

III. Proposals for Reform

Despite addressing major weaknesses in the original structure of Hatch-Waxman that have surfaced in recent years, the 2003 amendments do not address deeper, structural problems that emanate from the combined effect of Hatch-Waxman's special patent provisions, the limits of the antitrust laws to curb questionable patenting behavior, and deficiencies in the PTO's ability to screen out bad patents. As discussed *supra* at Part I(C), even after the 2003 amendments, pioneer drug companies have substantial incentives to engage in patent evergreening and to initiate Hatch-Waxman litigation to defend those patents. Some commentators have suggested that Hatch-Waxman's patent provisions are not relevant to the current economic environment in the pharmaceutical industry and should be repealed,¹ while others have highlighted a need for greater oversight of listing patents in the Orange Book. In addition or instead of these proposals to amend Hatch-Waxman, I suggest focusing future efforts on improving the quality of issued patents by instituting an inter partes opposition procedures.

Enabling competitors to challenge pharmaceutical patents earlier on in the life of a drug could reduce the social costs of improvidently granted pharmaceutical patents.² These costs are arguably more severe than the social costs of overpatenting in other industries, given the vital role prescription medicines play in enhancing the quality and length of lives.³ Indeed, the rash of consumer class actions in this area indicates

¹Engelberg, *supra* note 31, at 392. *See also* Rai, *supra* note 5, at ... (Suggesting that it should be possible to scale back Hatch-Waxman's special patent provisions if developments in genomics yields reductions in drug research and development costs).

²Patent litigation tends to be exceptionally costly, with legal expenses often exceeding one million dollars per party. Allison & Lemley, *supra* note 89, at 187.

³All patents impose a social cost, incurred as deadweight losses because some consumers are priced out of the market for a drug, and because monopolists keep the consumer surplus that would otherwise flow to consumers in a perfectly competitive market. The judgment of the patent system is that this cost is outweighed by the benefit to innovation. Lemley suggests that the social costs of issuing marginal bad patents are only litigation costs of asserting bad patents, legal fees on licensees and royalty payment, and the potential for the "mere existence" of bad patents to deter some lawful competitive conduct. He distinguishes the former as a social cost of the patent system itself, not a social cost of issuing bad patents. Lemley, *Rational Ignorance* at 1516, 1530. However, the lost consumer surplus and deadweight losses imposed by granting *each marginal bad patent* are also necessary inputs to evaluate whether the current system lets too many bad patents issue, not just the cost of litigation over bad patents.

that they will fight to vigorously reduce this type of error, if it is perceived as being too high.⁴

Currently, antitrust damages are the only remedy available to compensate consumers when invalid patents delay generic drug entry. Yet, holding pharmaceutical companies liable in antitrust for procuring or prosecuting patents is difficult in practice and is inherently limited in application to a small fraction of patents *within* the subset of successful generic outcomes. Assuming the high bar for finding pharmaceutical companies liable in antitrust is desirable, as a means for not over-detering or punishing companies for legitimately defending profits secured through patents, consumers have been harmed when patents on drugs are subsequently declared invalid. Moreover, relying on antitrust litigation to deter the worst instances of patent evergreening increases the overall costs of Hatch-Waxman litigation—whereas lessening the reliance on litigation could free-up more resources for companies to invest in innovation. Class action damages are also an inefficient way to provide restitution for consumers. The plaintiff’s bar will likely keep a significant portion of the disgorged profits, and matching the appropriate level of restitution to the consumers who paid excessively higher drug prices years earlier may be difficult and is less efficient than avoiding these harms in the first place. In sum, the antitrust laws are neither sufficient nor an ideal form to decrease the number of bad patents that issue from the PTO or weak infringement suits.

Restructuring patent institutions in an effort to improve patent quality is a long-term effort, and short-term strategies may be necessary to protect consumer interests in the coming years, as over 30 of the nations best-selling drugs (representing sales of over \$60 billion) come off-patent.⁵ These near-term fixes could be effectuated by abolishing the 30-month automatic stay, or by strictly monitoring patents listed in the Or-

⁴Of course, consumers focus only on “type II error,” which results when the PTO grants an invalid patent, and tend to overlook the costs of type I error resulting from the PTO denying patent to a truly patentable invention. *See* McDonald, *supra* note 18, at 74 (adapting McDonald’s description of errors in litigation outcomes to errors in prosecution outcomes.) The current system is likely skewed towards more type II error, which does harm consumers, but reform efforts should consider whether shifting the balance would unduly increase type I error, in favor of generic drug manufacturers. Properly structured opposition proceedings could strike a more equitable balance between these types of errors.

⁵James Frederick, “Stars align for Generic Drug Industry,” *Drug Store News*, February 16, 2004 (V. 26 issue 2, p. 43?). For a previous estimate from 2000, *see* National Institute for Health Care Management, *Prescription Drugs and Intellectual Property Protection* (August 2000) at 3, available at <http://www.nihcm.org/pharm.html>. (Reporting that “brand name drugs with combines U.S. sales approaching \$20 billion will go off patent” over the five year period from 2000-2005).

ange Book. On the other hand, the patent prosecution process is clearly skewed in favor of patentees, and the financial incentives for patent evergreening are overwhelming. Thus, effective long-term solutions must consider ways to diminish a patentee's ability to secure invalid patents.⁶

A. General Proposals for Reform

(1) *Eliminate Automatic 30-Month Stay*

Generally in patent infringement suits, a patentee must prove four factors to secure a preliminary injunction:

(1) A reasonable likelihood of success on the merits, (2) irreparable harm to its interests, (3) the balance of hardships tipping in its favor; and (4) public interest in favor of the injunction.⁷ Hatch-Waxman supplants this usual rule and provides pharmaceutical patentees with an automatic injunction. The rationales behind this provision include the assumption that a pioneer drug companies *will* suffer irreparable harm if a generic begins marketing during litigation, coupled with a concern that generic manufacturers that lose the litigation will be unable to pay damage awards.⁸ The 30-month stay provision arguably encourages pioneer manufacturers to initiate infringement litigation, even when their infringement claims are not likely to succeed on the merits, and may deter settlements. Some commentators have proposed eliminating this special treatment for pioneer pharmaceutical manufacturers, given their high rate of success in Hatch-Waxman litigation.⁹

Repealing the 30-month stay provision would benefit consumers by filling the deterrence gap created by the low likelihood of antitrust liability and absence of other penalties for securing a patent through inequitable conduct and initiating weak infringement actions. The corresponding harm to consumers should also be low:

⁶Glasgow, *supra* note 3, at 232.

