

NOTE

REALIZING TWO-TIERED INNOVATION POLICY THROUGH DRUG REGULATION

William E. Ridgway*

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INTRODUCTION

Patent law and drug regulation traditionally function within distinct, and largely adversarial, domains. That is, patent law's aim to encourage invention

* J.D. Candidate, Stanford Law School, 2006; B.S., Stanford University, 2003 (Chemical Engineering). Special thanks to Mark Lemley for his guidance on the paper that led to this Note. I am also indebted to Lindsey Powell and Catherine Leblond for their suggestions throughout the editing process. Above all, I am grateful to my wife, Jessica, for her unyielding support.

counteracts the costs and uncertainty associated with drug regulation's efforts to ensure the safety and efficacy of drugs. But this traditional view needs revision. In fact, their domains are merging, and their relationship is more the reverse: drug regulation's costs and its growing number of market-exclusivity provisions protect drug manufacturers against their weakening patent rights.

This counterintuitive twist on tradition derives from the logic of the public goods problem. Because ideas cost more to create than to copy, unregulated markets are thought to be incapable of sufficiently rewarding innovation. Yet creation costs alone do not trigger the public goods problem; rather, its extent is determined by the *ratio* of the cost of creating to the cost of copying. Thus, goods that are expensive to make but equally costly to copy, such as handmade furniture, evade these problems entirely. In fact, with a ratio close to one, copying becomes a socially desirable mechanism for generating competition.¹ Accordingly, patents, and intellectual property in general, strive to adjust the public goods ratio so that it approaches one and thereby ensure fair competition between creators and copiers.

But the emergence of an independent written description requirement seemingly undermines patent law's ability to remedy the public goods problem, especially for drug manufacturers. This new requirement tends to narrow patent scope within biotechnology,² and recent cases suggest its application may extend to other fields as well.³ Moreover, the rise of patenting on research inputs—as instigated by reduced patentability standards and the outburst of academic patenting through the Bayh-Dole Act⁴—means that the patent system increasingly extracts, rather than generates, revenue for drug manufacturers.⁵ As a result, drug manufacturers rely less exclusively on the patent system for protection.

As patent law's relevance to drug manufacturers continues to wane, drug regulation discretely shifts into the void. Drug regulation first explicitly crossed

1. See WILLIAM LANDES & RICHARD A. POSNER, *ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY* 23 (2003) ("Freedom to imitate, to copy, is a cornerstone of competition and operates to minimize monopoly profits.").

2. See, e.g., Duane M. Linstrom, *Spontaneous Mutation: A Sudden Change in the Evolution of the Written Description Requirement as It Applies to Genetic Patents*, 40 SAN DIEGO L. REV. 947, 970 (2003); Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 615-16 (1998); Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. TRADEMARK OFF. SOC'Y 209, 209-10 (1998); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 835 (1999); Harold C. Wegner, *The Disclosure Requirements of the 1952 Patent Act: Looking Back and a New Statute for the Next Fifty Years*, 37 AKRON L. REV. 243, 244 (2004).

3. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004).

4. Bayh-Dole University and Small Business Patent Procedures Act of 1980, Pub. L. No. 96-517, 94 Stat. 3019 (codified as amended at 25 U.S.C. §§ 200-211 (2006)).

5. See Rebecca S. Eisenberg, *The Shifting Functional Balance of Patents and Drug Regulation*, 19 HEALTH AFF. 119, 125 (2001) (noting this revenue-extracting consequence of the Bayh-Dole Act).

over to the patent domain with the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act).⁶ To facilitate the introduction of generic drugs, the Hatch-Waxman Act permits a manufacturer of a generic alternative to a pioneer drug to seek FDA approval by submitting a significantly less stringent abbreviated new drug application; to counteract this advantage to generics, the Act awards pioneers with a patent term extension.⁷ The Hatch-Waxman Act is generally considered a policy success, which likely contributes to lawmakers' unflinching support for the several subsequent Food and Drug Administration (FDA) provisions that confer market exclusivity through the regulatory process alone by limiting the approval of competing drugs.

And even though the Hatch-Waxman Act and its progeny suffer no shortage of scholarly treatment, virtually none of the literature deals with the implications of drug regulation's marked step into the patent domain.⁸ What is more, these explicit innovation policy provisions only begin the analysis—drug regulation also implicitly executes patent policy with subtle, though profound, influence.

Most notably, and contrary to drug manufacturers' standard rhetoric, FDA-imposed approval costs actually protect manufacturers because they equally impact all industry participants, including copiers. By imposing fixed costs upon all manufacturers, the FDA adjusts the critical public goods ratio toward one, thus decreasing both the benefits of drug copying and the need for drug patents. In this sense, the FDA turns drugs into handmade furniture, costly to create *and* to copy. Of course, the Hatch-Waxman Act seemingly moderates this unintended consequence by permitting generic manufacturers to pay less in fixed costs than pioneers. But as I later explain, the Hatch-Waxman Act's rule-based approach functionally restores drug regulation's implicit impact on the public goods problem.

When examined together, these concurrent developments reveal an important shift: patent law and drug regulation share responsibility for innovation policy within the drug industry—a system I call “two-tiered innovation policy.” Under this system, drug candidates receive baseline protection early on at the patenting stage and heightened protection through drug approval.

6. 21 U.S.C. § 355(j) (2006). *See generally* Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (codified in various sections of U.S.C.)

7. 21 U.S.C. § 355(j) (2006).

8. An article by Rebecca Eisenberg constitutes the lone exception. Her work highlights the ways that several of the FDA's exclusivity provisions do not enhance the safety and efficacy of drugs, but rather implement innovation policy. *See* Eisenberg, *supra* note 5, at 123 (citing the Orphan Drug Act and the pediatric extensions to the Food and Drug Administration Modernization Act of 1997 as examples of the FDA getting involved “in economic regulation lying outside its core scientific competence”). Her article provided the groundwork for this Note.

At first glance, a two-tiered system may seem organizationally inefficient. After all, assuming an optimized patent system, independent assistance from drug regulation will either be redundant or harmfully overprotective. Even if the system is nonoptimal, deploying an independent regulatory agency seems a roundabout approach to correction.

But I argue that this two-tiered system is an unintended consequence worth embracing, as it yields three crucial advantages. First, regulating intellectual protection in two stages aligns better with patent law's aim to remedy the public goods problem. Conferring protection at the patenting stage alone forces the system inefficiently to overprotect the drug candidate as if it were a product, even though the vast majority of patented candidates never reach the market. Dividing protection into two stages, by contrast, accommodates the reality that preapproval drug candidates suffer the public goods problem much less than postapproval products. Moreover, this heightened precision comes with virtually no additional costs: the FDA already tests a drug's utility (i.e., safety and efficacy) for independent policy reasons, so the system for subsequent examination already exists.

Second, and related, the FDA's approval process and its resulting quasi-intellectual property protection ease the pressure on the Patent and Trademark Office (PTO) unilaterally to differentiate utility when it determines patentability at such an early stage. With knowledge that the truly useful drug candidates will receive subsequent protection through drug approval, the PTO can confidently apply lower and more administrable utility standards to drug patent applications while narrowing scope accordingly.

Third, by shifting responsibilities from patents to drug regulation, this system focuses protection on commercialization. In patent law, commercializing is not particularly consequential—it is neither necessary to receive patent rights nor required to infringe them. That approach is troublesome both because it encourages patentees inefficiently to withhold commercialization and because it enables them to prevent others from pursuing noncommercial research. By contrast, the FDA only initiates protection after drug approval, which encourages patentees to commercialize. And rather than granting broad rights to exclude for any use, the FDA's quasi-protection applies only to drugs intended for distribution in the marketplace, thereby minimizing intellectual property's notorious obstruction at the research stage.

This Note proceeds in four Parts. Part I describes in greater detail the drug-approval process, focusing on the portions that are relevant to this Note. Part II argues that patent law's role in innovation policy continues to decline, especially with respect to drug patents. It first explains how the doctrine of written description effectively narrows the patent scope of key drug patents and then argues that after the rise of research inputs, patents often extract monopoly rents from drug manufacturers. Part III argues that drug regulation is increasingly a source of protection for drug manufactures. After briefly describing explicit policy provisions, the Note explains how the FDA implicitly

influences innovation policy with even greater consequence. Finally, Part IV further explains why this shift toward a two-tiered innovation policy is desirable, though in need of deliberate cross-institutional coordination.

I. OVERVIEW OF DRUG REGULATION

Congress drastically increased the FDA's role in drug regulation in 1962 when it amended the Food, Drug, and Cosmetics Act (FDCA) to require companies to "prove that new drugs are safe and effective prior to FDA approval."⁹ This simple statement transformed the industry. Drug approval now requires controlled clinical studies, which currently take six to eight years¹⁰ and cost up to \$1.7 billion dollars.¹¹ Moreover, the standards are exacting: only eight percent of the drugs that begin Phase I clinical trials ever get to market.¹²

A second FDA-inspired industry transformation resulted from the Hatch-Waxman Act. As discussed in the Introduction, the Act permits a manufacturer of a generic alternative to a pioneer drug to seek FDA approval by submitting a significantly less stringent abbreviated new drug application (ANDA).¹³ Rather than proving safety and efficacy, an ANDA only obliges a generic manufacturer to show that its drug is bioequivalent to the pioneer, uses the same active ingredients, and contains generally safe inactive ingredients.¹⁴ A

8. 21 U.S.C. §§ 301-397 (2006).

9. Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AMER. BD. FAM. PRAC. 362, 362-67 (2001).

10. Jim Gilbert et al., *Rebuilding Big Pharma's Business Model*, 10 IN VIVO: THE BUSINESS & MEDICINE REPORT 73 (2003) (executive summary), available at http://www.windhover.com/contents/monthly/exex/e_2003800191.htm; see also TUFTS CTR. FOR STUDY OF DRUG DEV., HOW NEW DRUGS MOVE THROUGH THE DEVELOPMENT AND APPROVAL PROCESS (2001), available at <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=4>.

12. FOOD & DRUG ADMIN., INNOVATION OR STAGNATION?: CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS (2004), available at <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html> ("[A] new medicinal compound entering Phase 1 testing, often representing the culmination of upwards of a decade of preclinical screening and evaluation, is estimated to have only an 8 percent chance of reaching the market. This reflects a worsening outlook from the historical success rate of about 14 percent.").

13. 21 U.S.C. § 355(j)(2) (2006).

14. *Id.*; PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS 571 (2d ed. 1991).

Note that there is no abbreviated approval process for biologics. See generally 42 U.S.C. § 262 (2006). Every biologic is a new or "pioneer" drug that must be supported by the full preclinical and clinical investigation. Unlike chemically synthesized drugs, whose functional characteristics generally do not vary significantly, the safety or effectiveness of a biologic cannot be evaluated simply by identifying the physical structure of the active ingredient. FOOD & DRUG ADMIN., FDA GUIDANCE CONCERNING DEMONSTRATION OF COMPARABILITY OF HUMAN BIOLOGICAL PRODUCTS, INCLUDING THERAPEUTIC BIOTECHNOLOGY-DERIVED PRODUCTS (1996), available at <http://www.fda.gov/cder/guidance/compare.htm>. Because conclusions about the safety and effectiveness of a biologic

bioequivalent drug, according to the FDA, delivers roughly the same amount of the active drug ingredient to the bloodstream around the internal organ that is intended to receive it.¹⁵ To show that the active ingredients are the “same as” those in the listed pioneer drug,¹⁶ an ANDA need not demonstrate chemical identity. Rather, clinical identity—the same primary structure, potency, and degree of batch-to-batch uniformity—is sufficient.¹⁷ Finally, under the so-called Bolar Amendment, testing to obtain information for an ANDA is protected from a pioneer’s infringement suits.¹⁸

Upon filing an ANDA, the FDA requires generic manufacturers to submit a patent “certification” pronouncing the existence of patents relevant to the pioneer.¹⁹ Holders of new drug applications (NDAs) for pioneer drugs identify and register these patents,²⁰ which the FDA compiles and publicizes in the so-called *Orange Book*.²¹ Such certifications generally fall into one of four categories:²² (1) those stating “that such patent information has not been filed” (i.e., the information is not in the *Orange Book*), (2) those stating “that such patent has expired,” (3) those stating “the date on which such patent will expire,” or (4) those stating “that such patent is invalid or will not be infringed

cannot be separated from the specific process used to manufacture it, the FDA requires manufacturers to demonstrate that not only the product but also the manufacturing process are safe and effective. *Id.*

15. 21 C.F.R. § 320.1(e) (2006) (defining bioequivalence as “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar circumstances in an appropriately designed study”).

16. 21 U.S.C. § 355(j)(2)(A)(ii) (2006).

17. *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313 (D.C. Cir. 1998). For inactive ingredients, the FDA approves unless “the inactive ingredients of the drug are unsafe” or “the composition of the drug is unsafe . . . because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included.” 21 U.S.C. § 355(j)(4)(H) (2006).

18. 21 U.S.C. § 271(e)(1) (2006) (“It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . .”). This statute overrides the Federal Circuit’s decision in *Roche v. Bolar*, 733 F.2d 858 (Fed. Cir. 1984), and has recently been broadened by the Supreme Court in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005).

19. 21 U.S.C. § 355(j)(2)(A)(vii).

20. § 355(b)(1) (requiring the applicant to file “the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug”).

21. An electronic version of the *Orange Book* is available at <http://www.fda.gov/cder/ob/default.htm> (last visited Feb. 1, 2006).

22. The only exception to this rule is if a company is not seeking approval for one of the drug’s uses. *See* 21 U.S.C. § 355(j)(2)(A)(viii) (2006).

by the manufacture, use, or sale of the new drug for which the application is submitted.”²³ For the first two categories, the FDA may approve the ANDA right away, and for the third, the FDA may approve it after pioneer patent expiration.²⁴

The process for certification within this fourth category, commonly called “Paragraph IV certification,” is more complex. First, the generic must notify the pioneer that it has filed an ANDA and describe the reasons it believes the patent will not be infringed, is invalid, or is unenforceable.²⁵ Once notified, the pioneer has forty-five days to file a lawsuit claiming patent infringement by the generic’s proposed product; if brought, the lawsuit postpones FDA approval for thirty months.²⁶ If the court determines that the proposed generic would infringe the patent, the ANDA will not be approved until the patent expires.²⁷ Conversely, conclusions of noninfringement or patent invalidity permit the FDA to approve the ANDA.²⁸ Approval may also occur at the end of the thirty-month stay, even if litigation is ongoing. Most generics, however, are unwilling to risk damages liability and wait until the end of litigation to bring the product to market.

Despite the extensive procedure described above, the abbreviated approval process yields staggering cost savings as compared to conventional NDA approval. On average, an ANDA for a generic product takes three to five years and costs about one million dollars²⁹—significantly less than standard NDA approval. That this price difference invigorated the generic market leads most to deem the Hatch-Waxman Act a success.³⁰ It is important to remember, however, that this success is compared to an original regime that was considerably inefficient by requiring generics essentially to repeat identical trials. Moreover, as explained in Part III, many of these same inefficiencies linger, even after Hatch-Waxman.

23. § 355(j)(2)(A)(vii).

24. § 355(j)(2)(B).

25. § 355(j)(2)(B)(ii).

26. § 355(j)(5)(B)(iii).

27. § 355(j)(5)(B)(iii)(II).

28. § 355(j)(5)(B)(iii)(I). Additionally, generics that successfully challenge under Paragraph IV certification receive 180-day exclusivity against competing generics. § 355(j)(5)(B)(iv).

29. See Richard J. Finday, *Originator Drug Development*, 54 FOOD & DRUG L.J. 227, 229 (1999).

30. See, e.g., Laura J. Robinson, *Analysis of Recent Proposals To Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47 (2003); see also MICHAEL WROBLEWSKI, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (2002), available at <http://www.ftc.gov/ogc/healthcare/wroblewski.pdf> (finding that generic drugs now comprise more than forty-seven percent of prescriptions filled—up from nineteen percent in 1984—and characterizing these results as a “record of success”).

II. PATENT LAW'S DECLINING INFLUENCE ON DRUG INNOVATION POLICY

A. *The Emergence of an Independent Written Description Requirement*1. *Written description and the anatomy of a patent*

Originally, the patent system only concerned itself with the end-product of the invention process and conferred monopolies on commercial products alone. But by the late eighteenth century, the patent system came to view society's benefit from an invention not only in terms of the new technology itself, but also its underlying technical know-how, and thus an independent disclosure rationale emerged.³¹ Today, the disclosure requirement is seen as the central bargain or "the quid pro quo of the right to exclude."³² Under such a rationale, patents promote progress by requiring patentees to describe their invention in a way that enables others to make and use the invention,³³ thereby adding technical know-how to the public domain. Accordingly, the Supreme Court now maintains that both goals (disclosure and invention) derive from patent law's constitutional directive, to "Promote the Progress of Science and useful Arts."³⁴

This disclosure bargain is evinced by the patent itself. The inventor's public disclosure of the invention is set forth in the patent text known as the specification, and society's grant of exclusive rights to the invention is set forth in the patent claims. The specification must provide a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms to enable any person skilled in the art to which it pertains . . . to make and use the same," and it must disclose the "best mode" known to the inventor of carrying out the invention.³⁵ The set of claims constitutes "the portion of the patent document that defines the patentee's rights,"³⁶ similar to the "metes and bounds" of a real property deed. In an infringement suit, courts focus on the claims to determine whether they "cover the alleged infringer's product or process."³⁷

Contrary to what the "bargain" metaphor may imply, the relationship

31. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 259 (3d ed. 2002).

32. J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 (2001) (citation omitted).

33. See 35 U.S.C. § 112 (2006).

34. U.S. CONST. art. I, § 8, cl. 8; see *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989) ("The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.").

35. 35 U.S.C. § 112 (2006).

36. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996).

37. *Id.* (citation omitted).

between specification and claims is not one to one; claims generally cover more subject matter than the specific invention disclosed in the specification. It is thought that otherwise restricting coverage to the patentee's actual invention would permit imitators to find minor variations and render the patent ineffective, so patents protect the patentee's so-called "inventive principle."³⁸

The patentee's claims are limited, however, by enablement, which requires that the specification teach one skilled in the relevant art how to make and use *all* the embodiments of the invention encompassed by the claims. Embodiments not disclosed in the specification are considered enabled if others can make and use them without "undue experimentation."³⁹

An independent written description requirement alters the existing relationship between specification and claims. The court's classic example is when a patent description discusses compound *A*, but enables those skilled in the art to make and use compounds *B* and *C* as well. Only *A* is enabled *and* described.⁴⁰ Although a simplification, this example demonstrates how an independent written description requirement tightens the connection between specification and claims. Embodiments encompassed by the claims must be both enabled and described in the specification. Indeed, under an independent written description requirement, correspondence between specification and claims approaches one to one.

