

# ARTICLE

## BUILDING A BETTER INNOVATION SYSTEM: COMBINING FACIALLY NEUTRAL PATENT STANDARDS WITH THERAPEUTICS REGULATION

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### TABLE OF CONTENTS

I. INTRODUCTION .....1038

II. BACKGROUND: THE PATENT SYSTEM  
AND ITS DISCONTENTS ..... 1041

III. RECENT JUDICIAL REFORM.....1042

    A. eBay Inc. v. MercExchange, L.L.C. ....1042

    B. KSR International Co. v. Teleflex Inc. ....1045

IV. THE WAY FORWARD .....1052

    A. *Possibilities for (Additional) Facially Neutral  
    Patent Reform* ..... 1053

    B. *FDA and Health Insurance Regulation*..... 1056

V. CONCLUSION.....1057

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## I. INTRODUCTION

Prompted by persistent complaints—particularly from the information and communication technology (ICT) industries—about the dangers allegedly posed by strong patents of poor quality, both the legislative and judicial branches have recently made attempts at patent reform. At least for the moment, legislative reform has been thwarted, largely by opposition from the biopharmaceutical industry.<sup>1</sup> The current logjam over legislative reform might lead to the pessimistic conclusion that reform is likely to be either zero sum (one set of industry interests is able to garner more votes than its opponent and override the legitimate interests of the other) or founded in disparate treatment of different industries (a departure from the much-heralded “unitary” nature of the patent system).

This Article argues that such a conclusion would be premature. One important counter to the pessimistic view is the example of the Supreme Court’s recent judicial reform. Although the biopharmaceutical industry has been quite opposed to this reform,<sup>2</sup> the evidence thus far suggests that the Court’s decisions may have only a limited impact on the legitimate interests of the industry. Specifically, although the Court’s decisions adopt a facially neutral approach, this approach is likely to have a disparate impact that leaves relatively untouched the patent law that surrounds core product claims to small molecule drugs. To put the point another way, the Court has, by adopting the “standards”-based approach of traditional patent jurisprudence,<sup>3</sup>

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1. In addition to the biopharmaceutical industry, universities, certain manufacturing interests, and some groups affiliated with small firm innovators (including small firms outside biopharmaceuticals) have also opposed reform. Although this Article focuses on the ICT versus biopharmaceutical divide, it touches on issues faced by small firm innovators in Part II.

2. In the nonobviousness case of *KSR International Co. v. Teleflex Inc.*, for example, the trade groups for the biotechnology and pharmaceutical industries—Biotechnology Industry Organization (BIO) and the Pharmaceutical Research and Manufacturers of America (PhRMA)—filed amicus briefs opposing any change in the nonobviousness standard. See Brief of Amicus Curiae Pharmaceutical Research and Manufacturers of America in Support of Respondents, *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350); Brief of Biotechnology Industrial Organization as Amicus Curiae Supporting Respondents, *KSR*, 127 S. Ct. 1727 (No. 04-1350). BIO and PhRMA also filed briefs endorsing the status quo in *eBay Inc. v. MercExchange, L.L.C.* See Brief of Amicus Curiae Pharmaceutical Research and Manufacturers of America in Support of Respondent, *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (No. 05-130); Brief of Biotechnology Industrial Organization as Amicus Curiae Supporting Respondents, *eBay*, 547 U.S. 388 (No. 05-130).

3. The literature on rules versus standards is, of course, voluminous. For a prominent economically oriented approach, see generally Louis Kaplow, *Rules Versus*

taken into account, at least in part, the disparate technical challenges associated with information creation and development for different innovators.

The analogy to antidiscrimination law is a compelling one: as students of antidiscrimination law know, facially neutral standards often have disparate impact. In the case of patents, the disparate impact is a feature, not a bug.<sup>4</sup> Moreover, when deployed properly, patent law's standards-based approach makes it sensitive not only to disparate technical challenges but also, in significant part, to disparate *economic* structures of information creation and development.<sup>5</sup>

Two other counters to the pessimistic view bear emphasis. First, to the extent that the outlier set of inventions appears to be biopharmaceutical therapeutics, this industry is embedded in a web of *non-patent based* market and regulatory structures that do much of the heavy lifting in terms of setting up barriers to entry and influencing price. The two most salient structures are Food & Drug Administration (FDA) regulation and the health insurance industry.<sup>6</sup> Although these non-patent structures are of course technologically specific, they are narrowly tailored to the

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*Standards: An Economic Analysis*, 42 DUKE L.J. 557 (1992). Standards have the obvious liabilities of increased uncertainty (until the standard is applied in a given case) and of requiring a competent decisionmaker to apply the standard. The important question of whether patent law *should* (in the main) be standards-based is beyond the scope of this short Article. I take on that question, concluding that a standards-based approach is both formally and functionally justified, in Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1116–22 (2003) (concluding that a standards-based approach is both formally and functionally justified).

4. *Accord* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1641–58 (2003) (discussing “micro” policy levers, implemented through standards like utility and level of ordinary skill in the art, that operate at the level of individual inventions but tend to have differential impact).

5. For some prior discussions of this point, see FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 3–14 (2003); Stuart Benjamin & Arti K. Rai, *Who’s Afraid of the APA: What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269, 276–278 (2006).

6. The idea that FDA regulation serves as “innovation policy” is hardly new. *See, e.g.*, Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007). The notion that the health insurance industry (which is itself highly regulated) heavily influences the structure of pharmaceutical innovation has been less discussed by patent law scholars. Health economists and health law scholars have emphasized this feature, however. *See, e.g.*, Patricia M. Danzon & Mark V. Pauly, *Health Insurance and the Growth in Pharmaceutical Expenditures*, 45 J.L. & ECON. 587, 589 (2002) (arguing that expansions in health insurance are largely responsible for growth in pharmaceutical expenditures); Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173, 207–08 (2001) (discussing insurance-induced moral hazard and the need for tort and contract law to allow health insurance firms to make cost—benefit trade-offs in coverage of pharmaceuticals).

peculiar economic questions raised by end product therapeutics. Thus applying FDA and health insurance regulation is likely to raise fewer problems of line drawing than attempts to develop a *sui generis* patent regime for biopharmaceutical innovation as a whole. To put the point another way, a patent law carve out for a given “industry,” which may be hard to define and may not be particularly homogenous in the types of innovation it produces, is neither fish nor fowl—neither an easily applied rule nor a policy and context sensitive standard. In contrast, FDA and health insurance regulation are, for the most part, narrowly tailored to the specific concerns raised by end product therapeutics.