⁷Glaxo Group Ltd. v. Ranbaxy Pharmaceuticals, Inc. 262 F.3d 1333, 1335-68 (Fed. Cir. 2001).

⁸See, e.g., Glaxo v. Ranbaxy, 262 F.3d at 1335 (reversing grant of preliminary injunction against Ranbaxy, even though it noted that the district court “*also* found that Glaxo stood to lose more money in sales of Ceftin® before the ‘181 patent expired than Ranbaxy’s total net worth.”)

⁹Engelberg, *supra* note 31, at 423.

repealing the 30-month stay in and of itself would not deter *legitimate* infringement suits, rather, it should deter infringement actions involving the weakest patents and most tenuous infringement claims. These are precisely the cases most likely to have been initiated primarily out of a desire to simply *delay* the onset of generic competition in order to reap the large revenues available during that period, to the detriment of consumers. Moreover, the federal courts have evidenced a concern for the long-term public interest in strong intellectual property rights, and the worry that courts will not protect pioneer drug companies from harm may be overstated. Finally, the prospect of damages should deter generic companies from viewing a repeal of the 30-month stay as an open invitation to infringe on presumptively valid patents on drugs. On the whole, eliminating the 30-month stay should not affect pioneer manufacturers' research investment decisions, but could greatly benefit consumers. In addition, an agreement to eliminate the stay could be traded off for an increase in the patent term extensions available under Hatch-Waxman, or an increase in the five-year period of FDA exclusivity.¹⁰

The pharmaceutical industry would vigorously oppose eliminating the 30-month stay altogether, as this was a key component in the Hatch-Waxman legislative contract.¹¹ The industry argues that the automatic stay is necessary because competition by a generic competitor that ultimately loses an infringement suit would always irreparably harm both the pioneer and generic manufacturers. Moreover, consumers may suffer from having to switch medications back to the brand-name drug.¹² The industry also asserts that obtaining preliminary injunctions is "especially difficult" for pioneer manufacturers, and that "Congress' concern that preliminary injunctions could not be relied upon to provide adequate protection of the patent rights of pioneer companies was well-founded," based on a perception that the federal courts are reluctant to grant this protection to patentees.¹³ As discussed below, these rationales are arguably outdated or overstate the

¹⁰This would grant a de facto delay of paragraph IV challenges, as well, because they may only be filed one year prior to the expiration of the initial exclusivity period. This may or may not be worth the trade-off, from a consumer-based perspective.

¹¹PhRMA White Paper, *supra* note -, at 24.

¹²*Id.* at 24-5.

¹³*Id.*

courts' unwillingness to protect patentees.

First the rationales in favor of an automatic injunction are arguably less applicable today than in 1984. The generic drug industry is itself now “big business,” and can afford to pay damages for infringement, including treble damages for willful infringement.¹⁴ Requiring generic manufacturers who want to begin competing during the patent litigation to post a bond should suffice to protect pharmaceutical companies from insolvent defendants. Moreover, most generic companies chose *not* to compete, even with final approval of an ANDA (due to expiration of the 30-month stay), until they have obtained at least a favorable district court judgment.¹⁵ On the whole, generic companies may not often oppose motions for preliminary injunctions—when they do, this suggests that the pioneer company’s infringement action is weak, given the enormous damages that would ensue if the generic competitor loses the infringement suit. In addition, the paragraph IV certification process could be amended to include an “optional” 30-month stay, under which a generic challenger could certify that it does not intend to compete during the litigation. This would eliminate the need to secure a preliminary injunction in Hatch-Waxman suit.

Second, if a generic company does seek to market its product during litigation, the time required to process an ANDA application—likely to be at least a eighteen months¹⁶—would afford time for litigating the preliminary injunction. Although the pharmaceutical industries argues that this is not enough time to “develop the case for and obtain a preliminary injunction,”¹⁷ it is over half of the period allotted by the stay for the *entire* litigation to conclude, and thus should be a sufficient amount of time to get through the preliminary phase of the litigation. In addition, generic manufacturers could use the preliminary injunction as a method for gauging the strength of its claims, which in turn could prompt them to abandon weak invalidity counter-claims.

¹⁴ *Id.*

¹⁵ FTC Study, *supra* note 12, at ----.

¹⁶ Findlay reports that ANDA approval takes approximately 18 to 30 months. Findlay, *supra* note --, at 228.

¹⁷ PhRMA White paper, *supra* note --, at 25.