2. Written description's impact on drug patents

The modern written description requirement⁴¹ requires that the patentee conceptually possess the invention during filing. It serves two purposes: to prevent patentees from changing their claims after the original filing date to track a competitor's product and to require greater description for biotechnology claims. The requirement's application to biological and chemical sciences derives from the doctrine of simultaneous conception and reduction to practice, which holds that "[i]n experimental sciences of chemistry and biology . . . [the] element of unpredictability frequently prevents a conception

38. See Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 846 (1990).

39. *In re Wands*, 858 F.2d 731, 736 (Fed. Cir. 1988).

40. *In re DiLeone*, 436 F.2d 1404, 1405 n.1 (C.C.P.A. 1971).

41. See Mark D. Janis, *On Courts Herding Cats: Contending with the Written Description Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J.L. & POL'Y 55, 62-70 (2000). The article characterizes written description's historical justification as "dubious." *Id.* at 63. The basic problem, according to Janis, is that the requirement derives from a Supreme Court case, *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356 (1822), which was decided at a time when United States patents were not required to contain claims. Janis, *supra*, at 63. Given this context, the language of *Evans* "clearly is directed towards satisfying this notice function, one which the modern written description does not require." *Id.*

separate from actual experimentation and testing.”⁴² For these uncertain sciences, proving actual conceptual possession requires heightened description.

In *Amgen, Inc. v. Chugai Pharmaceutical Co.*,⁴³ the Federal Circuit initiated its unique treatment of the biological and chemical sciences. Amgen’s patent contained claims to the DNA sequence encoding human erythropoietin (EPO), a protein that stimulates the production of red blood cells and a future pharmaceutical blockbuster. But prior to Amgen’s filing, Genetics Institute had isolated and purified the EPO protein and filed a patent disclosing a method of purifying and isolating the DNA sequence. This was not enough to invalidate Amgen’s patent, the court held, because Genetics Institute inadequately disclosed the invention in its application, which the court characterized as “simply a wish to know the identity of any material with that biologic property.”⁴⁴

The Federal Circuit heavily relied on *Amgen* in *Fiers v. Revel*,⁴⁵ in which three parties claimed patent rights to the DNA encoding human beta interferon. Revel’s patent application similarly failed to contain the exact DNA sequence, but the party nevertheless tried to distinguish *Amgen* based on the reason that its method was easier to carry out and such detail was therefore unnecessary. The court rejected that argument, finding that,

irrespective of the complexity or simplicity of the method . . . employed, conception of a DNA . . . requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.⁴⁶

With that holding, written description became the doctrine of choice for the court’s curious skepticism of patents on biological and chemical sciences.⁴⁷

The court controversially expanded written description from a priority policing doctrine to a fully independent requirement that applies to originally filed claims in *Regents of the University of California v. Eli Lilly and Co.*⁴⁸ The University of California (UC) claimed a patent for human insulin. UC had a

42. *Smith v. Bousquet*, 111 F.2d 157, 159 (C.C.P.A. 1940); *see also* *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991), *cert. denied sub nom.*, *Genetics Inst., Inc. v. Amgen, Inc.*, 502 U.S. 856 (1991) (applying same principle to biotechnology).

43. 927 F.2d 1200 (Fed. Cir. 1991).

44. *Id.* at 1206.

45. 984 F.2d 1164 (Fed. Cir. 1993).

46. *Id.* at 1169-70.

47. In other fields, “[c]onception is complete when one of ordinary skill in the art could construct the apparatus without unduly extensive research or experimentation,” *Sewall v. Walters*, 21 F.3d 411 (Fed. Cir. 1994), but for biotechnology, it appears the actual sequence is required. *See* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology Specific?*, 17 BERKELEY TECH. L.J. 1155, 1173-82 (2002). *But see* R. Polk Wagner, *Of Patents and Path Dependency: A Comment on Burk and Lemley*, 18 BERKELEY TECH. L.J. 1341, 1342-43 (2003) (distinguishing between micro- and macrotechnological specificity, and arguing against adopting the latter regime).

48. 119 F.3d 1559 (Fed. Cir. 1997).

stronger case than the parties in *Amgen* and *Fiers* because, along with the amino acid sequence of human insulin, which was known in the prior art, it disclosed the DNA sequence for rat insulin and a method for obtaining the sequence of human insulin.⁴⁹ But the court held that independent of enabling others to make and use the invention, the UC disclosure failed to describe the “structure, formula, chemical name, or physical properties” of the DNA sequence encoding for human insulin.⁵⁰

Perhaps influenced by the subsequent industry uproar, in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, the Federal Circuit stepped back from its original formalistic stance.⁵¹ Although the patent specification failed to recite the precise “structure, formula, chemical name, or physical properties,” the en banc court reversed the panel decision and insisted on a more holistic inquiry under which purely functional descriptions could suffice.⁵²

While several industry experts thought *Enzo* marked the beginning of the end of the written-description requirement,⁵³ so far, their predictions seem mistaken. To the contrary, the court continues to expand written description’s ambit. In *University of Rochester v. G.D. Searle and Co.*,⁵⁴ for example, the court extended the principle of written description to small-molecule chemistry. It held that Rochester scientists’ patent application for a COX-2 inhibitor drug selectivity screening method did not satisfy the written-description requirement because, “[e]ven with the three-dimensional structures of [the] enzymes . . . in hand,” a person with ordinary skill in the art could not predict what compounds might bind to and inhibit them.⁵⁵

Some commentators compare the Federal Circuit’s new approach to the “rule of capture” from the classic first-year property case, *Pierson v. Post*: “[w]hether it be a fox . . . or a DNA sequence, property rights vest with capture, not mere pursuit.”⁵⁶ But unlike real property, in patent law a rule of capture imposes more than just a formalistic annoyance “for the sake of certainty,” as the *Pierson* court held.⁵⁷ While both written description and the rule of capture affect timing by requiring potential property holders to wait until actual

49. *Id.* at 1567.

50. *Id.* at 1566.

51. 296 F.3d 1316 (Fed. Cir. 2002).

52. *Id.* at 1323.

53. See, e.g., Barbara Webb Walker & Sherry M. Carty, *Is the Viability of the Lilly Doctrine on the Decline?*, 21 NATURE BIOTECH. 943, 943-44 (2003) (“Recent cases indicate that the court is only applying the *Lilly* disclosure rule to certain fact scenarios and is willing to find that a functional description of genetic material meets the written description requirement where that function is sufficiently correlated to a particular known structure.”); see also *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1326 (Fed. Cir. 2003) (Rader, J., concurring) (“Fortunately, the viability of the *Lilly* rule is on the decline.”).

54. 358 F.3d 916 (Fed. Cir. 2004).

55. *Id.* at 925.

56. MERGES & DUFFY, *supra* note 31, at 859.

57. 3 Cai. 175 (N.Y. Sup. Ct. 1805).

capture, the analogy fails because in the patent context, the rule severely constricts the property right itself by limiting it to what the patentees “capture”—something patent law does not normally do.⁵⁸ Therefore, under this capture requirement, written description tends to narrow patent scope within the biological and chemical sciences.

B. *The Rise of Patented Research Inputs*

The relationship between patents and products is generally thought to be one to one: a drug manufacturer performs research, discovers a drug, and receives a single patent. But this is no longer the norm. Now, a given drug product typically arises from a combination of several patented research inputs.⁵⁹ For drug manufacturers, this shift turns patent rights into a catch-22: they extract licensing fees as much as they provide monopoly rents.⁶⁰ While

58. When the reward for discovering the sequence is limited to that sequence, it frees others to make the identical proteins using a different sequence. Covering all sequences for most proteins is impossible, especially ones like human heparin-binding growth factor from *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), for which approximately 10^{56} possible sequences exist. Thus, due to the degeneracy of the genetic code, written description particularly taxes DNA patent holders. Jeffrey S. Dillen, Comment, *DNA Patentability—Anything but Obvious*, 1997 WIS. L. REV. 1023, 1028. The degeneracy results from the fact that multiple codon sequences can code for the same protein. A gene is a sequence of DNA that codes for a protein. The DNA consists of four different nucleotide bases (A, G, C, and T). One or more codons, which are a group of three nucleotides, encode for a particular amino acid. And these amino acids are pieced together to make proteins. To complicate matters considerably, there are sixty-three possible codon triplets using the four bases and twenty amino acids found in proteins. This means that many amino acids are designed by more than one triplet. For example, the codons CGU, CGC, CGA, CGG, AGA, and AGG all code for the amino acid arginine. This creates degeneracy because multiple codon sequences can code for the same protein. See generally LUBERT STRYER, *BIOCHEMISTRY* 104, 109 (4th ed. 2000).

59. John P. Walsh et al., *Research Tool Patenting and Licensing and Biomedical Innovation*, in *PATENTS IN THE KNOWLEDGE-BASED ECONOMY* 285 (Wesley M. Cohen & Stephen A. Merrill eds., 2002). The methods of biotechnology are dependent upon these research tools. Defined broadly, the method includes “any tangible or informational input into the process of discovering a drug or any other medical therapy or method of diagnosing disease.” *Id.* at 287. According to Walsh, examples include “recombinant DNA, polymerase chain reaction, genomics, databases, microarrays, assays, transgenic mice, embryonic stem cells, or knowledge of a target, that is, any cell receptor enzyme, or other protein that is implicated in a disease and consequently represents a promising locus for drug intervention.” *Id.*; see also Scott A. Chambers, *Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AM. INTELL. PROP. L. ASS’N Q.J. 53, 59 (1995).