Finally, in those situations where neither existing patent law standards nor existing regulation specific to end product therapeutics is sufficiently sensitive to relevant considerations of economic policy, additional facially neutral standards could be implemented. Like patent law’s existing standards, these would operate at the level of invention and would not require attempts to draw blunt (over-inclusive and under-inclusive) lines between industries. Certain tweaks to FDA and health insurance regulation may also be worth contemplating.

A larger point that emerges from this analysis involves the need to avoid tunnel vision in thinking about regulatory systems that foster innovation. In many cases, the optimal resolution for a given policy puzzle may involve more than one system.<sup>7</sup>

Part II of the Article gives a brief background on the dissatisfaction with the patent system that spurred Supreme Court interest. Part III discusses the most salient recent cases and their relatively modest effects on core product claims to small molecule drugs. Part IV suggests mechanisms through which additional facially neutral patent reform as well as tweaks to FDA and health insurance regulation could be used to take account of remaining economic concerns.

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7. Stuart Benjamin and I discuss this larger point at some length in Stuart Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. (forthcoming 2008).

## II. BACKGROUND: THE PATENT SYSTEM AND ITS DISCONTENTS<sup>8</sup>

The Supreme Court has, in the last few years, rediscovered the area of patent law.<sup>9</sup> The Court's renewed interest in patent law appears to have been sparked by the growing tide of criticism of the patent system that began to emerge in the late 1990s. In 2003 and 2004, respectively, the Federal Trade Commission and the National Academy of Sciences issued prominent reports calling for (*inter alia*) the invigoration of the nonobviousness standard for determining patent validity.<sup>10</sup> In addition, starting in the late 1990s, various scholars began to emphasize the failure of the patent system to establish clear patent validity and scope when the patent is first issued.<sup>11</sup>

The evidence suggests that problems of obvious patents and patents with vague boundaries are particularly salient outside biotechnology and pharmaceuticals. Indeed, based on their assessment of renewal data, market value regressions, and stock market valuations before and after announcements of patent litigation, James Bessen and Michael Meurer argue that, by the late 1990s, publicly traded firms reaped benefits from patents that clearly exceeded the costs created by the need to defend against patent infringement suits in the chemical and pharmaceutical industries *only*.<sup>12</sup>

The scholarly focus on these industry-based differences notwithstanding, recent judicial reform does not purport to draw explicit distinctions based on industry. On the face of it, then, one might surmise that such reform would create problems for the biopharmaceutical industry. However, as the next section

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8. With apologies to Sigmund Freud, and more recently, Adam Jaffe and Josh Lerner, who authored a 2004 critique of the patent system titled *Innovation and Its Discontents*. The title of the Jaffe and Lerner book is a bit misleading, as it focuses on the patent system only. See generally ADAM B. JAFFE & JOSH LERNER, *INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT* (2004). In contrast, the empirical evidence (some of which is discussed further below) indicates that, for publicly traded manufacturing firms in most sectors, patents play only a small role in spurring innovation.

9. I say "rediscovered" because the Court was reasonably active in the patent arena during the period from 1940–1970. The number of cases it took during these periods averaged between 2 and 6 a year. See John F. Duffy, *The Festo Decision and the Return of the Supreme Court to the Bar of Patents*, in 2002 SUPREME COURT REVIEW 273, 288 (Dennis J. Hutchinson, David A. Strauss & Geoffrey R. Stone eds., 2003).

10. See FED. TRADE COMM'N, *supra* note 5, at 3; STEPHEN A. MERRILL, RICHARD C. LEVIN & MARK B. MYERS, NAT'L ACAD. OF SCIS., *A PATENT SYSTEM FOR THE 21ST CENTURY* 59 (2004).

11. See, e.g., Craig Nard, *Certainty, Fence-Building, and the Useful Arts*, 74 IND. L.J. 759 (1999).

12. JAMES BESSEN & MICHAEL MEURER, *PATENT FAILURE* 162–63 (2008).

discusses, the two most salient facially neutral cases, *eBay Inc. v. MercExchange, L.L.C.*<sup>13</sup> and *KSR International Co. v. Teleflex Inc.*,<sup>14</sup> have not thus far created significant problems, at least for legitimate interests of the industry in the form of core product claims to small molecule drugs.<sup>15</sup>

### III. RECENT JUDICIAL REFORM

#### A. *eBay Inc. v. MercExchange, L.L.C.*

In the 2005 legislative battle over patent system reform, the ICT industries challenged the Federal Circuit's bright line rule in favor of automatic permanent injunctive relief once validity and infringement had been determined.<sup>16</sup> The industries supported legislation that would have required courts to evaluate the "fairness" of injunctive relief in light of "all the facts and the relevant interests of the parties."<sup>17</sup> Opposition to this provision by the biopharmaceutical industry was one of the reasons that the 2005 patent reform bill failed in Congress.<sup>18</sup>

To a significant extent, the legislative logjam has been circumvented by the Supreme Court's decision in *eBay*. In that

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13. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

14. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 1727 (2007).

15. Ironically, a Supreme Court case that may create problems for certain sectors of the biotechnology industry (though it may alleviate problems for the pharmaceutical industry and for larger, vertically integrated biotechnology firms that manufacture products) is *Merck KGaA v. Integra LifeSciences I, Ltd.*, 545 U.S. 193 (2005), a case that involves the Court's interpretation of regulation aimed at facilitating the entry of generic pharmaceuticals. In that case, the Court held that the language of the Hatch-Waxman Act, which creates a statutory exemption from patent infringement liability for research done to generate data for an FDA submission, is sufficiently capacious to cover research not only on generic versions of patented drugs (the intention of the Hatch-Waxman drafters) but also research that yields data that does not ultimately end up being submitted to the FDA. *See id.* at 206-07. Some commentators have expressed concern that, after *Merck v. Integra*, the Hatch-Waxman research exemption will be interpreted broadly to cover a large percentage of research that uses the biotechnology industry's patented research tools. *E.g.*, Michael Sertic, Note, *Muddying the Waters: How the Supreme Court's Decision in Merck v. Integra Fails to Resolve Problems of Judicial Interpretation of 35 U.S.C. § 271(E)(1), the "Safe Harbour" Provision of the Hatch-Waxman Act*, 17 HEALTH MATRIX 377 (2007).