Third, the pharmaceutical company overstates the federal courts' aversion to granting preliminary injunctions. The industry claims that, "in fact, over the past twenty years, federal courts, and the Federal Circuit in particular, have granted preliminary injunctive relief for patent infringement in fewer and fewer instances."¹⁸ This is simply not an accurate depiction of the study cited by the industry to prove this assertion. Rather, the cited study noted that,

Many practitioners and commentators have suggested that, since the Court of Appeals for the Federal Circuit was established on October 1, 1982, there has been a *dramatic increase* in the number of preliminary injunctions granted in patent cases. This Article *confirms the accuracy of their claim* by presenting the results of a case study that surveyed all reported district court and appellate decisions, involving preliminary injunctions in patent litigation, which were issued between the establishment of the Federal Circuit and December 31, 1993.¹⁹

The study did find some variation in yearly rates – but for district courts, the rate of grants of preliminary injunctions wavered between 43 and 75 percent, with no discernible “trend” that would suggest they have been granting injunctive relief in fewer cases over time. The study did note a decline in the rate at which the Federal Circuit affirmed grants of preliminary injunctions for the last *few* years studied (1991 to 1993), which may or may not have continued during the past ten years. Also, the authors conclude that this may reflect an effort to force district courts to *substantiate* their decisions and to emphasize the need for district courts to adequately and more fully consider the irreparable injury factor.²⁰ Yet, the irreparable injury factor may presumptively weigh in favor of pioneer companies in most cases, given the disruptive effect of generic competition on pricing.

Indeed, regarding the “irreparable harm” prong, litigation over antibiotic drugs offers useful insights and suggests that preliminary injunctions could work for all pharmaceutical patents.²¹ The 30-month stay pro-

¹⁸ *Id.* at 24, citing M.A. Cunningham, Preliminary Injunctive Relief in Patent Litigation, 35 IDEA 213 (1995), and Finnegan, Henderson, Faraow, Garrett, & Dunner, L.L.P.

²⁰ *Id.* at 233.

²¹ Engelberg, *supra* note 31, at 423.

visions do *not* apply to antibiotics for which a new drug application was filed prior to November 21, 1997, because these antibiotics are exempted from Orange Book listing requirements.²² Yet, district courts have been more than willing to weigh the short-term public interest in receiving generic drugs as quickly as possible against the long-term public interest in enforcing intellectual property rights.²³ Still, pioneer companies do not win preliminary injunctions in all such cases; this suggests that eliminating the automatic stay could accelerate generic competition in meritorious cases.²⁴

Finally, the industry argues that because the patent infringement analysis is “highly complex and technical,” it “may be virtually impossible to demonstrate a likelihood of success on the merits without the benefit of discovery.” Although true, this too may overstate the burden placed on pioneer drug manufacturers. With respect to validity, the generic company will bear the burden of presenting evidence of invalidity – if they do not present such evidence, the patentee need not establish his rights to enforce the presumptively valid patent.²⁵ Thus, the fact that preliminary injunction occurs prior to extensive discovery may benefit the patentees in this regard. Moreover, demonstrating a “likelihood of success” does not require a full-scale trial, although if the challenger raises a substantial question of invalidity in light of the patentee’s rebuttal evidence, the pioneer drug company will lose on this issue. Yet, if there is a substantial question of invalidity, it may warrant not granting a preliminary injunction, given generic companies’ rates of success in Hatch-Waxman suits. The issue on infringement will be more difficult for pioneer manufacturers to prove. Again, however, the patentee only need show a “reasonable likelihood” of success on the infringement claims. If a

²²Pharmacia & Upjohn Co. v. Ranbaxy Pharmaceuticals, Inc., 2003 WL 23016042 (Fed. Cir. Dec. 23, 2003)(Citing Food and Drug Administration (FDA) Modernization Act of 1997, Pub.L. No. 105-115, 111 Stat. 2326, Title I, § 125(d)(2)).

²³See, e.g., Glaxo Group Ltd. V. Apotex, Inc., 2003 WL 1918246 (Fed. Cir. Apr. 22, 2003)(unpublished)(affirming preliminary injunction preventing Apotex from marketing generic version of antibiotic Ceftin).

²⁴See Glaxo v. Ranbaxy, 262 F.3d. at 1339 (vacating preliminary injunction granted by district court preventing Ranbaxy from marketing Ceftin (cefuroxime axetil), based on Glaxo’s failure to prove likelihood of success on the merits of infringement claim); Novo Nordisk A/S v. Bio-Technology Gen. Corp., 52 Fed. Appx. 142, 145, 147 (Reversing grant of preliminary injunction against Bio-Technology and Teva, finding Novo’s patents on a method of producing synthetic human growth hormone to be *vulnerable* to claims of invalidity in light of prior litigation involving same patents. The court noted, “vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial.”)

²⁵*Id.* at 223

generic company is willing to risk paying damages for infringement, and possibly treble damages for willful infringement, the case may involve precisely the type of patent for which a bioequivalent product can be easily designed without infringing on the patent.

Eliminating the 30-month stay is vulnerable to the general argument that it would “tip” the delicate balance of Hatch-Waxman too far in favor of generic companies, and thus erode incentives to innovate. As already noted, the preliminary injunction method should provide effective protection for patentees. Moreover, some re-tipping may be warranted based on how skewed the current system is in favor of pioneer drug companies. Another problem might be that a generic manufacturer who ultimately prevails could obtain damages for profits lost during the preliminary injunction and after receiving FDA approval for its ANDA.²⁶ This could easily be avoided, however, by writing statute to exclude damage awards in such cases. Finally, eliminating the 30-month stay could *reverse* the Orange Book listing problem—pioneer companies might improperly *fail* to list applicable patents, which could frustrate the development of generic drugs. Therefore, eliminating the 30-month stay may necessitate “adding teeth” to the listing requirements through a use-it-or-lose-it policy, under which pioneer companies could be estopped from alleging infringement of patents not listed in the Orange Book.²⁷ This might appear to entail a more complex scheme, but in fact it could be simpler because then *all* of the patents relevant to a drug could be listed in the Orange Book, including process patents (for manufacturing the drug) and others that may be asserted against a generic competitor *outside* of the Hatch-Waxman framework.

Commentators have also suggested that inequitable applications of the 30-month stay could be avoided by better policing of Orange Book listings by the FDA, which currently plays only a ministerial role in the

²⁶ See *Pharmacia v. Ranbaxy*, 85 Fed. Appx. at 206. (Affirming preliminary injunction in Vantin® litigation. The district court ordered Pharmacia to post two \$15,000,000 bonds to cover profits lost during subsequent to FDA approval during the litigation. The Federal Circuit vacated the portion of the bond required to cover the time prior to the issuance of the preliminary injunction, as it was Ranbaxy’s decision not to market the drug during that time period).