60. See Eisenberg, *supra* note 5, at 125 (noting this consequence of the Bayh-Dole Act); see also NAT’L INSTS. OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS PRESENTED TO THE ADVISORY COMMITTEE TO THE DIRECTOR (1998), available at <http://www.nih.gov/news/researchtools/index.htm> (finding that licenses for research tools “often involve future royalty obligations or rights to future intellectual property that constrain future opportunities for research funding and technology transfer”). Several empirical studies demonstrate the critical role played by early-stage patents on end-stage drug products. See, e.g., Richard C. Levin et al., *Appropriating*

this new reliance on research inputs is, in part, a natural consequence of the increasing technological complexity of drug research, patent law provided legal support by lowering the patentability standards and permitting the propertization of early-stage federal research through the Bayh-Dole Act.⁶¹

Within the drug industry, the requirement that an invention be nonobvious has been considerably weakened—a result largely imposed by changes to the doctrine of written description. The reasoning behind the nonobviousness requirement is fairly straightforward: to merit property protection, inventions must not only be new but must also constitute an “inventive leap.”⁶² The correlation between written description and nonobviousness is a bit more obscure. As discussed in the previous section, written description now requires disclosure of information that is generally routine, albeit tedious, to acquire. But if patentability requires these rote processes, then, conversely, their absence cannot preclude patentability. So normally, nonobviousness prevents patenting on inventions for which the inventive step is merely routine, but written description renders the doctrine more permissive.⁶³

As a result of this doctrinal shift, patenting in early-stage research is relatively easy. While these lax standards certainly ease the burden on drug manufacturers, they disproportionately help smaller industry participants such as nonprofits, biotechnology startups, and university labs.

The Bayh-Dole Act also shares responsibility for invigorating early-stage patenting. The Act transferred exclusive control over many government-funded inventions to universities and businesses for the purpose of promoting the participation of universities and small businesses in the development and commercialization process.⁶⁴

Critics of the resulting growth of commercial activity within research

the Returns from Industrial Research and Development, in 3 BROOKINGS PAPERS ON ECONOMIC ACTIVITY 783 (Martin N. Baily et al. eds., 1987); John P. Walsh et al., *supra* note 59, at 285; Wesley Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* (Nat'l Bureau of Econ. Res., Working Paper No. 7552, 2000) (discussing the importance of patents relative to other mechanisms of appropriation across various industries and concluding that patents are particularly important in the pharmaceutical arena).

61. Bayh-Dole University and Small Business Patent Procedures Act of 1980, Pub. L. No. 96-517, § 6(a), 94 Stat. 3019, 3019-28 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (2006)).

62. ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 183 (3d ed. 2003).

63. The situation in *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), illustrates this phenomenon. In the case, the Federal Circuit overruled the PTO's decision that Deuel's patent was rendered obvious by a European patent that disclosed the amino acid sequence, even though the subsequent steps required to arrive at Deuel's patent product were routine in biotechnology. See also Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RES. L. REV. 691, 700-01 (2004) (discussing the effect of written description on the obviousness inquiry).

64. The government gets a royalty-free, nonexclusive license to use for government purposes (including use by government contractors).

universities focus their ire on the way patenting and licensing scientific discoveries interferes with traditional academic functions. Receiving less attention, however, is how the change enables universities to leverage their research and extract some monopoly returns from drug manufacturers. Of course, Bayh-Dole claims that such patenting merely facilitates the transfer of research technology.⁶⁵ But independent of the important question of whether innovation is better promoted by university patenting or mere publishing,⁶⁶ choosing the former regime inevitably redirects some financial rewards toward universities.

C. Drug Patenting as Copyright

A helpful analogy to this new patent landscape in the drug industry does not require reaching to obscure real property rules such as the rule of capture; indeed, one is readily available within intellectual property: copyright. Written description bends patenting in biological and chemical sciences toward a quasi-copyright regime.

Even though patents and copyrights arise from the same constitutional basis and similar underlying theory—to remedy the public goods problem—they have separate requirements and rights corresponding to the distinct subject matter to which they apply. Copyright protection is comparatively narrow; it only covers expression, not underlying ideas.⁶⁷ Yet the copyrightability standards are quite weak: any expression fixed to a “tangible medium” is copyrighted so long as it exhibits only a modicum of creativity.⁶⁸ Likewise, written description tends to limit patent rights to the literal compound, the expression of the invention. It additionally constricts the nonobviousness test, permitting patents on new, albeit routine advancements.

Because copyright protects expression alone, it imposes fewer social costs than patents because others are free to copy underlying ideas. Judge Learned Hand articulates this expression-idea distinction most eloquently:

If Twelfth Night were copyrighted, it is quite possible that a second comer might so closely imitate Sir Toby Belch or Malvolio as to infringe, but it would not be enough that for one of his characters he cast a riotous knight who kept wassail to the discomfort of the household, or a vain and foppish steward

65. The Bayh-Dole Act states that its purpose is “to use the patent system to promote the *utilization* of inventions arising from federally supported research or development.” 35 U.S.C. § 200 (2006) (emphasis added).

66. See David C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL’Y 99 (2001) (empirically assessing the impact of the Bayh-Dole Act and other factors on university patenting and licensing).

67. MERGES ET AL., *supra* note 62, at 323.

68. *Id.*

who became amorous of his mistress.⁶⁹

Therefore, turning patent protection into a copyright-like regime decreases the social costs of exclusionary rights within drug research. So long as researchers refrain from using the specific compound, copying underlying ideas is permissible.

The obvious disadvantage of copyright-like protection is that it reduces incentives to invent⁷⁰—a trend that would seem particularly troublesome to drug manufacturers considering their costly research. But as described in the next Part, this change effectively transfers, rather than diminishes, protection. And as drug regulation expands its role in protecting manufactures, patent law's growing irrelevance becomes less consequential.

III. DRUG REGULATION'S GROWING IMPACT ON INNOVATION POLICY

This Part demonstrates that Congress frequently uses the FDA to craft innovation policy, thereby encroaching on patent law's traditionally exclusive domain and departing from the agency's core competency. Moreover, as Part III.B reveals, these explicit provisions constitute only a fraction of the story. FDA policies that ostensibly advance the agency's traditional goals profoundly impact the patent domain by remedying the problem of public goods.

A. Explicit Innovation Policy Provisions

The FDA offers pharmaceutical patent holders three categories of quasi-intellectual property protection. One category simply extends patent term: the Patent Term Restoration Act restores up to five years of patent term for the time during clinical testing and FDA approval.⁷¹ It is easier for the FDA to

69. *Nichols v. Universal Pictures Corp.*, 45 F.2d 119, 121 (2d Cir. 1930).

70. Several commentators criticize written description for failing to provide adequate incentives to invent. *See, e.g.*, Steven J.R. Bostyn, *Written Description After Enzo Biochem: Can the Real Requirement Step Forward Please?*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 131, 151 (2003); Robert L. Harmon, *Must a Patent Describe an Accused Infringement?*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 153, 154 (2003); Linstrom, *supra* note 2, at 970; Mueller, *supra* note 2, at 615-16; Pitlick, *supra* note 2, at 209-10; Rai, *supra* note 2, at 835 (1999); Wegner, *supra* note 2, at 244 (2004); Warren D. Woessner, "Do-Over!"—*The Federal Circuit Takes a Second Look at Enzo v. Gen-Probe*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 275, 285 (2003); Stephen J. Burdick, Note, *Moba v. Diamond Automation, Inc.: Questioning the Separate Written Description Requirement*, 19 BERKELEY TECH. L.J. 133, 151 (2004); Jennifer L. Davis, Comment, *The Test of Primary Cloning: A New Approach to the Written Description Requirement in Biotechnological Patents*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 469, 487-88 (2004); John C. Stolpa, Case Comment, *Toward Aligning the Law with Biology? The Federal Circuit's About Face in Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 4 MINN. INTELL. PROP. REV. 339, 366 (2003). *But see* Zhibin Ren, Note, *Confusing Reasoning, Right Result: The Written Description Requirement and Regents of the University of California v. Eli Lilly & Company*, 1999 WIS. L. REV. 1297, 1324.

71. 35 U.S.C. § 156 (2006). On average, this provision increases patent term by over

boost protection by extending patent term than by adjusting patent scope because the FDA deals with already patented drugs that have established scope.

The FDA also confers market exclusivities through the regulation process itself by restricting drug approval within a specific field.⁷² For example, if a drug qualifies for orphan-drug status by treating a disease that affects fewer than 200,000 Americans, drug manufacturers receive tax incentives and seven years of FDA exclusivity against all other drug approval, so long as a competitor's product is not "clinically superior."⁷³

Finally, some provisions only restrict abbreviated approval, like new drug applications, which earn manufacturers a five-year reprieve from generic approval. Other examples include the FDA's grant of three-year exclusivity against generic competition to pioneers in exchange for performing further clinical studies for a supplemental indication⁷⁴ and the six months of exclusivity against generics the FDA tacks on for patentees in exchange for testing their drugs in the pediatric population.⁷⁵

Admittedly, the Patent Term Restoration Act is distinct from the other provisions because, at least in theory, it does not add protection but merely offsets the value lost through differential treatment of pioneers and generics. This rationale cannot explain the additional exclusivities, however. They plainly supplement rather than offset protection, thereby supplanting patents' role in drug regulation.