16. *Patent Act of 2005: Hearing on H.R. 2795 Before the H. Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary*, 109th Cong. 77-78 (2005) (statement of Computer & Communications Industry Association).

17. Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

18. *See, e.g., Amendment in the Nature of a Substitute to H.R. 2795, The "Patent Act of 2005" Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary*, 109th Cong. 28-29 (2005) (statement of Robert B. Chess, Executive Chairman, Nektar Therapeutics) ("If you allowed courts to weigh equities and balance hardships, our patents would be weakened, and research and development would suffer.").

case, the Court unanimously held (*contra* the Federal Circuit) that permanent injunctive relief was not mandatory in cases where validity and infringement had been proven. The Court left to the discretion of the trial court the question of whether injunctive relief should be granted in any given case.<sup>19</sup>

A concurring opinion by Justice Kennedy specifically identified as problematic the imposition of injunctive relief in those cases (common in the ICT industries) where the plaintiff's patent represents only a small portion of the ultimate infringing technology.<sup>20</sup> In such cases, the availability of injunctive relief can give the patent holder leverage to extract rents in excess of the contribution actually made by the patentee.<sup>21</sup>

Though it is facially neutral, the *eBay* decision does not appear to have created significant problems for the biopharmaceutical industry. Lower court cases interpreting *eBay* tend to find irreparable harm, and grant injunctive relief, in cases where the patentee and the infringer are competitors.<sup>22</sup> A large percentage of biopharmaceutical litigation involves this situation. The prototypical example is a challenge by a generic to a brand name pharmaceutical firm's patent-based monopoly over a given drug.<sup>23</sup>

One might argue that the *eBay* decision could pose problems for smaller biotechnology firms that do not themselves manufacture products (and hence would not be in direct competition with the alleged infringer) but, instead, create technology and early-stage products that they then license to manufacturing firms. On this view, injunctive relief prevents

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19. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006).

20. *Id.* at 396–97 (Kennedy, J., concurring).

21. *See id.*

22. *Compare* *TiVo Inc. v. EchoStar Commc'ns Corp.*, 446 F. Supp. 2d 664, 669–70 (E.D. Tex. 2006) (finding irreparable harm in cases concerning direct competitors), *Smith & Nephew, Inc. v. Snythes*, 466 F. Supp. 2d 978, 983 (W.D. Tenn. 2006) (same), *and* *Visto Corp. v. Seven Networks, Inc.*, No. 2:03-CV-333-TJW, 2006 WL 3741891, at \*4 (E.D. Tex. Dec. 19, 2006) (same), *with* *z4 Techs. v. Microsoft Corp.*, 434 F. Supp. 2d 437, 440–41 (E.D. Tex. 2006) (finding no irreparable harm where the parties do not compete), *and* *Paice L.L.C. v. Toyota Motor Corp.*, No. 2:04-CV-211-DF, 2006 WL 2385139, at \*5 (E.D. Tex. Aug. 16, 2006) (same).

23. To be sure, in several biopharmaceutical cases involving *preliminary* injunctive relief, district courts have invoked *eBay* to deny such relief. *See, e.g.,* *Altana Pharma AG v. Teva Pharms., USA, Inc.*, 532 F. Supp. 2d 666, 681–82 (D.N.J. 2007); *Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, No. 05-CV-1887 (DMC), 2007 WL 2669338, at \*13 (D.N.J. Sept. 6, 2007). Even before *eBay*, however, the Federal Circuit had made it clear that denying preliminary injunctive relief was appropriate in these types of circumstances. *See* *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) (noting that it is within the discretion of the district court to grant or deny a preliminary injunction).

larger firms from simply infringing patented technology held by smaller firms, secure in the knowledge that in the worst case scenario all the larger firm will have to do is pay damages not significantly larger than the cost of a license. Thus, to the extent that promoting small firms and “markets for technology”<sup>24</sup> should be an objective of innovation policy (on the theory that small firms are likely to be more innovative than large firms),<sup>25</sup> one might argue that *eBay* could prove detrimental to innovation both in the biopharmaceutical industry and more generally.

This view may, however, underestimate the flexibility afforded trial courts by the *eBay* standard. The Court’s decision observes that “[s]ome patent holders . . . might reasonably prefer to license their patents, rather than undertake efforts to secure the financing necessary to . . . [do the] market[ing] themselves. Such patent holders may be able to satisfy the traditional four-factor test, and we see no basis for categorically denying them the opportunity to do so.”<sup>26</sup> In an instructive opinion, the district court noted in the *eBay* remand that irreparable harm may be found where a patentee is seeking to develop its patent in partnership with others.<sup>27</sup> In contrast, where the patentee secures revenues by approaching firms that have already developed so as “to maximize the value of a license,” monetary damages should be sufficient to compensate for infringement.<sup>28</sup>

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24. See generally ASHISH ARORA, ANDREA FOSFURI & ALFONSO GAMBARELLA, *MARKETS FOR TECHNOLOGY: THE ECONOMICS OF INNOVATION AND CORPORATE STRATEGY* (2001).

25. The relative innovativeness of small versus large firms has long been mooted. From a theoretical standpoint, economists like Oliver Williamson (and more recently Clay Christensen, William Baumol, and Ashish Arora) have argued that the “high powered incentives” of small firms and markets are likely to produce more breakthrough inventions than the lower-wattage incentives of large firms. See *id.*; William J. Baumol, *Entrepreneurial Enterprises, Large Established Firms and Other Components of the Free-Market Growth Machine*, 23 *SMALL BUS. ECON.* 9 (2004). Additionally, to the extent that competition is more likely to arise in environments with many small firms, Kenneth Arrow’s argument that competition breeds innovation also militates in favor of small firms. Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Innovation*, in *THE RATE AND DIRECTION OF ECONOMIC ACTIVITIES: ECONOMIC AND SOCIAL FACTORS* 609 (Richard Nelson ed., 1962). Empirical evidence on the question is mixed. However, it does suggest that at least in some industries, small firms do indeed produce a disproportionate share of breakthrough inventions. See Benjamin & Rai, *supra* note 7. In the biopharmaceutical industry in particular, the large number of R&D alliances between small and large firms testifies to the innovativeness of small firms. At a minimum, small firms play an important role in the innovation ecosystem.

