time advantages disappear, creating a greater risk of loss due to free-riders. In fact, the gap between patentable and unpatentable pharmaceuticals is even greater when factoring in the possible extension of protection through acquisition of a new use patent.[23] Developers would have trade dress protection for the organoleptic properties of the medications, such as the color, scent, shape, or texture of pills.[24] However, since this protection requires lead time and entails high marketing costs to create secondary meaning, it is not a sufficient *ex ante* incentive to invest.

Part of the reason for the gap in protection between patentable and unpatentable pharmaceuticals is because patents reward the invention of drugs but not their development.[25] The novel and

[19] *See* 35 U.S.C. § 102.
[20] *See id.* § 103.
[21] Some common examples of these may include Ayurvedic medicine, Chinese medicine, homeopathic remedies, or peppermint essential oils.
[22] *But see generally* Andrew Vickers, *Alternative Cancer Cures: "Unproven" or "Disproven"?*, 54 CA CANCER J. CLIN. 110–118 (2004), https://onlinelibrary.wiley.com/doi/epdf/10.3322/canjclin.54.2.110 (arguing that many complementary and alternative cancer treatments have been investigated).
[23] FISHER & SYED, *supra* note 1, at 5.
[24] Kelley Clements Keller, *Free Riders at the Drugstore: Generics, Consumer Confusion, and the Public Good*, 12 CHI.-KENT J. INTELL. PROP. 184, 189–91 (2013) (explaining legal protection for organoleptic properties of pharmaceutical products).
[25] Roin, *supra* note 4, at 515–16.

nonobvious requirements for pharmaceutical patents mean that a drug's efficacy is insufficient to warrant protection[26] (although efficacy must also be shown in order to receive a patent).[27]

While traditional medicines and home remedies are good examples because they are categorically unpatentable interventions, they are not the only types of treatments that are under-developed due to unpatentability. A number of drugs that are researched, and are shown to be biologically plausible, move from patentability to unpatentability due to an unfortunate application of the novel and nonobvious criteria.

Under three different scenarios, drugs can enter the public domain and become unpatentable before ever having actually been developed.[28] In the first scenario, researchers publish preliminary research about a drug without any evidence of therapeutic value.[29] In at least five cases, courts have held that this type of initial publication undermined a drug's novelty—the publication anticipated the invention even absent treatment data or animal testing results.[30] In the second scenario, researchers disclose that a new drug is ineffective, though the drug is later shown to be effective.[31] In at least two cases, courts found that a publication disparaging a drug was as anticipatory of the invention as if the publication had disclosed the drug's effectiveness.[32] Thus, the drugs were not novel. In the third scenario, researchers disclose a new drug without recognizing their own discovery.[33] In three cases over a two-year period, the Federal Circuit found that this type of disclosure prevented drugs from being novel, even though the drugs had never previously been developed.[34]

Although these are "only" ten cases, consider that each case has resulted in an undeveloped drug that could have provided treatment to a vast number of patients, many of whom missed out on oncological interventions. One such case would be unfortunate; ten is a call for action. The rules that result in this outcome have a basis in a logical proposition that inventions already known to the public should be free for all to use.[35] But its broad application in these cases has meant that inventions not yet in existence in the market are unprotectable. Its broad application also pits academic research against drug development and creates a perverse incentive – if a

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[26] *Id.*
[27] *Id.* at 522 n.98 ("The [Patent & Trademark Office] usually requires evidence of efficacy from laboratory or animal models for the targeted conditions" before issuing the patent.).
[28] *Id.* at 522.
[29] *Id.*
[30] *Id.* at 522–23.
[31] *Id.* at 522.
[32] *Id.* at 524.
[33] *Id.* at 522.
[34] *Id.* at 525–26.
[35] *Id.* at 526 n.113 (citing Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371, 383–84 (2005) (The inherent-anticipation doctrine is a "categorical judgment that an invention already being used by the public shouldn't be patentable because someone discovers information about how it works.")).

potential drug could have a salutary impact on a medical condition, it is better for academic researchers to stop their investigations and not publish their data. If the data were published, the drug would become unpatentable and there would be no incentive to develop it because the developer would pay for the clinical trials to get FDA approval, but a second-comer could immediately make a copy. Yet this is unlikely because of the pressure on academic researchers to publish their work.[36] It's a practical ethical dilemma: publish knowing that the research will be unlikely to be put into practice due to its effect on patentability or sit on the research and risk loss of professional advancement.