B. Implicitly Remediating the Public Goods Problem

As discussed in the Introduction, patents encourage invention by remedying the public goods problem,⁷⁶ which is determined by the *ratio* of the

two years. CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 37-39 (1998).

72. Apparently, this category has become the method of choice. In addition to those discussed in the text, proposals for other approval exclusivities abound. One of the more creative is the so-called "wildcard exclusivity." In exchange for developing products for biodefense purposes, namely antibiotics, companies receive "'wildcard' extended market exclusivity for any drug within [their] portfolio." Jeffrey L. Fox, *Concerns Raised over Declining Anti-infectives R&D*, 21 NATURE BIOTECH. 1255, 1255-56 (2003).

73. 21 U.S.C. § 360(c) (2006).

74. § 355(j)(4)(D)(iv).

75. § 355(a). The provision's purpose is to remedy the lack of information about drug effects in children, but it has been criticized for tending to protect blockbuster drugs that treat conditions rarely seen in children, such as arthritis, ulcers, hypertension, and adult-onset diabetes. See LARS NOAH & BARBARA A. NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 824 (2002).

76. See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (recognizing that federal patent laws "embod[y] a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy"). Technically, this baseline embodies two distinct theories: reward and inducement. In the

cost of creating to the cost of copying. By drastically increasing the cost of bringing drugs to the market, the FDA seemingly exacerbates the public goods problem. Indeed, drug manufacturers' standard rhetoric in support of strong patent protection often includes lamenting drug-approval costs. The rhetoric, however, is wrong. Although the approval process no doubt imposes extra costs for drug creators, as long as the competitor's drug is nonbioequivalent, imitators face equivalent costs. And by imposing fixed costs upon all industry participants, creators and imitators, drug approval actually mitigates the public goods problem: the critical ratio approaches one when identical costs are added to both the numerator and the denominator, as depicted by the simple formula below.⁷⁷

$$\text{Public Goods Problem} = \frac{\text{Creation Costs}}{\text{Imitation Costs}} \rightarrow \frac{\text{Creation Costs} + \text{FDA Costs}}{\text{Imitation Costs} + \text{FDA Costs}}$$

Yet imposing identical costs on creators and imitators epitomizes the inefficiencies Hatch-Waxman intends to solve. Indeed, under the general logic of Hatch-Waxman, the extent of a drug's testing should inversely relate to its similarity to an already approved drug. This trend is depicted by the column labeled "Standards" in Table 1. Drug candidates extremely similar to an approved drug, though not technically bioequivalent, should not face requirements identical to those for a completely new drug. But as shown in Table 1, this scenario is precisely what Hatch-Waxman creates: a drug is either bioequivalent or not. In the long-standing debate between rules and standards, Hatch-Waxman unambiguously chooses rules.⁷⁸

Under this rule-based approach, the FDA's pre-Hatch-Waxman Act inefficiencies linger, as depicted in Figure 1.⁷⁹ Before the statute, all drugs

former, patents are rewards to inventive activity, and in the latter, patents should only be granted to inventions induced by the patent system. See A Samuel Oddi, *Un-Unified Economic Theories of Patents—The Not-Quite-Holy Grail*, 71 NOTRE DAME L. REV. 267, 273-282 (1996).

77. A reverse phenomenon is developing with respect to copyright within the digital context. The virtual elimination of the costs of production and distribution makes the ratio of the cost of creation to the cost of imitation approach infinity. Mark A. Lemley & R. Anthony Reese, *Reducing Digital Copyright Infringement Without Restricting Innovation*, 56 STAN. L. REV. 1345, 1374-75 (2004) ("The great promise of digital dissemination—the virtual elimination of the costs of copy production and distribution—is a mixed blessing for copyright owners. Content owner costs go down as they embrace digital dissemination but so do the costs of counterfeiters. Indeed, as the costs of producing and disseminating copies approach zero, the public goods problem gets worse, because the *ratio* of the cost of creation to the cost of imitation approaches infinity.") (emphasis in original).

78. Note that drug approval is rule-based with respect to these initial categories (i.e., pioneer or generic) but seemingly embraces a standards-based approach for general testing (i.e., whether the drug is safe and efficacious). See *infra* note 81.

79. Figure 1 depicts the relationship between drug-approval costs and a given drug's similarity to an already approved competitor. The dotted line shows the standards-based approach, and the two steps, ANDA and NDA, represent the costs under Hatch-Waxman.

faced identical approval standards. But Hatch-Waxman only altered the standards for drugs bioequivalent to already approved ones. Otherwise, the past regime remains. The diagonal line in Figure 1 approximates the inverse relationship between approval costs and similarity to a competitor under a purely standards-based approach to the safety and efficacy determination.⁸⁰ Along the x-axis labeled “Similarity to Competitor,” “0” represents no similarity, “1” is identical, and “B” is bioequivalent. If a competitor’s drug is bioequivalent, it faces ANDA approval costs; if not, it must pay the new drug rate, labeled NDA.⁸¹ The area below the NDA line and above the diagonal line represents the lingering inefficiencies. Because competitors developing similar but nonbioequivalent drugs must pay amounts beyond what safety and efficacy would require under a standards-based approach, the area above the diagonal line essentially functions as a tax on competitors who develop similar but not bioequivalent drugs or, in patent parlance, design-around.

Table 1. Approval Costs Under Hatch-Waxman and a Standards-Based Approach for Three Categories of Drugs

| | Approval Costs | |
|-------------------------------|----------------|--------------|
| | Standards | Hatch-Waxman |
| Bioequivalent | Low | Low |
| Similar But Not Bioequivalent | Medium | High |
| Dissimilar | High | High |

Note: The middle row depicts how approval costs for similar but not bioequivalent drugs diverge under the two approaches.

This design-around tax renders patent scope less relevant. In other industries, companies seek to design around a competitor’s patent because it capitalizes on the competitor’s good idea without infringing its patent rights. Forestalling this very threat is what makes additional patent scope so valuable. But Hatch-Waxman reduces the attractiveness of design-around because, at

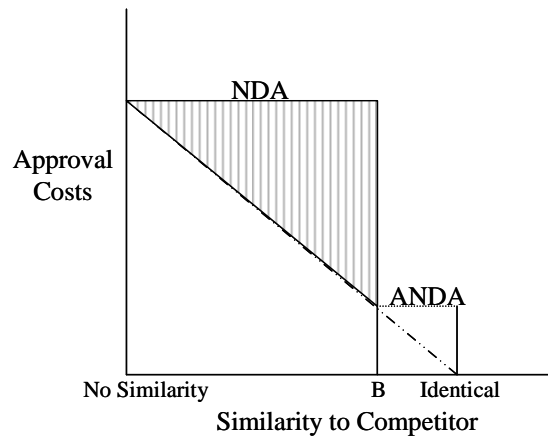
The region with vertical lines represents the so-called “design-around tax” imposed by Hatch-Waxman’s rule-based approach.

This Figure is intended to demonstrate the effects of Hatch-Waxman conceptually. Compared to actual costs, Figure 1 oversimplifies in two respects: (1) the costs are not as binary, meaning that the similarity to an already approved drug does influence NDA costs; and (2) the cost difference between ANDA and NDA is more severe, which tends to counteract the consequences of the first simplification. Thus, this Figure illustrates that, to the extent Hatch-Waxman employs a rule-based approach, it functionally imposes a design-around tax on drug manufacturers who compete with already approved products.

80. This relationship is oversimplified, as it is unlikely to be precisely linear.

81. Though the FDA’s underlying rule, that a drug be safe and efficacious, suggests that the NDA process should change according to the drug’s similarity to other approved drugs, in practice it does not because of the standardization of the number of trials and test subjects. See Richard J. Findlay, *Originator Drug Development*, 54 FOOD & DRUG L.J. 227 (1999).

Figure 1. Hatch-Waxman's Design-Around Tax

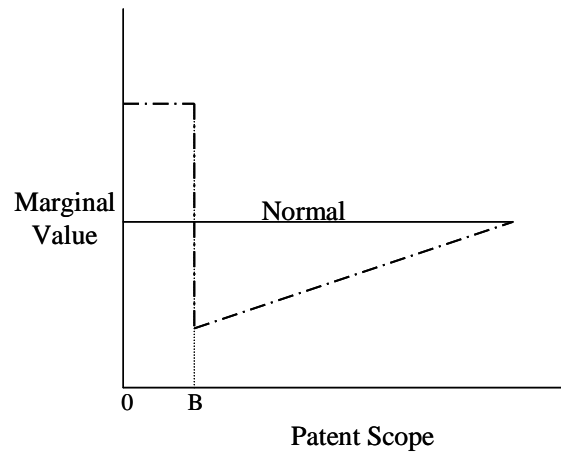


least with respect to approval costs, it eliminates the advantages that developing a similar drug would naturally produce. As a result, the additional patent scope benefits the patentee less than it normally would. Figure 2 depicts this phenomenon by comparing normal patents with drug patents according to marginal value of scope.⁸² The horizontal line labeled “Normal” represents the standard marginal value of patent scope. The line need not be exactly horizontal; indeed, a number of other contextual factors may affect patent scope’s marginal value. But increasing patent scope generally enhances value proportionally, so the marginal value remains constant.