26. *eBay*, 547 U.S. at 393.

27. *MercExchange, L.L.C. v. eBay, Inc.*, 500 F. Supp. 2d 556, 571–72 (E.D. Va. 2007). In this regard, the district court’s opinion was in accord with the Supreme Court’s refusal to categorically exclude universities from the possibility of injunctive relief.

28. *Id.* at 572. The question of how smaller entities that market technologies should be treated for purposes of injunctive relief was the subject of a hotly contested Federal

### B. KSR International Co. v. Teleflex Inc.

In *KSR*, the Supreme Court addressed the Federal Circuit's position that, in situations where a prior art reference has to be modified or combined with another prior art reference to show the obviousness of a particular patent claim, the challenger (or PTO examiner) must find within the prior art a "teaching, suggestion, or motivation" (TSM) to modify or combine.<sup>29</sup> Both the FTC and NAS reports had criticized this so-called TSM requirement, and particularly criticized cases like *In re Lee*,<sup>30</sup> in which the Federal Circuit had appeared to enunciate a bright line rule requiring written evidence of TSM.<sup>31</sup> As the reports emphasized, such a requirement unduly lowers the bar for nonobviousness. For example, Internet business method patents often apply prior art business methods to a network such as the Internet. Forcing examiners or challengers to identify a specific written suggestion that a specific business method can be implemented via software in a networked environment excludes the common sense and ordinary knowledge of the average artisan.

In its *KSR* decision, the Supreme Court determined that although the TSM test provides a "helpful insight"—and possibly represents a safeguard against hindsight bias—using TSM in a rigid and formulaic manner (and particularly using it so as to require written evidence) fails to account for the creativity of the average scientist against whom obviousness has long been evaluated.<sup>32</sup> The Court also opined that in some cases, the fact

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Circuit appeal, *Buffalo Technology Inc. v. Commonwealth Scientific and Industrial Research Organization* (CSIRO). The patentee in question, CSIRO, is an Australian research institute that generates and licenses technology (in this case a software patent that reads on a wireless LAN standard). The district court's decision granting injunctive relief to CSIRO emphasized the *eBay* Court's reluctance to exclude categorically injunctive relief for licensors. The court's decision also argued that a failure to grant such relief would create irreparable harm by making it difficult for CSIRO to license its patents and thus support its research enterprise. See *Commonwealth Scientific & Indus. Research Org. v. Buffalo Tech. Inc.*, 492 F. Supp. 2d 600, 601–604 (E.D. Tex. 2007). The Federal Circuit decision, issued September 19, 2008, ultimately did not reach the question of remedies, as it found that the district court had erred in its nonobviousness determination.

29. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740–41 (2007) (discussing the Federal Circuit's position).

30. *In re Lee*, 277 F.3d 1338, 1343–44 (Fed. Cir. 2002).

31. See FED. TRADE COMM'N, *supra* note 5, at 14–15 (arguing that rigid application of the TSM rule with written evidence results in issuance of patents in obvious invention and harms competition); MERRILL, LEVIN & MYERS, *supra* note 10, at 59–62, 87–88 (detailing dilution of the nonobviousness standard in recent court decisions, resulting in increased issuance of patents on obvious inventions).

32. *KSR*, 127 S. Ct. at 1741–43 ("The obviousness analysis cannot be confined . . . by overemphasis on the importance of published articles and the explicit content of issued patents.").

that a given combination was “obvious to try” could suggest obviousness. According to the Court,

[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.<sup>33</sup>

The *KSR* case thus strengthens the nonobviousness standard. Moreover, the arguments it deploys about combinations or modifications are facially neutral—the case gives no indication that the biopharmaceutical industry is exempt from its holding. On the face of it, then, *KSR* might be viewed as detrimentally affecting the biopharmaceutical industry, which had no quarrel with the older, more lax standard.

But this view of *KSR*, and of the patent law, is too simplistic. First, Federal Circuit cases involving the nonobviousness of small molecule chemical compounds have never adhered to a bright line rule requiring a written teaching, suggestion, or motivation to modify or combine prior art references. Rather, even prior to *KSR*, these cases looked more broadly at the skill of the chemist utilizing the person having ordinary skill in the art (PHOSITA) standard.<sup>34</sup>

Second, though it is facially neutral, the standards-based approach enunciated by the Supreme Court does take into account the disparate technical realities of information creation and development in different contexts. The Court’s *KSR* decision emphasizes that a rigid TSM requirement is particularly inappropriate where (as in the case before it, which involved an adjustable electronic gas pedal) the invention in question results from the combination or modification of “predictable” technologies used “according to their established function.”<sup>35</sup> Similarly, as the quote from the Court’s discussion of the

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33. *Id.* at 1742.

34. For a similar point, see generally Rebecca S. Eisenberg, *Pharma’s Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375 (2008). Indeed, many nonobviousness cases decided by the Federal Circuit even prior to *KSR* did not use a rigid version TSM test. The test appears to have had particular prominence in a few decisions involving appeals from the PTO that misconstrue core principles of administrative law. In contrast, many other Federal Circuit decisions did not even mention the test. See Benjamin & Rai, *supra* note 7, at 290–292, 331–32.

35. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739–40 (2007).

“obvious to try” question makes clear, “obvious to try” means obvious only in situations involving a “finite number of identified, predictable solutions.”<sup>36</sup>

In the biopharmaceutical sciences, by contrast, the scientific reality faced by the PHOSITA is often one of unpredictability—relatively small variations in chemical structure can yield unexpected differences in function.<sup>37</sup> Indeed, under such long-established cases as *In re Dillon*, variations with unexpected properties are the key to finding nonobviousness once a prima facie case for obviousness has been established.<sup>38</sup> Moreover, as noted earlier, the *Dillon* prima facie test for obviousness—which looks (quite properly, given what the chemist PHOSITA actually does in her day-to-day work) at whether the prior art gives “reason or motivation” to make a modification to a structurally similar prior art compound—has not limited itself to written evidence of reason or motivation. The *KSR* case thus undermines neither *Dillon*’s emphasis on unexpected properties nor its prima facie test.