²⁷ Caffrey & Rotter, *supra* note 2, at ¶ 96 (recommending this change).

process.²⁸ This would entail a less dramatic shift in rights than fully eliminating the automatic injunction, but would require the FDA to make decisions about the scope of patent claims. Evaluating the listability of patents would direct even *more* of FDA's resources from considerations of safety and science to mere administration. The courts, on the other hand, are skilled in construing patents, and the preliminary injunction hearing could speed up the entire course of litigation. Thus, eliminating the stay should be more efficient than enhanced policing of the Orange Book. Nevertheless, fact that Congress did *not* include any provisions mandating a larger role for the FDA in the 2003 Medicare Act implies that it would not support scaling back the 30-month automatic stay.

(2) Provide Automatic Disgorgement of Profits When Generics Win

An alternative to eliminating the 30-month stay would be to award damages to generic manufacturers and consumers *whenever* litigation yields a finding of non-infringement or invalidity, not only in cases finding antitrust liability.²⁹ The general answer to this argument is that such a rule would deter too many patent applications, and hence too much valuable inventive activity.³⁰ In fact, patentees cannot completely protect themselves against the subsequent invalidation of a patent, as invalidating non-prior art is often in the hands of their competitors and unavailable until well after a patent application is filed.³¹ Holding patentees liable for disgorgement of profits in *any* losing Hatch-Waxman case might also cause inequitable outcomes in some cases.

(3) Abolish Continuation Applications

The availability of continuation applications is potentially a significant source for continuing abuse by the pharmaceutical industry.³² When continuations are taken into account, the PTO issues patents on over 85

²⁸ See, e.g., *Id.*; Wharton, *supra*, n.21 at 1060-3.

²⁹ Caffrey & Rotter, *supra* note 2, at ¶ 98 (recommending a scheme that transfer damages to a government drug benefit plan in cases in which a generic manufacture ultimately prevails. It is not clear whether they would limit this to cases involving antitrust violations).

³⁰ Robert P. Merges, As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform, 14 Berkeley Tech. L.J. 577, 599 (1999).

³¹ *Id.*

³² Lemley & Moore, *supra* note 74, at 69.

percent of the application chains that are filed.³³ At the same time, continuations cause delay that creates uncertainty among competitors, and issued patents based on continuation applications are more likely to be litigated and declared invalid.³⁴ Moreover, as discussed *supra* in Part II(B)(2), allowing continuations has facilitated pharmaceutical patent evergreening.

Changing the patent term to 20 years from filing and eliminating multiple 30-month stays may have already sufficiently reduced the incentive to evergreen prescription drugs through continuations.³⁵ Nevertheless, To the extent that pioneer companies can continue improperly using continuation applications to skirt the prohibition against double patenting, the problem may call for additional judicial or legislative scrutiny. In addition, continuation applications may still play a prominent role in the pharmaceutical industry. A *late-issued* patent filed in the Orange Book can still delay generic entry, even if it expires on the same date of other patents covering the drug, because of the element of surprise caused by listing a new patent in the Orange Book. A generic competitor may have spent years designing a product that does not infringe on listed patents; that research may be partially derailed by the claims in the newly-issued patent. Moreover, even without multiple stays, each patent involved in the litigation adds to the length, cost, and complexity of the Hatch-Waxman litigation. In particular, resolving the validity of patents that issue from continuation and divisional applications will add a good deal of factual complexity to the case, since these patents may have spent years or even decades a prosecution involving multiple examiners years before the litigation commences.³⁶

Lemley and Moore propose abolishing continuation applications while retaining divisional applications, although they ultimately conclude that this solution would be “overkill.”³⁷ An alternative to abolishing

³³*Id.* at 69, n.22 (referencing empirical studies by Cecil D. Quillen, Jr. et al.)

³⁴*Id.* at 73-75.

³⁵Lemley & Moore, *supra* note 74, at n.85. (Any continuations or divisionals filed after June 7, 1995 have the term twenty years from the earliest claimed filing date.)

³⁶*See, e.g.*, Bristol-Myers Squibb Co. v. Pharmachemie B.V., 2004 WL 516234 (Fed. Cir. March 17 2004),

³⁷Lemley & Moore, *supra* note 74, at 97.

continuations would be to allow generic competitors to require pioneer companies to publish continuation applications that have been pending for over a certain number of years.³⁸ Enforcement could be achieved by creating a publication analogous to the Orange Book for *pending* patent applications that claim approved drugs. Companies who failed to meet the publication requirements would be automatically estopped from later listing the patent in the actual Orange Book. This suggestion assumes that the automatic 30-month stay provision remains intact; otherwise, patentees would not have any incentive to list those patents.

(4) Eschew the Patent System In Favor of FDA-Enforced Exclusivity

This paper focuses on the problem of consumer harm caused by, and research and litigation resources diverted to sequential patents. Although litigation over these patents concerns only a subset (and perhaps a shrinking subset) of Hatch-Waxman litigation, they remain a substantial hurdle to generic entry and represent resources that could be diverted towards more valuable drug research.³⁹ Therefore, the proposals discussed throughout focus on limiting the ability of pioneer companies to delay generic competition by procuring questionable patents on *ancillary* aspects of a drug, and to prevent them from initiating infringement actions they are likely to lose solely in order to take advantage of the automatic 30-month stay.