The growing adoption of technology transfer offices by universities and academic medical centers has a mediating effect on this issue, as tech transfer professionals and attorneys work with physician scientists on invention capture to prevent the premature disclosure of innovations, and work with industry to license and commercialize discoveries. But the risk remains of well-intentioned basic science researchers undercutting a pharmaceutical innovation's market viability.

The typical patent prosecution process can also work against the patentability of undeveloped drugs. Because developers must file patent applications at an early stage in order to avoid inadvertent disclosure (and thus unpatentability) and to avoid being "beaten to the punch" by a competitor, the developers often do not yet know the exact final chemical formula of the drug at the time of filing.[37] As a result, the developers broadly claim a number of formulas under consideration in order to ensure that they are establishing priority over the final product.[38] These claims function as disclosures, even of the ultimately-unclaimed formulas, and prevent the formulas from being claimed in future patent applications.[39] In other words, any formulas claimed during the prosecution process, even if disclaimed later, lose their novelty and thus their patentability. Even though a potential drug has never been developed, it is unpatentable because it appears in the prosecution history of a different patent application. Because these compounds are no longer patentable, pharmaceutical firms have no incentive to reinvestigate their potential. In these cases, patent law is actually preventing pharmaceutical innovation.

V. To Encourage Investment in Unpatentable Innovation, a Patent Complement is Needed

Because of patent law's novel and nonobvious requirements, there is under-investment in biologically plausible pharmaceuticals. Thus, to encourage investment in unpatentable

[36] *Id.* at 527 ("[R]esearchers are rewarded more for publishing their research results than for patenting them and are thus prone to disclosing new drugs before securing patent rights over them.").
[37] *Id.* at 529.
[38] *Id.*
[39] *Id.*

innovation in pharmaceuticals, a complement to the federal patent law is needed. In order to encourage innovation, this complement would need to—at a minimum—allow the innovating firm to recover its development costs.[40] These are the costs that would not be repeated by the innovator in the production of a later copy, nor repeated by a competitor in the production of a copy.[41] The protection afforded by this complement would not substitute for patent protection, but could, by lowering the risk of total loss, begin to alleviate the under-investment problem.

A complement to the current patent law could take many forms: modifying the federal patent law to take a sector-specific approach to issues in particular industries,[42] new federal statutes that explicitly adjust policy levers in light of federal interpretation of patent law,[43] and state legislation.

Professors Dan Burk and Mark Lemley advise against modifying federal patent law as a whole.[44] Over time, the patent prosecution system has transitioned from a unitary system to a heterogeneous one. Getting a patent in some industries, such as pharmaceuticals, is a lengthier, more difficult, and more expensive process than in others, such as software.[45] Additionally, patents in pharmaceuticals typically cover a single product, whereas in other industries a patent may cover a component or process present in many products.[46] Because of the different roles that patents play in different industries, making wholesale changes based on sector-specific concerns is ill-advised.[47]

Other potential roadblocks to this approach include legal barriers, such as TRIPS obligations, and practical concerns, such as patent overlap: a drug delivery system could be classified as a medical device, a pharmaceutical, or a biotechnology;[48] a medical technology could incorporate biotech and software;[49] and, new fields that inevitably emerge would throw a wrench into the system.[50] Burk and Lemley ultimately argue that the courts are in the proper position to address

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[40] Douglas Gary Lichtman, *The Economics of Innovation: Protecting Unpatentable Goods*, 81 MINN. L. REV. 693, 694 (1997).
[41] *Id.*
[42] *See* Burk & Lemley, *supra* note 12, at 1630 ("If different industries acquire, value, and use patents differently, . . . then it seems easy to conclude that we need different patent statutes for each industry.").
[43] For example, the Semiconductor Chip Protection Act of 1984, Pub. L. No. 98-620, 98 Stat. 3335, extended protection to semiconductors despite the fact that these are "obvious" innovations. Lichtman, *supra* note 40, at 713.
[44] Burk & Lemley, *supra* note 12, at 1578 (explaining because of the potential for rent seeking and the inability of industry-specific statutes to respond to changing circumstances, "policy-makers should be cautious about trading our uniform patent system for an industry-specific one.").
[45] *Id.* at 1590.
[46] *Id.*
[47] *Id.* at 1578.
[48] *Id.* at 1635.
[49] *Id.* at 1636.
[50] *Id.*

patent-related innovation issues,[51] given that the Supreme Court has placed with the courts the responsibility to adapt the patent statute to new technologies.[52]