For this reason, in the aftermath of *KSR*, the pharmaceutical case law on core product claims to small molecules has not been markedly different. Indeed, in *Takeda v. Alphapharm*, a case involving the patented diabetes drug Actos, a variation of a previously known compound, “compound b,” Judge Lourie began by noting that the *Dillon* test for “prima facie obviousness for chemical compounds is consistent with the legal principles enunciated in *KSR*.”<sup>39</sup> Judge Lourie also affirmed the district court’s factual finding that the prior art would not have led a researcher who wanted to find a diabetes drug to compound b. Nor would it have suggested the particular changes to compound b made by the patentee.<sup>40</sup> Thus the prima facie case for obviousness had not been made.

Similarly, in the case of *Ortho-McNeil v. Mylan*, Chief Judge Michel upheld a lower court determination regarding the nonobviousness of topiramate, the active ingredient in Ortho’s Topamax drug. Like Judge Lourie in *Takeda v. Alphapharm*, Judge Michel emphasized that the ordinary artisan would have had no reason to start with the structurally similar compound

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36. *Id.* at 1742.

37. Of course, if and when the capacity for quantitative prediction in chemistry improves, the unpredictability of chemistry may decrease.

38. *See In re Dillon*, 919 F.2d 688, 692–93 (Fed. Cir. 1990).

39. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007).

40. *See id.* at 1357–60.

that the Ortho scientists had used. Nor would they have had reason to choose “(among several unpredictable alternatives) the exact route that produced topiramate as an intermediate.”<sup>41</sup> As such, the prima facie case for nonobviousness had not been made. Even if it had been made, moreover, topiramate had unexpected properties that could overcome the prima facie case.<sup>42</sup>

Of course, post-*KSR*, the Federal Circuit has decided cases in which it has struck down claims to particular chemical compounds. But these are not cases that would necessarily have been decided differently prior to *KSR*. For example, in *Aventis v. Lupin*, Judge Linn determined that a purified (or “resolved”) composition that had previously existed only in racemic form was obvious over the prior art racemic form.<sup>43</sup> However, there was no evidence in that case that the claimed composition was difficult to isolate or that it displayed any unexpected properties in its resolved form.<sup>44</sup>

In the midst of the *KSR* litigation (after the oral argument, but before the Supreme Court’s decision was handed down), the Federal Circuit did decide one case, *Pfizer v. Apotex*, that suggested significant changes for the pharmaceutical industry. In that case, Chief Judge Michel held that Pfizer’s patent on an amlodipine besylate salt was obvious given the amlodipine maleate prior art. He found such obviousness even though the maleate version had significantly different properties than the besylate version (specifically, greater stability for purposes of manufacturing) and even though finding the maleate version required sifting through a list of 53 anions.<sup>45</sup> However, given subsequent case law that has emerged from the Federal Circuit, it appears that the *Pfizer* case may be an outlier. Chief Judge Michel may have been anticipating a more dramatic decision from the Court than the Court ultimately rendered.

Ultimately, because the *Dillon* test does not appear to have been affected by *KSR*, many of the most common types of patent applications sought by the biopharmaceutical industry will continue to pass muster. Consider, for example, the prominent category of so-called “me-too” drugs. Such drugs typically work on the same protein target as their predecessors and are

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41. *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

42. *See id.* at 1365.

43. *See Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1301–03 (Fed. Cir. 2007).

44. *Id.* at 1302.

45. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1362–63, 1369 (Fed. Cir. 2007).

therefore considered part of the same therapeutic class as these predecessors.<sup>46</sup> However, in order to avoid patents on predecessor drugs (which generally claim not simply a single molecule but at least some structural variations), manufacturers of me-too drugs have to make them substantially distinct as a structural matter from their predecessors. Therefore patents on these drugs should continue to be valid post-*KSR*.<sup>47</sup>

Some have suggested that *Pfizer* is not an outlier, and thus the Supreme Court's invigoration of the nonobviousness standard may affect the pharmaceutical industry in those cases where firms file additional patent applications on salts or formulations that are already covered by one or more core structural patents.<sup>48</sup> But the pharmaceutical firm practice of filing additional applications on very small structural variations has always been one that has had more to do with peculiar features of the 1984 Hatch–Waxman regime for approval of generic drugs than with patent law *per se*. In other words, many of these patents might have been considered obvious even pre-*KSR*. In particular, because salts are so close structurally to their prior art predecessors, their obviousness has always been a close question under the *Dillon* test.<sup>49</sup>

Applications on salts and other small structural variations have nonetheless been worth filing because Hatch–Waxman authorizes automatic thirty-month stays of generic approval by the FDA based solely on the existence of such patents.<sup>50</sup> Indeed, prior to 2003, pharmaceutical firms could string together sequential thirty-month stays based on multiple patents, including new patents secured after a generic had declared its intention to market, based on its belief that existing patents had expired or were invalid.<sup>51</sup>

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46. See, e.g., Arti K. Rai et al., *Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery*, 8 YALE J. HEALTH POL'Y L. & ETHICS 1, 4 (2008) (noting that drugs typically work by affecting the activity of protein targets).

47. The larger pressure on me-too drugs is likely to come not from patent law but from a trend on the part of insurers to encourage the use either of generics or of brand-name drugs within a given class on which discounts have been negotiated. In 2005, 68% of employers who provided insurance reported using tiered programs of co-payment to encourage such lower-cost purchases. David Blumenthal, *Employer-Sponsored Insurance—Riding the Health Care Tiger*, 355 NEW ENG. J. MED. 195, 199 (2006).

48. See Michael Enzo Furrow, *Pharmaceutical Patent Life-Cycle Management After KSR v. Teleflex*, 63 FOOD & DRUG L.J. 275, 311 (2008).

49. See Eisenberg, *supra* note 34, at 398–99.

50. See Gerald J. Mossinghoff, *Overview of the Hatch–Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 190 (1999) (describing various elements of the Hatch–Waxman Act).