As noted previously, however, generic companies are increasingly challenging *basic* drug patents.⁴⁰ This growing threat could make it more difficult to secure the investments needed to bring new drugs to market precisely because of the uncertain force of a presumptively valid, but untested patent. Efforts to improve the quality of issued patents through opposition proceedings may not have much impact on enhancing pioneer companies' confidence in the strength of basic drug patents, because generic companies will likely not challenge the patent until *after* the drug proves to be a commercial success. Moreover, efforts to reduce

³⁸For example, the time period could be 5 years—93% of patents have prosecution times less than 5 years. Lemley & Moore, *supra* note 74, at Appendix A, Table 1. Also, in general, patent applications are supposed to be published eighteen months after they are filed, however, the PTO retains discretion not to publish applications, and “the anemic publication rules in U.S. patent law are unlikely to have much effect.” *Id.* at 88.

³⁹*See infra* Part III(D)(1).

⁴⁰The cases involving Relafen®, OxyContin®, and Paxil®, discussed *supra* at Parts I and II, are three examples of this trend, although the former two cases also illustrate the general difficulties faced by the PTO in effectively screening patents.

improvidently granted patents might result in certain compounds never reaching the market. One way to address this more fundamental problem would be to create a system in which the FDA enforces a longer term of market exclusivity, on par with the eighteen- to nineteen-year effective patent term enjoyed in other industries, and to eschew patent protection altogether. Or, the five-year term of market exclusivity for a new chemical entity could be extended to a lesser degree.

Assessing the impact of such a dramatic change is beyond the scope of this paper, although one initial problem is that it may be difficult to implement. As with proposals to reform the Orange Book listing procedures, this would essentially require the FDA to make assessments about patentability and infringement. Many “me too” drugs embody related, but patentably distinct chemical compounds for treating identical indications.⁴¹ Thus, if the line were not drawn at the *indication* level (which arguably it should not be), the FDA would have to assess which of a related subset of drugs would be precluded from receiving FDA approval. This would require the FDA to engage in patent-like determinations about which species of drugs within a genus of compounds are too closely related. Although consumers also criticize pharmaceutical companies for investing in “me too” drugs rather than drugs aimed at new, untreated indications, the competition that ensues from this type of competition may also benefit consumers. Also, “me too” drugs represent substantial profit sources, and the pharmaceutical industry might be reluctant to enact changes that could threaten these drugs.⁴²

⁴¹For example, Zantac®[®], Tagament®[®], Pepcid®[®], and Axid®[®], are related drugs that treat acid reflux; Prilosec®[®], Prevacid®[®], Aciphex®[®] and Protonix®[®] are a different type of drug but treat the same indication. Viagra®[®], Cialis®[®], and Letriva®[®] all treat erectile dysfunction. Lipitor®[®], Zocor®[®] and Lovastatin®[®] are all statins that lower cholesterol.

⁴²For example, worldwide sales of Lipitor exceeded \$8 billion in 2001, sales of Zocor topped \$5.6 billion. See Donald L. Barlett & James B. Steele, “Why We Pay So Much for Drugs,” *Time*, February 2, 2004, p. 44.

B. Improving Patent Quality Control through Administrative Proceedings

Parts I and II of this paper have discussed the incentive pharmaceutical companies face to seek as many patents on a drug as possible, because of the 30-month stay afforded under the Hatch-Waxman regime and the remote possibility of facing antitrust or other damages for having prosecuted an invalid patent. Moreover, the costs of prosecuting a patent through the PTO range from \$5,000 to \$100,000,⁴³ which is nearly nothing compared to the fully capitalized cost of developing a new pharmaceutical, now estimated at over \$800 million dollars.⁴⁴ Given the chance that any one of those additional patents may prove critical to later blocking a generic competitor, the payoff of any given sequential patent on a drug could range in the millions of dollars. In addition, the incentive to patent as many aspects of a drug as possible arises in a regime in which issued patents receive a high degree of deference, even though a number of experts have suggested that the patent examination system that does not impose a sufficiently rigorous review of patent applications and results in the issuance of patents of insufficient quality.⁴⁵ Thus, even beyond the context of the pharmaceutical industry, critics have advocated instituting procedures that would open up the patent prosecution system to adverse parties, either before or shortly after a patent issues.⁴⁶

There are several factors that contribute to poor patent quality control. Patents are a growth industry, with over 166,000 patents issuing in 2001—nearly two and a half times the number that issued in 1984.⁴⁷ The rate of patent applications has grown even faster, reaching 326,508 applications in 2001, nearly three times the number of applications in 1984.⁴⁸ Even if this growth reflects a surge in innovation, the additional

⁴³Stuart J.H. Graham, Bronwyn H. Hall, Dietmar Harhoff, & David C. Mowery, Patent Quality Control: A Comparison of U.S. Patent Re-examinations and European Patent Oppositions, published in *Patents in the Knowledge-Based Economy*, Wesley M. Choen & Stephen A. Merrill, Eds, (National Academies Press: Wash. DC 2003) p. 83 (Noting that it is likely that most patent prosecutions cost less than \$10,000).

⁴⁴PhRMA White paper, *supra* note -, at 7.

⁴⁵*Id.* at 75.

⁴⁶*Id.*

⁴⁷www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf, last visited April 5, 2004.

⁴⁸*Id.* This cannot be used to calculate an exact “grant rate” because it can take a number of years for a patent to issue.

time constraints on examiners could affect patent quality, and commentators have expressed concern that with the dramatic rise in the yearly patent applications, compromises to patent quality may be inevitable.⁴⁹ Continuation applications allow patentees to wear down examiners;⁵⁰ this problem is exacerbated by the compensation system for examiners.⁵¹ Lax prior art disclosure requirements⁵² and the *ex parte* nature of prosecution creates information asymmetries favorable to the applicant.⁵³ Nevertheless, a granted patent always enjoys a presumption of validity that must be overcome by clear and convincing evidence. This presumption of validity is even stronger in the pharmaceutical context because of the force of the automatic 30-month stay.⁵⁴ Patent oppositions counteract this skew by inviting competitors into the system, who have superior knowledge of the prior art and the non-obvious contributions of patent claims.