Drug patents after Hatch-Waxman systematically deviate from this norm. Achieving scope beyond bioequivalence is extremely important to prevent competitors from easily developing bioequivalent drugs with abbreviated approval. Consequently, up to the bioequivalence point labeled “B,” a drug’s patent scope earns heightened marginal value. After bioequivalence, the FDA’s design-around tax kicks in, rendering patent protection less relevant and causing the marginal value of patent scope to drop off. Patent scope’s marginal value does not fall to zero, however, because injunctions under patent law’s property rules prevent competition more effectively than the FDA’s design-around tax—a quasi-liability rule. Moreover, as Figure 1 demonstrates, the tax’s magnitude decreases with further dissimilarity to the competitor. Marginal value of scope thus increases to normal levels once the patents cover completely dissimilar products.

82. Figure 2 illustrates the marginal value of additional patent scope. The horizontal line labeled “Normal” represents this relationship under normal conditions, and the dotted line represents the relationship under Hatch-Waxman.

Figure 2. Patent Scope's Marginal Value Under Hatch-Waxman



IV. ADVANTAGES OF TWO-TIERED INNOVATION POLICY

Written description's scope-narrowing effect, in conjunction with the FDA's increasing utilization of explicit and implicit provisions, shifts intellectual property protection away from patent law and toward the FDA, resulting in a two-tiered system. One response is to revert back to the earlier regime: eliminate written description and minimize the FDA's explicit and implicit impact on patent policy. But this option may be as undesirable as it is unrealistic. As discussed in this Part, a two-tiered model better aligns with patent law's justification, decreases pressure on the PTO to make early utility judgments, and expands the public domain by focusing exclusivities on commercializing a specific use.

A. Aligning with Patent Law's Justifications

Patent law intends to calibrate protection according to the extent of the public goods problem; thus, the most relevant costs are those that creators face but imitators can bypass. But the current system decides patentability long before many of these costs are borne, especially for pharmaceuticals.⁸³ Therefore, patent scope must integrate these potential costs to remedy the problem effectively. And accounting for future costs proves problematic because for most drug candidates, these postpatent costs never actually

83. Given the high levels of investment and risk, obtaining protection early in the development process is desirable, both to safeguard the interests of owners, investors, and other stakeholders and to preempt competitors who may be working on similar products and therapies.

accrue—a situation that forces patent law either to over- or underprotect.

To illustrate the point, consider the following hypothetical: Start with one-hundred patentable drug candidates. These drugs at least merit scope corresponding to their prepatenting costs.⁸⁴ Assume five of these drugs survive postpatent screening, namely clinical testing, while the others quickly fail with respect to their intended use. The five drugs proceed through full clinical trials and incur some of the postpatent costs discussed above. Also, assume the five cannot be distinguished from the other ninety-five during the patentability stage.⁸⁵ To remedy the public goods problem according to average costs for these one-hundred drug candidates, scope should correspond to prepatenting costs plus five percent of the potential postpatenting costs.

Yet this approximation quickly deviates from its justifications when the five candidates emerge and face subsequent costs without adequate protection. And the other candidates get windfall protection for unrealized postpatent costs. Because patentability is determined in one stage, patent law's best solution is to protect according to the drug's best-case scenario. But this merely obscures the problem by shifting the inefficiencies. Instead of drastically underprotecting blockbuster drugs, the regime systematically gives overprotection to an abundance of failed candidates.⁸⁶

The FDA's quasi-protection, in conjunction with written description, permits a more precise solution to the problem of public goods. By enabling technology-specific decreases in patent scope, written description can protect drug candidates according to prepatent costs alone. And the FDA, whose quasi-protection benefits the drug candidate survivors, integrates the postpatent costs only if they actually accrue.⁸⁷

Of course, the fact that expanding the examination process from one stage to two improves precision is not particularly surprising. In all segments of the law, adding process typically increases precision. But most laws remain imprecise because process is costly,⁸⁸ and this highlights why the two-tiered system is so compelling: it increases precision with virtually no added process costs. The system for subsequent examination already exists—the FDA already

84. This reference to costs only includes those that augment the problem of public goods. Costs that similarly affect imitators are not included.

85. The problem of distinguishing utility is further discussed in Part IV.B, *infra*.

86. That failed candidates receive overprotection may not seem problematic because nobody enforces useless patents. But as discussed in Part IV.C, *infra*, these drugs only fail with respect to specific indication; other uses may arise, which overprotection discourages.

87. The two-tiered system does not, as this simplified account tends to suggest, eliminate all problems related to under- and overprotection, because several candidates face postpatent costs without gaining FDA approval.

88. Indeed, debate over patent reform does not ask whether the proposed reexamination procedures will improve the PTO, but whether it is worth the cost. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1531-32 (2001) (concluding that a sparing inquiry serves as the optimal level of examination for all patent applications because so few patents are the subject of licensing or litigation).

tests a drug's utility (i.e., safety and efficacy) for independent policy reasons. So this heightened precision comes with virtually no additional costs.

B. Decreasing Pressure on the PTO To Determine Utility

Patent law normally ignores the utility doctrine because the market already incentivizes useful inventions. That is, a patent's exclusivity right is only beneficial to the extent that it protects something people want to buy. And if the patentee's invention fails to catch on, like, say, the toe puppet,⁸⁹ nobody is hurt by the monopoly.⁹⁰ Concerns arise, however, for the *potentially* useful inventions described above and, consequently, for industries dominated by such inventions. Because the market rewards usefulness at any time during the patent term,⁹¹ it often encourages capture of potentially valuable sectors. By applying patent law's essentially nonexistent utility requirement to industries dominated by early-stage research, courts may promote stockpiling rather than developing.⁹²

Increasing the utility requirement to hold off patentability until the truly useful drugs emerge from the candidates seems to be the solution, and it is the direction the Supreme Court took in *Brenner v. Manson*.⁹³ Manson argued for the utility of a process for making a certain steroid on the basis that the steroid was being tested for possible tumor-inhibiting effects in mice and that his compound was closely related to an effective steroid.⁹⁴ The Court rejected Manson's argument: "Unless and until a process is refined and developed to this point—where specific benefits exist in currently available form—there is

89. U.S. Patent No. 5,830,035 (issued Nov. 3, 1998). After distributing this draft, several people have remarked to me that their children love toe puppets, so I must acknowledge that, at least for some people, the resulting supracompetitive pricing is no joking matter.

90. See Giles S. Rich, *The Principles of Patentability*, 42 J. PAT. OFF. SOC'Y 75, 85 (1960) ("If [an invention] is a total dud, how is the public injured by a patent on it?").

91. MERGES & DUFFY, *supra* note 31, at 255.

92. See Matthew Erramouspe, Comment, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 UCLA L. REV. 961, 961-65 (1996) (characterizing the race to patent the human genome as a modern-day gold rush).

93. 383 U.S. 519 (1966). The *Manson* decision was quite controversial. See *In re Kirk*, 376 F.2d 936, 947-66 (C.C.P.A. 1967) (Rich, J., dissenting); *In re Jolly*, 376 F.2d 906, 910-32 (C.C.P.A. 1967) (Smith, J., dissenting); Iver Cooper, *Patent Problems for Chemical Researchers—The Utility Requirement After Brenner v. Manson*, 18 IDEA 23 (1976); Paul H. Eggert, *Uses, New Uses, and Chemical Patents—A Proposal*, 51 J. PAT. OFF. SOC'Y 768 (1969); Harold S. Meyer, *Utility Requirement in the Statute*, 49 J. PAT. OFF. SOC'Y 533 (1967); Eric P. Mirabel, "Practical Utility" Is a Useless Concept, 36 AM. U. L. REV. 811 (1987); Lawrence R. Velvel, A Critique of *Brenner v. Manson*, 49 J. PAT. OFF. SOC'Y 5 (1967); Brent Nelson Rushforth, Comment, *Patentability of Chemical Intermediates*, 56 CAL. L. REV. 497 (1968). But see Teresa M. Summers, Note, *The Scope of Utility in the Twenty-First Century: New Guidance for Gene-Related Patents*, 91 GEO. L.J. 475, 508-09 (2003) (advocating a heightened utility test).

94. *Manson*, 383 U.S. at 531.

insufficient justification for permitting an applicant to engross what may prove to be a broad field.”⁹⁵ To clarify its policy, the Court added: “[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”⁹⁶

But *In re Brana*⁹⁷ considerably weakened chemistry and biotechnology’s uniquely strict utility requirement. Brana’s chemical compound was “highly effective” in two *in vivo* tumor models in animals, which was sufficient for the Federal Circuit: “Usefulness in patent law, and in the particular context of pharmaceutical inventions, necessarily includes the expectation of further research and development.”⁹⁸ Four months after *Brana*, the PTO finalized its Utility Guidelines, which instructed examiners not to reject for lack of utility “[i]f the applicant has asserted that the claimed invention is useful for any particular purpose (i.e., a ‘specific utility’) and that assertion would be considered credible by a person of ordinary skill in the art.”⁹⁹

These lenient standards brought a deluge of patents—most notoriously for partial DNA segments called expressed sequence tags (ESTs). In reaction to industry outcry, the PTO released the 2001 Utility Examination Guidelines, which added the requirement that the assertion of utility be “specific” and “substantial.” The PTO’s training materials define specific utility as “a utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.”¹⁰⁰ Substantial utility must define a “real world” use for which no further research is necessary to identify or reasonably confirm.¹⁰¹

This history demonstrates the difficulty of administering the utility requirement with any degree of precision, especially in industries with long-term research and development timelines. Nearly every upstream development can be framed as useful; indeed, the grant application process often requires such posturing. And raising utility standards too high effectively bars patenting in early-stage research. No doubt there exists a theoretical point along the spectrum of research and development that balances the problem of potential utility with the need for patents.¹⁰² But expecting the PTO and the judiciary

95. *Id.* at 534-35.