51. Such “evergreening” practices have been curtailed to some extent by Hatch–

On the face of it, *KSR* could have a greater impact on biologic protein therapeutics than it does on the small molecule drugs typically manufactured by the pharmaceutical industry. According to *In re Kubin*,<sup>52</sup> a recent case from the PTO's Board of Patent Appeals and Interferences (BPAI) (currently on appeal to the Federal Circuit), *KSR* calls into question the Federal Circuit's much-criticized *In re Deuel* decision.<sup>53</sup> In that 1995 case, Judge Lourie established a bright-line rule that *methods* for finding DNA sequences did not represent appropriate prior art for *product* claims to such sequences.<sup>54</sup> The BPAI decision in *Kubin* states that, after *KSR*, product claims to DNA sequences should be considered obvious if the method for finding the DNA sequence was routine in the art.<sup>55</sup> Whether or not the BPAI is correct in holding that *KSR* speaks directly to the question,<sup>56</sup> the Federal Circuit may take up the invitation to overturn a case that has long been criticized as technologically and doctrinally indefensible.

For present purposes, a potential overruling of *Deuel* is of particular interest because commentators have pointed to the case as a prominent example of the manner in which the Federal Circuit has set up an "industry-specific" regime for

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Waxman amendments passed in 2003 that limit brand name drug makers to stays based on patents filed before a generic declares its intention to market. However, even with this limitation, Hatch-Waxman continues to create incentives to file relatively marginal patent applications. Perhaps the most salient incentive—untouched by the 2003 amendments—is a provision that allow brand name manufacturers to maintain monopolies based on weak patents through settlement with the first generic challenger. So long as the settlement agreement requires that the first generic challenger refrain from transferring to any subsequent generic entrant the first generic's statutory right to a 180-day period of exclusive marketing of the generic, potential entrants have limited financial incentive to undertake a challenge. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1101(a)(2)(A), 117 Stat. 2660, 2448–57 (codified at 21 U.S.C. § 355(j)(5)(B)(iii)); see also Furrow, *supra* note 48, at 287.

52. *In re Kubin*, 83 U.S.P.Q.2d 1410, 1414 (B.P.A.I. 2007).

53. *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995).

54. *See id.* at 1559.

55. *In re Kubin*, 83 U.S.P.Q.2d at 1414.

56. It is not clear that *KSR* does in fact speak directly to the holding in *Deuel*. The BPAI argues that *KSR* casts doubt on the proposition, noted briefly in *Deuel*, that "obvious to try" does not establish obviousness. The *Deuel* holding does not rest on this proposition, however. Moreover, as noted earlier, the *KSR* court's rejection of the "obvious to try" proposition is limited to those cases where the number of possible solutions that are "obvious to try" is finite and predictable. The *KSR* holding is thus consistent with the longstanding patent law principle that an invention can be obvious if it is "obvious to try" and such a trial would have a "reasonable expectation of success." To the extent that the *KSR* holding casts doubt on *Deuel*, it is not because of any new articulation of the "obvious to try" doctrine but, rather, because of the *KSR* court's general disapproval of bright line rules.

biotechnology.<sup>57</sup> On this view, Judge Lourie's implicit aim in articulating a technologically problematic nonobviousness standard for gene sequences was to allow sequences that could serve as therapeutic products to be patentable for economic reasons (i.e., because firms would require a patent in order to have an incentive to take the therapeutic sequence through expensive clinical trials) even when they were not patentable as a technical matter. From this perspective, if *Deuel* is in fact overturned, the result could be problematic as an economic matter, at least for patents on gene sequences that claim therapeutic products.

Once again, however, the significance of patent law to returns on investment may be exaggerated. In the case of protein therapeutics and other biologics, a major source of protection from competition has been the absence of a Hatch–Waxman type regime for biologics. Without such a generics regime—which allows the generic competitor to rely on the brand name therapy's safety and efficacy data and thus circumvent the barrier to entry otherwise created by FDA requirements of such data—there is no significant threat from loss of patent protection.

Moreover, *Deuel* itself can hardly be considered a successful example of industry-specific patent law. To the contrary, it is a blunt instrument that creates difficulties of at least two sorts. First, because *Deuel* effectively replaces nonobviousness with a novelty standard, the case allows patents not only on obvious therapeutic proteins but also on obvious gene sequences that serve as research tools. Races to claim such obvious research tool patents<sup>58</sup> may not (at least thus far) have created an anticommons or patent thicket for follow-on researchers. However, a significant reason has been that these patents can be, and have been, evaded through secret infringement.<sup>59</sup> In the future, such secret infringement may not be possible if the hopes of some biologists (particularly systems and synthetic biologists) to develop transparent biological standards are realized.<sup>60</sup>

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57. See Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1178–80, 1185 (2002).

58. Arti Rai, *Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials*, 2 WASH. U. J.L. & POL'Y 199, 205–06 (2000).

59. John P. Walsh, Ashish Arora & Wesley M. Cohen, *Working Through the Patent Problem*, 299 SCIENCE 1021, 1021 (2003) (“Infringement of research tool patents is hard to detect, and because of the long drug development process, the 6-year statute of limitations may expire before infringement is discovered.”).

60. See Sapna Kumar & Arti Rai, *Synthetic Biology: The Intellectual Property Puzzle*, 85 TEX. L. REV. 1745, 1757 (2007) (noting this point).

In addition, under boilerplate patent law, the doctrinal logic of *Deuel* mandates that patent protection for biologics must be (at least in theory) quite narrow in scope—if methods cannot serve as prior art for DNA sequence claims, they cannot serve as part of the tool kit by which the ordinary artisan is shown how to “make and use” a genus of DNA sequences.<sup>61</sup> Brand name biologics firms are currently emphasizing the ineffectual protection afforded by this narrow scope when they insist that the various generic biologics bills currently being considered by Congress must provide a long (e.g., fourteen-year) data exclusivity period for the brand name manufacturer.<sup>62</sup> (In contrast, for new chemical drugs, data exclusivity for the brand name new chemical entity generally lasts about five years.)<sup>63</sup> *Deuel* thereby illustrates the tremendous line-drawing difficulties with using garden-variety patent law to take into account a problem that arises not in an “industry,” but, rather, in the narrower context of end-product therapeutics.<sup>64</sup>

#### IV. THE WAY FORWARD

This Part considers briefly how additional facially neutral patent reform measures, as well as tweaks to FDA and health insurance regulation, could take into account remaining economic concerns.