An alternative to oppositions would be to reverse the presumption of patent validity or scale back the presumption to cover only prior art references actually considered by an examiner.⁵⁵ This does not seem ideal for the pharmaceutical industry, however, because it would introduce even *more* uncertainty (and hence risk) for companies in structuring their product portfolios and forecasting revenues. Although there is always some risk associated with patent portfolios that investors must consider,⁵⁶ increasing the possibility that patents on blockbuster drugs will be invalidated would likely trigger *increases* in drug prices, perhaps during the early years of a drug's life when the FDA guarantees exclusivity, in order to ensure adequate return on (now riskier) investments. On the other hand, improving patent quality would bolster investor confidence in patent portfolios and enhance public perception of the credibility of the patent system.

⁴⁹ See, e.g., Gerald J. Mossinghoff & Vivian S. Kuo, Post-Grant Review of Patents: Enhancing the Quality of the Fuel of Interest, 85 J. Pat. & Trademark Off. Soc'y 231, 232 (2003).

⁵⁰ In addition to the cases discussed *supra* at Part II(B)(2), many other of the cases I reviewed involved patents that issued after one or multiple continuation applications, such as the Purdue (OxyContin®) case.

⁵¹ *Merges*, *supra* note 246, at 608-9.

⁵² *Kesan*, *supra* note 6, at 766.

⁵³ *Lemley & Moore*, *supra* note 74, at 66.

⁵⁴ *Lemley*, Rational Ignorance, at 1530.

⁵⁵ See *Kesan*, *supra* note 6, at 776; *Lemley*, Rational Ignorance at 1529-30.

⁵⁶ *Id.* at 1522-3.

Overall, there is a growing movement favoring opposition proceedings as a means to shift patent validity claims from the federal courts towards an administrative process housed in the PTO.⁵⁷ Congress has already enacted two forms of post-grant reexamination procedures, and one bill was proposed to implement inter partes opposition proceedings in the U.S. Other major patent systems in the world already have forms of post-grant opposition procedures.⁵⁸ This section briefly reviews reexaminations, which are currently available as a means to challenge issued patents, and patent oppositions.

(1) *Reexaminations*

The patent statutes currently provide for both ex parte and inter partes reexamination procedures, under which an issued patent may be reexamined for patentability in light of the prior art. The goals underpinning reexaminations are to reduce patent litigation and reinforce investor confidence in the certainty of patents.⁵⁹ The ex parte reexamination procedure enacted in 1980 has not been widely utilized due to perceived shortcomings, and the inter partes procedure is relatively new and was recently amended, making its impact still unclear.

Under the ex parte procedure, a third party competitor may request reexamination of patent claims by providing in writing a new prior art reference to the PTO, which may initiate a reexamination if it determines that the cited art raises a substantial new question of patentability.⁶⁰ The reexamination occurs mostly

⁵⁷See Qin Shi, Reexamination, Opposition, or Litigation?: Legislative Efforts to Create a Post-Grant Patent Quality Control System, 31 AIPLAQJ 433, 456 (Fall 2003); Merges, *supra* note 246, at 610.

⁵⁸See Mossinghoff & Kuo, *supra* note 255, at 233, 243-248 (describing features of the European and Japanese systems); Kesan, *supra* note 6, at 781-783 (discussing the Japanese and German systems).

⁵⁹*Id.* at 437; Mossinghoff & Kuo, *supra* note 255, at 235.

⁶⁰Shi, *supra* note 265, at 439-440, summarizing 35 U.S.C. § 302-306. “New” previously required the prior art not to have been considered by the examiner during the initial application. Congress overruled the Federal Circuit on this issue and provided that a substantial new question of patentability may be raised by a piece of prior art previously cited in the prosecution history of the patent. *Id.* at 443, 449.

between the PTO and patentee; the third party challenger may file only one written response to a statement addressing patentability by the patentee and has no right to appeal an unfavorable determination to the Board of Patent Appeals and Interferences or the federal courts.⁶¹ The reexamination procedures are not widely used and experience suggests that they are used more by patentees to *strengthen* their patents, while competitors prefer to preserve the prior art for litigation, where they are on more equal footing vis-à-vis the patentee.⁶²

Recognizing the shortcomings of the *ex parte* reexaminations, Congress added Chapter 31 to the Patent Act in 1999 to provide optional *inter partes* reexamination procedures.⁶³ The statute enhanced the adversarial nature of the proceedings, however, it was still quite restrictive of challengers' rights and was amended in 2002. In its current form, third parties may request a reexamination on the basis of prior art, and the PTO will institute an *inter partes* reexamination of the patent if it finds that the cited prior art raises a substantial new question of patentability.⁶⁴

As with *ex parte* reexaminations, prior art previously cited by or to the Office may serve as a basis for reconsideration in an *inter partes* proceeding.⁶⁵ The *inter partes* reexaminations have more of an adversarial flavor compared to *ex parte* reexaminations: each party receives any communication filed by either the patent owner or challenger and has the opportunity to respond in writing to the comments.⁶⁶ Also, both parties have the right to appeal any final decision.⁶⁷ However, all communication is in writing and there is no

⁶¹*Id.* at 440. The patentee may appeal an unfavorable determination.

⁶²*Id.* at 441-2. Patentees can strengthen their patents by submitting a newly discovered piece of prior art to the examiner. If the examiner retains or amends the claims in light of the prior art, it prevents competitors from using the prior art as a basis for challenging validity in litigation. Also, if the claims are rejected as invalid during reexamination, the patentee can appeal the decision.

⁶³*Id.* at 442, discussing the Patent Litigation Reduction Act of 1999.

⁶⁴35 U.S.C. §§ 311-313 (2001, Supp. 2003).

⁶⁵§ 312(a).