96. *Id.* at 536.

97. 51 F.3d 1560 (Fed. Cir. 1995).

98. *Id.* at 1568.

99. Utility Examination Guidelines, 60 Fed. Reg. 36,263 (July 14, 1995).

100. U.S. PATENT & TRADEMARK OFFICE, REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS 5 (emphasis in original), available at <http://www.uspto.gov/web/menu/utility.pdf> (last visited Feb. 18, 2006).

101. *Id.* at 6. Under these new guidelines, the Federal Circuit upheld the rejection by the PTO of a claim to five ESTs in a patent application as unpatentable for lack of utility under 35 U.S.C. § 101. *In re Fisher*, 421 F.3d 1365, 1379 (Fed. Cir. 2005).

102. Because of these competing issues, for industries such as biotechnology, utility is essentially “a timing device, helping to identify when an invention is ripe for patent protection.” Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the*

consistently to find that point across diverse technologies is unrealistic. Moreover, the unpredictability of success in the drug industry prevents accurate utility judgments until actual drug approval.¹⁰³

Because of the involvement of the FDA, the PTO's utility standard for drug candidates need not be so precise. The FDA enables the PTO to err on the side of patenting for drug candidates according to its current utility guidelines, while decreasing scope through written description. Patent law normally shuns such narrow scope because it permits competitors to design around the patent easily.¹⁰⁴ But minimal standards are sufficient because the FDA—the ultimate arbiter of utility for drug candidates—adds quasi-protection to the truly useful products. Rather than determining protection according to one utility judgment, the two-tiered inquiry—patentability and marketability—minimizes the administrability problems that arise in the drug industry because of its long-term and unpredictable research timelines.

C. Focusing Protection Where It Counts

The attribute of the patent system perhaps most surprising to law students as they first venture into an intellectual property class is the breadth of the exclusionary right that patents confer. According to our intuitions, a patent should prevent others from selling a copy of your patented product, but that is about all. The patent right is much more expansive, however. For example, it allows you to prevent others who, through brilliant insight, discover an unforeseeable new use, even if the new use would not compete with your product. In fact, the right allows you to prevent use even where the inventor of the new use is not selling anything at all. This counterintuitive breadth does not derive from moral or economic rationales; rather, pragmatic considerations, such as detection and enforcement problems, provide the soundest basis for patent's extension beyond what the public goods problem requires.

As this Part explains, the FDA's unique role as gatekeeper for drug products essentially nullifies many of these pragmatic considerations. As a

Patent System, 53 VAND. L. REV. 2081, 2087 (2000). For a good discussion of the need for early-stage patents, see Phanesh Koneru, *To Promote the Progress of Useful Art[icle]s?: An Analysis of the Current Utility Standards of Pharmaceutical Products and Biotechnology Research Tools*, 38 IDEA 625, 667-70 (1998).

103. This result would effectively cloak research and development in secrecy and has already been rejected by the Federal Circuit. *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) ("FDA approval . . . is not a prerequisite for finding a compound useful within the meaning of the patent laws.").

104. See *Philip A. Hunt Co. v. Mallinckrodt Chem. Works*, 177 F.2d 583, 585 (2d Cir. 1949) ("If the claims were limited to the 'concise and exact terms' in which the specifications ordinarily describe a single example of the invention, few, if any, patents, would have value, for there are generally many variants well-known to the art, which will at once suggest themselves as practicable substitutes for the specific details of the machine or process so disclosed.").

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TWO-TIERED INNOVATION POLICY

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result, the two-tiered system is capable of conforming to our economic intuitions and minimizing the social costs imposed by broad exclusionary rights.

1. *Focus on a drug's use*

Product patents on new inventions cover all (even unforeseen) uses, while those who discover new uses of old inventions are rewarded with process patents, or the ability to exclude others from practicing the invention for the particular use.¹⁰⁵ Patentees undoubtedly prefer the former. Process patents not only provide narrower property rights, they also suffer two limitations that further diminish their comparative value: (1) if the original product patent is still in force, it will block a process patent's rights to practice of the new use, and (2) the infringement of a process patent is often difficult to detect and enforce.¹⁰⁶

To illustrate these limitations, consider a process patent that covers the use of a certain chemical as a pesticide. If an inventor already discovered the chemical for use as, say, a shampoo, and received a product patent, then the original inventor can block this new and no doubt unforeseeable use of the chemical as a pesticide, and the process patentee must seek a license to get permission to practice her invention. To make matters worse for our hapless new patentee, selling the chemical itself does not necessarily infringe the process patent; she must determine whether consumers actually put the chemical in their hair or on their crops, which increases detection costs and forces the patentee to file an inefficiently large number of infringement suits.¹⁰⁷ Patent law's bias toward product patents therefore tends to encourage too much research into new compounds and too little research into new uses for old compounds.¹⁰⁸

To avoid these incorrect incentives, some commentators advocate eliminating product patents on compounds altogether and, instead, rewarding inventors with process patents on the uses they have discovered, so that the original inventor would only be able to patent the chemical's use as shampoo.¹⁰⁹ But the detection and enforcement problems mentioned above prevent implementing such proposals. In the drug industry, process patent holders confront this problem acutely because FDA approval for a certain indication does not prevent doctors from prescribing for off-label use.¹¹⁰

105. MERGES ET AL., *supra* note 62, at 139.

106. See MERGES & DUFFY, *supra* note 31, at 393.

107. See *id.* at 394.

108. See, e.g., Harold L. Marquis, *An Economic Analysis of the Patentability of Chemical Compounds*, 63 J. PAT. OFF. SOC'Y 3, 40-42 (1981).

109. See, e.g., Eggert, *supra* note 93, at 915-17.

110. Physicians may prescribe and pharmacists may dispense drugs for purposes that are not indicated on the manufacturer's FDA-approved labeling, so long as the drug is not

Other than patent term extension, drug regulation exclusivities function more like process patents, as they prevent approval for a given indication. So when a certain treatment for high blood pressure has the convenient side effect of promoting hair growth, the manufacturer must carry out a new approval process to get Rogaine.¹¹¹ This process corrects patents' perverse incentives while better managing enforcement problems. Though doctors may prescribe off-label use, the drug itself must be approved—the FDA is always the gatekeeper.¹¹² Market exclusivities that limit or increase costs of drug approval restrict a necessary step, even for off-label means. The FDA's marketing restrictions, which only permit advertising according to approved indications, additionally prevent a competitor from promoting new, unapproved uses.¹¹³

2. Focus on commercialization

In patent law, commercializing is neither necessary to receive patent rights nor required to infringe them. The FDA, however, effectively requires commercialization because it initiates protection at drug approval. And rather than granting broad rights to exclude from making, selling, or using, the FDA's quasi-protection applies only to drugs intended for distribution in the marketplace. This distinction remedies two of patent law's shortcomings.

First, tying extra protection to actual commercialization corrects patent law's occasionally dysfunctional incentives. In most circumstances, market forces sufficiently encourage patentees to commercialize their inventions. But when patentees overvalue their patents, withhold to avoid competing with a product they have already commercialized, or delay in order to extract royalties from others' sunk costs, the market often fails.¹¹⁴ These scenarios largely arise

prescribed for an experimental purpose and the "off-label" use is supported by valid scientific opinion, usually in the form of peer-reviewed literature or some other authoritative text. Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments, 59 Fed. Reg. 59,820 (Nov. 18, 1994).

111. See, e.g., MedicineNet.com, *Minoxidil*, <http://www.medicinenet.com/minoxidil/article.htm> (last visited Feb. 18, 2006).

112. See 21 U.S.C. § 355(a) (2006) (providing that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug").

113. Advertisements—which include those published in journals, magazines, other periodicals, and newspapers; and broadcast through media such as radio, television, and telecommunications systems—must include: the established name, the brand name (if any), the formula showing quantitatively each ingredient, and information in brief summary which discusses side effects, contraindications, and effectiveness. 21 U.S.C. § 352 (2006).

114. See Michelle Armond, Comment, *Introducing the Defense of Independent Invention to Motions for Preliminary Injunctions in Patent Infringement Lawsuits*, 91 CAL. L. REV. 117, 117-20 (2003) (criticizing so-called "submarine patents" that capitalize on competitor's sunk costs); Julie S. Turner, Comment, *The Nonmanufacturing Patent Owner: Toward a Theory of Efficient Infringement*, 86 CAL. L. REV. 179, 183 (1998) (citing two "litigation-inducing reasons" for a patentee's failure to commercialize as subjective

because not commercializing is of no consequence to patentee's rights. Under the two-tiered scheme, however, commercializing increases protection. Only when patentees survive the approval process and bring a drug to market do the FDA's protections confer. This scheme at least discourages patentees from inefficiently withholding commercialization.

Second, the FDA's extra protection only applies to competitors' commercialization, as compared to patents, which generally prevent even noncommercial use.¹¹⁵ Shifting the role of protection from patents to the FDA thus expands the scope of free noncommercial use in early drug research. Advocates of such open access within patent law typically suggest invigorating the experimental-use defense. Their proposals, which would provide a defense against infringement suits for certain kinds of noncommercial research, generally borrow from copyright's fair use exemption,¹¹⁶ but this unfortunately includes its self-defeating vagueness.¹¹⁷ Unless clearly exempted by these proposed multifactor tests, the brooding presence of a potential infringement suit will likely deter even the most risk-seeking researchers.