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61. See Burk & Lemley, *supra* note 57, at 1179–82.

62. See, e.g., BIOTECHNOLOGY INDUS. ORG., A FOLLOW-ON BIOLOGICS REGIME WITHOUT STRONG DATA EXCLUSIVITY WILL STIFLE THE DEVELOPMENT OF NEW MEDICINES 4 (2007), available at [http://www.bio.org/healthcare/followonbkg/FOBSMarket\\_exclusivity\\_20070926.pdf](http://www.bio.org/healthcare/followonbkg/FOBSMarket_exclusivity_20070926.pdf).

63. *Id.* at 1.

64. Whether this 14-year data exclusivity will in fact be necessary is an open question, however. If, as appears likely, Congress decides that biologics are sufficiently different from small molecule drugs that bioequivalence cannot be proven through simple comparisons of end products (consistent with the view taken by some scientists and by most brand name biologics makers that, in the area of biologics, “the process is the product”), there will be no such thing as a “generic” biologics manufacturers. Rather, we will have “follow-on” manufacturers that themselves have to submit independently developed safety and efficacy data based on their own manufacturing processes. In that case, the number of follow-on manufacturers may be quite limited. Additionally, both brand name and follow-on manufacturers will likely be able to charge supra-competitive prices even after patents expire. For thorough discussions of these points, see, for example, D.M. Dudzinski & A.S. Kesselheim, *Scientific and Legal Viability of Follow-On Protein Drugs*, 358 NEW ENG. J. MED. 843 (2008); Henry G. Grabowski, David B. Ridley & Kevin A. Schulman, *Entry and Competition in Generic Biologics*, 28 MANAGERIAL & DECISION ECON. 439 (2007). The current debate over biologics legislation is thus yet another illustration of the manner in which patent law *per se* often has only a limited role to play in the ultimate pricing structure of biopharmaceutical products.

*A. Possibilities for (Additional) Facially Neutral Patent Reform*

As noted earlier, technically obvious patents of the type conferred by *Deuel* have been justified as useful from an economic policy standpoint. Currently, they may not be absolutely necessary, as the absence of a generic biologics regime confers barriers to entry at least as significant as those conferred by patent law. However, if *Deuel* is overturned, and a generics biologics regime is in fact implemented, some additional protections for technically obvious protein therapeutics may be necessary. More generally, to the extent that the inability to secure patents on technically obvious, or even nonnovel, therapeutics is a persistent problem, FDA administered rights of exclusive marketing for such therapeutics represent a possible solution.<sup>65</sup> As this Article has argued, disrupting the patent system to address problems raised by one type of invention can generate all sorts of undesirable collateral consequences.

Of course, regulatory regimes that focus on one type of invention raise political economy concerns that the regime will be unduly favorable to the interests of the industry that manufactures the invention. Indeed, this political economy concern represents an important additional argument against industry-specific patent regimes (that is, in addition to the problem of line-drawing, discussed above). However, in the case of FDA exclusivities, the problem may be mitigated to some extent by the existence of a robust generic pharmaceutical sector.

A different problem with reliance on FDA-administered rights is the possibility that, even outside the area of biopharmaceutical therapeutics, the validity standards of the patent system may not always account for all relevant economic considerations. I turn next to this more general issue.

From the standpoint of economic policy, the relevant question is whether validity standards promote innovation (both initial invention and any necessary development/commercialization) that would not have happened “but for” the incentive of the patent.<sup>66</sup>

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65. Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. (forthcoming 2009). Roin further notes that the duration of such rights might be based on the FDA’s determination of the therapeutic value of the drug. To some extent, the Orphan Drug Act, which is administered by the FDA and confers marketing exclusivity on unpatentable therapeutics that address the needs of small disease populations, could be a model.

66. Benjamin & Rai, *supra* note 7, at 277. This is the classic economic frame for the inquiry into patent validity. Some more recent discussions on how patent validity, particularly nonobviousness, should be analyzed focus not on the “but for” question (which necessarily looks at a single invention) but on the more complex question of how nonobviousness could be used to channel researchers into lines of inquiry that are

The doctrinal construct of the PHOSITA—particularly a PHOSITA that, post-*KSR*, actually has the skill of the average scientist in a given area of innovation—already reflects economic considerations to some extent. Where knowledge in a particular area of science or technology is relatively well codified—and hence the innovation is rapid and not too expensive—the PHOSITA construct will deliver the economically desirable result of a nonobviousness standard that is high.<sup>67</sup> Additionally, the time-honored canon that an innovation that is obvious to try can nonetheless be worthy of a patent if the uncertainty associated with actually making the innovation is high, takes economic considerations into account.<sup>68</sup> Uncertain innovations are precisely the types of expensive innovations for which a relatively low nonobviousness standard is likely to be a necessary “but for” incentive.<sup>69</sup>

Conventional patent doctrine has been quite successful in using technical uncertainty as a proxy for the ultimate economic inquiry. However, in certain limited cases, it may be appropriate to engage in the reverse inquiry—that is, to use the high cost of an R&D project as an indication of technical uncertainty. Indeed, as Robert Merges has noted, although patent law doctrine has not formally used high cost as a proxy for technical uncertainty, various cases have done so informally.<sup>70</sup> Explicitly acknowledging

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superior from a social welfare perspective to alternative lines of inquiry (even if all such lines of inquiry would satisfy the “but for” standard). See, e.g., Michael J. Meurer & Katherine J. Strandburg, *Patent Carrots and Sticks: A Model of Nonobviousness*, 12 LEWIS & CLARK L. REV. 547 (2008). A discussion of how such a comparative inquiry might work (either for a patent examiner or for the courts) is beyond the scope of this Article. However, the challenges (and risks of error) associated with administering this type of inquiry are likely to be significant. At some level, the analysis proposed by these discussions appears to require government institutions to pick scientific and technological “winners and losers.” But one well-rehearsed reason for having a patent system is that it does not require such expertise on the part of government institutions.