For a federal solution outside of the courts, Congress could address the problem without disturbing patent law with an industry-specific statute, such as a pharmaceutical corollary to the Semiconductor Chip Protection Act (SCPA), which granted protection upon registration to semiconductor chips even though they were "obvious" inventions.[53] An act like SCPA could extend protection to drugs previously known but now produced for the first time, regardless of whether the compound at issue had been previously mentioned in the prosecution history of another pharmaceutical patent. While this would seemingly give "novelty" a unique definition in only one area of patents, the proposed act could give *sui generis* protection (as with the SCPA) rather than patent protection. If the *sui generis* protection were weaker than patent protection, this would improve the state of unpatentable innovation without diminishing or changing the current incentives for patentable innovation.

VI. Could a Carefully-Crafted State Law Offering Limited Protection Survive Preemption and Property Supplement Patent Law?

State law may provide another viable option for providing an incentive to invest in pharmaceutical innovation. State laws that frustrate the purpose of a federal law and the objectives of Congress are preempted.[54] Thus, state laws that co-opt patent law's goals are preempted. The Supreme Court has found that Congress, by carefully defining which inventions may receive patent protection, by negative inference defined which innovations are free for all to use.[55] As a result, the Court has held that state laws are preempted when those state laws try to provide patent-like protection to innovation that the federal law deems unpatentable.[56] But a state law that provides weaker protection and does not co-opt patent law's goals could avoid preemption.

The Supreme Court broadly applied preemption to conflicts between federal patent law and state law in the case of *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*[57] In *Bonito Boats*, a Florida

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[51] *Id.* at 1579, 1678 ("If patents are to drive innovation in biotechnology, rather than merely invention, . . . courts must take account of the cost and uncertainty of post-invention testing and development.").
[52] Diamond v. Chakrabarty, 447 U.S. 303, 321–22 (1980) (extending patent law to cover living organisms and any other subject matter made by humans).
[53] Lichtman, *supra* note 40, at 713 (summarizing the Act).
[54] Gade v. Nat'l Solid Wastes Management Ass'n, 505 U.S. 88, 98 (1992) (stating preemption exists "where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress' [citations].")
[55] Lichtman, *supra* note 40, at 695.
[56] *Id.* at 695–96 (summarizing *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964) and *Compco Corp. v. Day-Brite Lighting*, 376 U.S. 234 (1964)).
[57] Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141 (1989).

statute provided protection for boat hull designs, which were not protected by patent law.[58] The statute forbade copying a boat hull using "direct molding," which was the most efficient method of copying.[59] Even though the statute prohibited only one method of copying, the Court held that the statute's prohibition of reverse engineering of a product in the public domain provided a patent-like protection unavailable under patent law.[60] Thus, the Florida statute was preempted by federal patent law because inventions not protected by patents were free for all to use.[61]

However, in *Kewanee Oil Co. v. Bicron Corp.*,[62] the Supreme Court held that state trade secret laws that offered a form of intellectual property protection inferior to patent protection survived federal preemption. In *Kewanee Oil*, an Ohio statute prohibited misappropriation of a trade secret.[63] Protection was enforced against those in whom the secret was confided rather than against the public,[64] and there was no protection against discovery by accidental disclosure or reverse engineering.[65] The Court held that trade secret law provides a weaker protection than patent law provides and that trade secret law does not frustrate the goals of patent law.[66] The Court found that trade secret law has no effect on patentable inventions.[67] Trade secret laws form an important step in encouraging research, because if firms could not protect their technological innovations through patent law, they would be unlikely to invest in R&D in the first place because of the risks of loss with no remedy.[68] Additionally, the Supreme Court found

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[58] *Id.* at 1424–45.
[59] *Id.* at 158.
[60] *Id.* at 160 ("In essence, the Florida law prohibits the entire public from engaging in a form of reverse engineering of a product in the public domain. This is clearly one of the rights vested in the federal patent holder, but has never been a part of state protection under the law of unfair competition or trade secrets.").
[61] *Id.* at 159–60 ("[I]deas in general circulation [must] be dedicated to the common good unless they are protected by a valid patent." (quoting Lear, Inc. v. Adkins, 395 U.S. 653, 668 (1969)).
[62] Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974).
[63] The statute defined a trade secret as:

> [C]onsist[ing] of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers.