⁶⁶§ 314

⁶⁷§315(a)-(b). Parties must first appeal to the Board of Patent Appeals and Interferences and then may appeal that decision only to the Federal Circuit. *See* §§ 134, 141 (A patent owner, or a third-party requester in an *inter partes* reexamination proceeding, who is in any reexamination proceeding dissatisfied with the final decision in an appeal to the Board of Patent Appeals and Interferences under section 134 may appeal the decision only to the United States Court of Appeals for the Federal Circuit).

opportunity for a hearing, which is a major shortcoming because it does not place the competitor on par with the patentee.⁶⁸ So long as inter partes reexaminations resemble an initial examination more than litigation, it will limit their appeal as an alternative to litigation.⁶⁹ Finally, a challenger is estopped from later asserting invalidity of any claim determined to be valid and patentable, on any grounds that were or could have been raised during the proceeding.⁷⁰ Despite mild improvements over the old procedure, the current inter partes reexamination are not a favorable forum for generic manufacturers to challenge pharmaceutical patents.

(2) Opposition Proceedings

Opposition proceedings have the same goal of reexaminations – to improve patent quality control – but they can differ from reexaminations in several ways. First, opposition procedures can occur before or after a patent is granted. Pre-grant oppositions have the advantage of affording greater certainty in the validity of granted patents and possibly reducing bias in favor of the patentee.⁷¹ However, pre-grant opposition proceedings may be resisted in the U.S. because they require earlier publication of patent applications. Post-grant opposition proceedings must occur within a set period of time after the patent is granted, for example, nine months in the case of the European Patent Office (EPO).⁷² Second, challenges may be based on failure to meet *any* of the requirements for patentability, not only the subset of invalidity claims based on anticipation.⁷³ Third, opposition proceedings may be more adversarial in nature, in part because they are open to greater types of evidence, and because oral hearings may be permitted or sometimes required.⁷⁴

Proposals for inter partes opposition procedures have been considered, but not passed, by Congress. In 2001, Congressman Howard Berman introduced a House Bill to establish post-grant opposition proceedings

⁶⁸Shi, *supra* note 265, at 444.

⁶⁹Shi, *supra* note 265, at 461.

⁷⁰35 U.S.C. § 315(c).

⁷¹See Kesan, *supra* note 6, at 777. This bias arises because the PTO may not favor invalidating patents it has granted, because it makes their examination process look worse. This is probably more true for reexaminations, where examiners, rather than Administrative Opposition Judges, are reviewing the claims.

⁷²Shi, *supra* note 265, at 470. The Japanese Patent Office (JPO) time limit is six months.

⁷³Mossinghoff & Kuo, *supra* note 255, at 244, 247. The EPO allows third party opponents to bring initiate proceedings based on several grounds of invalidity, the JPO opposition grounds are mostly coextensive with the grounds of patent issuance.

⁷⁴Shi, *supra* note 265, at 452, 469-70. Both the EPO and JPO provide for oral examinations, at least in some instances.

through an administrative opposition panel comprised of 18 Administrative Opposition Judges (AOJs).⁷⁵ This proposal was modeled on the European and Japanese systems, although it would have allowed only written communications between the parties.⁷⁶ An AOJ would have been allowed to consider any relevant evidence in assessing the patent validity, including depositions, affidavits, and other documents, whether in voluntary or compelled form.⁷⁷ The bill died in committee, perhaps having been eclipsed by the amendments to the inter partes reexamination proceedings, which were debated over roughly the same period of time.⁷⁸

(3) Opposition Proceedings versus Reexaminations

The major benefit of opposition proceedings over patent reexaminations lies in the more adversarial nature of patent oppositions, where advocates for each side can introduce evidence and arguments in support of their position. A recent empirical study indicates that about 24 percent of patents challenged in a reexamination proceeding are confirmed in full, about 10 percent are revoked in full, no outcome is noted in 23 percent of cases, and in the remaining 43 percent claims were added, cancelled, and/or amended.⁷⁹ In European opposition proceedings, by contrast, the opposition was rejected 22 percent of the time, 35 percent of challenged patents were revoked, and the patent was amended in 33 percent of cases.⁸⁰ Thus, revocation occurs much more frequently in the EPO opposition proceedings than in U.S. reexaminations. In addition, the study found that reexamination proceedings are initiated by the *patent* owner in more than 40 percent of the cases, which “hardly qualifies [reexaminations] as the sort of adversarial procedure that EPO oppositions represent.”⁸¹

Overall, these data conform with the perception that opposition proceedings are more effective vehicles for enhancing patent validity is correct, because third parties have been unable to mount meaningful validity

⁷⁵For a more complete description of the proposal (H.R. 1333 in the 107th Congress), see Kesan, *supra* note 6, at 779-780, Shi at 451-454.

⁷⁶Mossinghoff & Kuo, *supra* note 255, at 240.

⁷⁷Shi, *supra* note 265, at 452.

⁷⁸Kesan, *supra* note 6, at 777

⁷⁹Graham, et al., *supra* note -, at 101.

⁸⁰*Id.* at 111.

⁸¹*Id.* at 114.

challenges under the reexamination system.⁸² Therefore, this section advances opposition proceedings as the preferred method for administrative proceedings in the U.S.

C. Improving Pharmaceutical Patent Quality by Amending Hatch-Waxman in Conjunction with Instituting Opposition Proceedings

Commentators have suggested that the incremental effects of policy changes to intellectual property regimes should be assessed at the industry level.⁸³ This seems especially true in the pharmaceutical industry, where efforts to implement successful administrative proceedings must be considered against the backdrop of incentives created by the Hatch-Waxman framework. In the event that a general opposition procedure is proposed again on some future date, Congress should explicitly consider how the system could interact with Hatch-Waxman in order to not miss out on an opportunity for significant reform. Alternatively, legislators *could* implement administrative proceedings that would assess only pharmaceutical patents through the Hatch-Waxman framework, rather than waiting to pass a larger bill with the potential to significantly affect patent institutions. Some key questions for assessing the feasibility and practicality substituting Hatch-Waxman litigation with administrative proceedings to assess *pharmaceutical* patents include:

- (1) What general characteristics of opposition proceedings would promote use of the administrative forum?
- (2) What additional changes to the Hatch-Waxman Act, including some previously discussed, would be *necessary* to effectuate a shift away from Hatch-Waxman litigation?
- (3) Would be possible to realize the main benefit of opposition proceedings—determining the validity of pharmaceutical patents earlier in the life of a drug—given the frequency of such claims and other characteristics of Hatch-Waxman suits?