67. John Barton, *NonObviousness*, 43 IDEA 475, 492–493 (2003); Robert Hunt, *Patentability, Industry Structure, and Innovation*, 52 J. INDUS. ECON. 401 (2004) (arguing that the nonobviousness standard should be high where an “industry” is innovating rapidly). Barton and Hunt invoke the idea of “industry”-based patent law and suggest their approach is “industry-specific.” However, as this Article has argued, the facially neutral PHOSITA standard, which operates at the level of invention (or categories of invention), is a much more fine-tuned mechanism for implementing policy goals than blunt constructs like an “industry.”

68. See Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 18–19 (explaining the nonobviousness standard from an economic point of view).

69. See generally *id.* (discussing the need for a low nonobviousness standard where the R&D question is uncertain).

70. *Id.* at 43–50.

high cost as an indicator of technical uncertainty would not be a significant doctrinal stretch.<sup>71</sup>

In models such as Merges's that counsel a low nonobviousness standard where the cost associated with R&D is high, the inquiry into a patent application's validity is generally framed as taking place at the end of the R&D process. Thus both uncertain/costly research *and* uncertain/costly development prospects count in favor of the patent applicant. One limitation of these models is that they do not explicitly account for cases (perhaps most prominently biopharmaceutical therapies but perhaps also other cases) where the inquiry into patent validity is made very early (perhaps too early) in the R&D process. To put the point another way, these models do not account for those areas of innovation that follow the prescription (and description) associated with Edmund Kitch's view that patents should be granted on early-stage "prospects" rather than complete inventions.<sup>72</sup>

In cases where patent validity determinations are made early in the process, a patent examiner (or, subsequently, a court) who uses even the most expansive definition of technical uncertainty could, under current law, legitimately find the prototype invention in question obvious, both to try and to make. This is because the technical uncertainty in question involves *future* commercialization difficulty. In such cases, it might be appropriate for the *future* cost and uncertainty of commercialization to be a reason for granting a patent.<sup>73</sup>

Of course, there are reasons to question whether patent examiners (and, to a significant but perhaps lesser extent, courts) would have the institutional competence to referee claims that abnormally high cost, past or future, reflected technical uncertainty. In many if not most cases, patentees would no doubt be tempted to make vigorous arguments about how their costs reflected underlying technical uncertainty. A large percentage of these arguments could be based on dubious data or simply reflect

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71. It bears emphasis that high cost *per se* (e.g., the high cost associated with, say, building a highway) should not be a reason for granting a patent. Allowing patents to be issued for projects (again, for example, highway building) that do not contribute any sort of technical information to the world would raise serious constitutional concerns. The constitutional mandate requires, after all, that patents advance progress in the "useful Arts." In contrast with highway building, the applied research involved in development contributes significant technical information to the world. I thank John Golden for pressing me on this point.

72. See Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977).

73. Benjamin & Rai, *supra* note 7, at 277–78.

inefficient R&D processes. In the *ex parte* process typically used by patent examiners, the result might be overly generous patent grants. In court proceedings, the result could be “battles of economic experts” that would probably be even more intractable than current battles of scientific experts. Thus arguments where cost, past or future, is being used as a proxy for technical uncertainty should be subject to a significantly higher burden of proof than direct technical arguments in favor of patentability.

A logical counterpart (and counterweight) to using cost as a reason for allowing patents might involve denying patents on the basis of low cost. Under the latter doctrine, an invention that was technically nonobvious might be deemed unpatentable because there was no good economic reason for patenting it. Again, for reasons of institutional competence, economic nonpatentability should be subject to stricter evidentiary burdens than technical nonpatentability. The patent examiner or challenger that wanted to invoke the doctrine should certainly (at a minimum) bear the burden of proof.

#### *B. FDA and Health Insurance Regulation*

As noted earlier, the possibility of FDA-administered marketing exclusivity periods for nonnovel, or obvious, therapeutics is an interesting one. For purposes of fostering social welfare goals, some additional tweaks in the role of the FDA could also be useful. For example, some prominent commentators have argued that, for drug approval purposes, the FDA should require not simply testing against a placebo (as is often the case currently) but, rather, against the best available drug in the relevant therapeutic class. Approval would be withheld if the drug under scrutiny did not have a superior effectiveness or safety profile.<sup>74</sup>

Approval *per se* should not necessarily be conditional on testing against a best-in-class drug. As Mike Scherer has noted, because differences in efficacy would probably be smaller than in placebo-controlled trials, such head-to-head comparisons would require significantly larger sample sizes in order to achieve statistical significance.<sup>75</sup> Requiring firms to fund such trials may add unduly to the costs of drug development. But publicly funded, FDA-administered comparative testing of drugs would

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74. MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 240–41 (2004). Marcia Angell is a former editor in chief of the medical profession's flagship journal, the *New England Journal of Medicine*.

75. F.M. Scherer, *Uncertainty and Choice: The Challenges of Pharmaceutical Efficacy, Safety, and Cost*, 28 *MANAGERIAL & DECISION ECON.* 267, 277–278 (2007).

provide a useful public good. Specifically, such publicly funded testing would generate much-needed information for insurance markets that need to make cost-benefit determinations about coverage. Thus such public funding is certainly worth considering.

Finally, it bears emphasis that both statutory and common law regulatory structures need to be reformed so as to provide protection against tort liability for insurance firms that make cost-benefit determinations about pharmaceutical and biologic coverage. Although a discussion of such reform is beyond the scope of this Article, several health law scholars (perhaps most prominently my colleagues Clark Havighurst and Barak Richman) have provided useful frameworks for thinking about such reform.<sup>76</sup>

## V. CONCLUSION

This Article has argued that facially neutral patent reform can achieve economic policy goals—including accommodating the legitimate interests of different industries—without forcing decisionmakers to make crude line-drawing determinations. Additionally, to the extent that the biopharmaceutical sector may need innovation policy that explicitly addresses peculiar problems associated with end product therapeutics, such policy is more effectively supplied through tweaks in FDA regulation and regulation of insurance markets than through changes in patent law. A larger point emerges from this analysis: in addressing any given innovation policy challenge, analysts should consider carefully the full range of regulatory systems available. In many cases, the best solution to the challenge may involve invoking more than one system.

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76. See generally Clark C. Havighurst & Barak D. Richman, *Who Pays? Who Benefits? Distributional Issues in Health Care*, 69 *LAW & CONTEMP. PROBS.* 7 (2007).