By contrast, the two-tiered model establishes clearer rules. Because approval is the final but necessary step in commercializing drugs, the FDA can maximize the free-use domain by withholding second-stage protection until approval. Granted, the first stage of patenting confers property rights contrary

overvaluation and unwillingness to compete with a current product); *see also* Michael J. Meurer, *Controlling Opportunistic and Anti-Competitive Intellectual Property Litigation*, 44 B.C. L. REV. 509 (2003) (discussing generally the anticompetitive effects of intellectual property litigation based on questionable rights).

115. In *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005), the Supreme Court unanimously set aside the Federal Circuit's holding that narrowly interpreted the statutory safe harbor of 35 U.S.C. § 271(e)(1) (2005). Writing for the Court, Justice Scalia found "it apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA." *Merck*, 125 S. Ct. at 2380 (emphasis in original). The Court explicitly declined to address the question of research tools, noting in a footnote that it was not expressing a view about whether § 271(e)(1) exempts from infringement the use of "research tools" in the development of information for the regulatory process. *Id.* at 2382 n.7.

116. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1017-18 (1989); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 179-80 (1987); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 17 (2001); Janice M. Mueller, *The Evanescent Experimental Use Exception from United States Patent Infringement Liability: Implications for University/Nonprofit Research and Development*, 56 BAYLOR L. REV. 917 (2004); Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1205 (2000); Eyal H. Barash, Comment, *Experimental Uses, Patents, and Scientific Progress*, 91 NW. U. L. REV. 667, 669 (1997).

117. As Lawrence Lessig notes, fair use is functionally a right to a lawyer. *See* LAWRENCE LESSIG, *FREE CULTURE: HOW BIG MEDIA USES TECHNOLOGY AND THE LAW TO LOCK DOWN CULTURE AND CONTROL CREATIVITY* 292 (2004) (criticizing the "fuzziness" of fair use).

to an open environment. But in light of additional FDA protection, such patents need narrowing via written description until they only remedy prepatent costs. Therefore, as protection continues to shift to the FDA, the first-stage patent regime should look more like copyright: patents for drug candidates need only prevent literal copying.

The strategy for promoting an open research environment under this regime is importantly distinct from an experimental-use exemption. Experimental use applies to all subject matter but exempts certain uses not intended for commercialization. The two-tiered model limits exempted subject matter but generally permits all uses other than actual distribution to the marketplace with the same indication. Normally, such expansive use rights alarm patentees because, without broader property rights, they suspect infringing competitors will go undetected. But because all competitors must eventually pass through approval with the FDA, preapproval free use does not lead to the threat of undetectable commercialization.

Indeed, the difference in enforcement is striking. In theory, both FDA and patent protections apply to all competitors: the FDA prohibits the introduction into interstate commerce of new drugs except pursuant to approved NDAs,¹¹⁸ and a patent restricts others from making, selling, or using its subject matter. But in practice, the FDA inspires obedience much more than patents do.¹¹⁹ Patents are frequently infringed without enforcement for a number of reasons, including lack of detection and high litigation costs.¹²⁰ In the rare circumstances in which drugs are distributed without approval, the FDA acts with swift and draconian measures, such as seizure, massive fines, and even strict criminal liability.¹²¹ Moreover, the government assumes enforcement responsibilities, a nontrivial expense for manufacturers in the patent law context.¹²²

118. 21 U.S.C. § 355(a) (2006).

119. Rebecca Eisenberg points out how pharmaceutical companies already exploit this distinction to remedy the problem of parallel trade. Eisenberg, *supra* note 5, at 124-27. Patent law often fails to prevent arbitrage because many countries permit the importation and resale of patented products purchased abroad, which the Treaty on Trade Related Aspects of Intellectual Property Rights (TRIPs) does not prevent because of its exception for exhaustion of intellectual property rights. *See id.* The pharmaceutical industry prevents parallel imports through the FDA instead, by prohibiting importation of products made for foreign markets governed by different labeling requirements and even reimportation of previously exported U.S.-manufactured drugs. *See id.*

120. *See* John R. Allison et al., *Valuable Patents*, 92 GEO. L.J. 435, 435, 441 (2004) (noting that ninety-nine percent of patent owners never enforce their rights and that, in light of litigation costs, a rational patent owner will not file suit unless the expected return is at least a few million dollars).

121. *See* 21 U.S.C. § 333 (2006). The food and drug law is distinct from ordinary regulatory and criminal law in that the defendant can be held criminally liable “without proof of knowledge of the event or intention to perform the act that results in a violation.” 1 JAMES T. O'REILLY, *FOOD AND DRUG ADMINISTRATION* § 8.02 (2005).

122. Over the more than 2500 patent lawsuits filed each year, the average cost of

Relying on the FDA rather than patent litigation for protection virtually eliminates the detection problem, which should affect the scope of the patent right. This insight borrows from the punitive damages scholarship, which posits that the optimal fine is the harm divided by the probability of detection.¹²³ Here, the optimal patent scope is likewise a function of an ideal scope divided by the probability of detection. When the FDA is in charge of enforcement, the probability of detection approaches one, so the optimal patent scope should narrow—a consideration that the FDA also integrates by protecting commercialization only.

Finally, expanding use rights also comports with patent law's underlying goal: to "promote . . . Progress."¹²⁴ Rhetoric in support of freeing basic, noncommercial research via an experimental-use exemption often draws on the ideal of the pure researcher, driven by knowledge rather than profit. Yet "progress" appreciates profit-driven researchers as well. Under the two-tiered model, drug manufacturers receive exclusivity rights for their specific drug instead of the broad drug class. This approach frees others, whether motivated by profit or not, to experiment on the numerous embodiments within the drug class to search for new uses. The FDA still implicitly and explicitly protects the pioneer, but only by controlling direct competition according to the drug's use.

CONCLUSION

That these counteracting trends in patent law and drug regulation developed independently is as troubling as it is opportune. At minimum, an operative two-tiered system requires policymakers to acknowledge its existence. Until then, all of the careful balancing between competition and protection that innovation policy entails is largely in vain. One cannot, after all, competently balance interests when many of them are ignored.

Within patent law, written description functions over- and underinclusively for the purposes of two-tiered innovation policy within the drug industry. Under the rationales discussed in Part III, written description should treat all drug candidates with equal rigor. In practice, written description applies to biologics with greater consistency than to chemically synthesized drugs. Equivalent treatment appears to be the trend, however.¹²⁵ But only coordination will ensure that written description aligns with the rationales for

litigation is upward of \$4 million. Kelly C. Hunsaker, *Taking Care of Business: Patent Reform Should Promote Innovation, Not Imitation*, S.F. CHRON., Aug. 30, 2005, at B7.

123. A. Mitchell Polinsky & Steven Shavell, *Punitive Damages: An Economic Analysis*, 111 HARV. L. REV. 869 (1998); see also A. Mitchell Polinsky & Steven Shavell, *The Economic Theory of Public Enforcement of Law*, 38 J. ECON. LIT. 45 (2000).

124. U.S. CONST. art. I, § 8, cl. 8.

125. In *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004), the court extended the principle of written description to small-molecule chemistry.

two-tiered protection.¹²⁶

Within drug regulation, the FDA often frames its economic exclusivities in terms of health and safety. Besides being dishonest, this maneuvering tends to deflect the heightened scrutiny such measures deserve. To be sure, using two tiers complicates innovation policy. Instead of solely fine-tuning patent law's balance between protection and competition, drug innovation policy must also balance between institutions—complexities that caution against the FDA's seemingly haphazard approach thus far. With close attention to institutional balancing, subsequent policies must acknowledge and coordinate this interrelationship to realize effective two-tiered innovation policy.

On a broader level, this two-tiered system marks a fundamental shift for innovation policy. Since the late eighteenth century, the patent system has viewed society's benefit from an invention not in terms of the new technology itself, but in terms of its underlying technical know-how.¹²⁷ Inspired by Lord Mansfield's famous opinion in *Liardet v. Johnson*,¹²⁸ this shift from finished products to technical information allegedly invigorated the patent system and fueled the Industrial Revolution.¹²⁹ In light of this history, the two-tiered system's shift toward protecting drug *products* seemingly turns back the clock.

But, in fact, this system evades the still-persistent debate about whether products or information constitute the benefits of patent protection. It deftly achieves both by recognizing that these benefits require distinct incentives—baseline patent protection for disclosure of information and heightened regulatory protection for actual products—a fortuitous solution which, within this historical context, is long overdue.

126. Written description also applies to nondrug candidates, for which the FDA provides no justification. The other justifications that may exist are outside the scope of this Note.

127. MERGES & DUFFY, *supra* note 31, at 259.

128. 481 N.B. 173 (K.B. 1778). In *Liardet v. Johnson*, Lord Mansfield stipulated that a patentee must file a full and detailed specification to qualify for a patent and is often said to have enshrined the disclosure theory in patent doctrine. *Id.* But see CHRISTINE MACLEOD, INVENTING THE INDUSTRIAL REVOLUTION: THE ENGLISH PATENT SYSTEM, 1660-1800, at 49-53 (1988); John N. Adams & Gwen Averley, *The Patent Specification: The Role of Liardet v. Johnson*, 7 J. LEGAL HIST. 156 (1986).

129. See MACLEOD, *supra* note 128, at 49-53; Adams & Averley, *supra* note 128, at 156.