Id. at 474–75. The current definition under the Uniform Trade Secrets Act (UTSA)—the basis for most state trade secrets statutes—is similar, though the federal definition is broader. Kelley Clements Keller & Brian M.Z. Reece, *Economic Espionage and Theft of Trade Secrets: The Case for a Federal Cause of Action*, 16 TUL. J. TECH. & INTELL. PROP. 1, 14–15, 14 n.72 (2013) (comparing UTSA to Economic Espionage Act of 1996). Either definition would encompass scientific formulas such as chemical compounds.
[64] *Kewanee Oil*, 416 U.S. at 473.
[65] *Id.* at 476.
[66] *Id.* at 489–90.
[67] *Id.* at 491.
[68] *Id.* at 485–86.

that trade secret law complemented patent law by playing a role in preventing the issuance of invalid (i.e., public domain) patents.[69] Thus, the Ohio statute was not preempted.

A state law that acts like patent protection is preempted, while a state law that provides weaker protection than patent protection is not. Professor Douglas Lichtman made a strong case that *Bonito Boats* was incorrectly decided,[70] and that federal courts should allow state laws that prohibit the easiest method of copying, so long as those state laws do not undermine the incentives created by patent law.[71] However, until the Supreme Court overturns the reasoning of *Bonito Boats*, we must assume that state laws similar to that at issue in *Bonito Boats* will be preempted.

Thus, if a state law is to avoid preemption, it must look more like a trade secret statute. Trade secret statutes can "increase the 'excludability' of public goods by penalizing activities that corrode self-help measures adopted by innovators."[72] A state could modify its trade secret statute to provide a form of enhanced but limited protection, but this would be tricky in pharmaceuticals without being able to prohibit some method of reverse engineering.

Another problem with trying to use trade secret law in place of patent law to protect innovation is the need to make irreversible decisions early in the process. As with the inversion of patents (i.e., secrecy vs. disclosure), trade secrets would require firms to make early decisions they could not change. Firms would need to pre-determine whether a potential intervention is patentable. If so, they would need to file an application at the earliest appropriate stage to avoid disclosure and beat competitors. If not, they would need to take special steps to prevent disclosure of the complete formula. If a developer were to make an incorrect judgment (e.g., that an invention was patentable when in reality it was not) and disclose the invention as part of a patent application, that disclosure would foreclose any possibility of utilizing trade secret protection. Once the cat is out of the bag, it cannot go back inside. Further, if a patent application eviscerates potential protection under trade secret law, firms would be less likely to take the chance of applying. Borderline innovation (e.g., drugs that incorporate traditional medicines, home remedies, or unpatentable drugs) would as a result be less likely to be made public. Additionally, academic researchers are under great pressure to publish, and offering additional trade secret protection to industry would not reduce this pressure on academics.

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[69] *Id.* at 489.
[70] Lichtman, *supra* note 40, at 729 n.89 (disputing the Court's finding that the statute at issue does not survive preemption but not the Court's final judgment).
[71] *Id.* at 716 ("Because state laws that allow innovators to recover their development costs . . . merely transform markets for unpatentable goods into markets that more closely resemble traditional markets," they do not undermine patent law).
[72] FISHER & SYED, *supra* note 1, at 4.

There is also the issue of trade secret disclosure in the course of enforcing trade secret protection. In some states that are home to pharmaceutical or biotech companies (including California, Massachusetts, and frequent state of incorporation, Delaware), state laws require early disclosure with particularity of the trade secret at issue in order to proceed to discovery.[73] Under these rules, trade secrets shift status from allegedly-misappropriated to public knowledge, at which point the value of the secret is lost.

For these reasons, it does not seem that state law is a viable avenue to promote unpatentable innovation in pharmaceuticals. Absent a modification of the reasoning from *Bonito Boats*, state laws that prohibit any kind of reverse engineering seem destined for preemption. Trade secret law, while offering a form of protection, is not conducive to keeping chemical compounds a secret from competitors, and enforcement of trade secret law by pharmaceutical companies would entail early disclosure of the secret to the public. Trade secret law may only be a viable route if pharmaceutical companies were to develop the technology to encrypt pills. The solution to the problem of unpatentable innovation in pharmaceuticals is likely federal: Congress passing a federal sector-specific complement, or a change in the courts' interpretation of early patent prosecution claims as a disclosure that destroys novelty.

[73] Keller & Reece, *supra* note 63, at 15–16 n.81 (citing jurisdictions that have made early trade secret disclosure a substantive requirement of their laws).