(1) Structuring Opposition Proceedings: General Characteristics

The general characteristics advocated by proponents of opposition procedures are a good starting point.

⁸²Merges, *supra* note 2, at 611-12.

⁸³Levin et al., *supra* note 5, at 816.

A dedicated panel of administrative opposition judges should hear pharmaceutical challenges, rather than the patent examiners.⁸⁴ Proceedings should be more adversarial and permit oral hearings as well as allow in broader types of evidence; otherwise generic competitors will be unlikely to utilize the PTO forum over district courts. Challengers should be able to predicate their opposition based on any issue of patentability, including utility, double patenting, novelty (anticipation), non-obviousness, and the enablement/best mode requirement.⁸⁵ Both parties should have a right to appeal an adverse decision—perhaps directly to the Federal Circuit, in order to enhance the efficiency of the system. Other characteristics to consider are timing (whether oppositions should occur before or after the patent issues), whether litigation should be stayed pending the administrative proceedings, and whether administrative decisions should be granted preclusive effect.

Generic drug manufacturers should be able to request an opposition proceeding after a patent issues. The time period for filing an opposition should be longer than six or nine months, however, given the long time frames required bring new drugs to market and the risk that a newly discovered chemical will have no commercial value. For each 5,000 to 10,000 compounds screened by pharmaceutical company, 250 enter pre-clinical testing, 5 enter clinical testing, but only 1 is approved by the FDA.⁸⁶ Presumably most, if not all, of the new chemical entities that enter pre-clinical testing are protected by patents. If a patent could only be challenged within a year of issuance, generic companies would either *overchallenge* patents (as a way of prospecting), or the system would be useless as a means to challenge original patents on drugs that may nevertheless be invalid, such as the patents on Relafen® and OxyContin®. On the other hand, if one focuses on the problem of patent evergreening, pre-grant challenges may make more sense than post-

⁸⁴Mossinghoff & Kuo, *supra* note 255, at 252; Shi, *supra* note 265, at 471.

⁸⁵It is worth highlighting that administrative proceedings can be used to resolve issues of pharmaceutical patent validity because there are no damages involved. A generic that has not yet filed an ANDA *seeks* only a declaratory judgment, not damages; thus there is no sixth amendment right to a jury trial. Shi, *supra* note 265, at 458.

⁸⁶PhRMA White Paper, *supra* note 4, at 8.

grant oppositions.⁸⁷ Sequential patents on drugs, which have been responsible for delaying generic entry in many cases, such as in the Augmentin® and Wellbutrin® cases, may issue nearly concurrently with expiration of the original patents. Therefore, pre-grant oppositions might be crucial for steering litigation over marginal patents into the administrative system. Additional empirical research on the average amount of time that elapses between issuance of a patent and Hatch-Waxman litigation would aid in determining whether oppositions should occur pre- or post-grant (or perhaps both?).

A second question is whether the district courts should have discretion to grant a stay of proceedings pending resolution of an opposition procedure. Under the current reexamination statutes, the Director of the PTO is given the power to suspend the reexamination pending court proceedings, and a court may stay proceedings while the patent is reexamined.⁸⁸ In patent oppositions an AOJ should clearly have discretion to suspend the opposition proceedings, in order to allow a district court to hear validity and infringement claims together. However, granting district judges the discretion to stay proceedings could delay generic entry in some cases. One potential benefit opposition proceedings offer is faster resolution of validity claims, in part because an AOJ does not consider issues of infringement. Bifurcating the claims could thus reduce the judicial burden of patent litigation on the district courts without significantly delaying generic competition.⁸⁹ On the other hand, if the validity and infringement claims are both “close” issues, waiting for the administrative decision before commencing infringement litigation would ultimately delay generic entry. Overall, it seems that judges should have the *discretion* to stay Hatch-Waxman proceedings until the administrative decision, in order to tailor individual cases to the most efficient processes.

Finally, a losing third party opponent should not be estopped from re-asserting invalidity claims in a later infringement action, for the simple reason that it would likely spell the death-knell for this administrative

⁸⁷ See Kesan, *supra* note 6, at 777-84 for other arguments in favor of pre-grant opposition systems.

⁸⁸ Mossinghoff & Kuo, *supra* note 255, at 237, citing 35 U.S.C. §§ 306, 318.

⁸⁹ Beyond resolving questions validity, the opposition proceeding could inform a Markman hearing construing the patent claims.

proceeding. Estopping competitors might deter generic manufacturers from ever choosing administrative proceedings over litigation.⁹⁰ The benefits of opposition proceeding inure largely to the public and generic manufacturers, and the attendant benefit of greater certainty to the patentee flows mainly from winning a favorable decision in the opposition proceeding. Moreover, because other generic competitors would not be precluded from later asserting invalidity claims, the benefit of precluding the initial generic challenger would be negligible. Thus, the benefit of estoppel would not outweigh its potential deterrence effect.

Estoppel might prevent generic challengers from utilizing opposition proceedings. If an opposition is brought fairly early in the life of a drug, the generic may still be years away from market launch and might lack sufficient resources to sustain an appeal at that point in time (although given the financial health of generics, this may be an unlikely problem). Second, generic competitors are less likely than pioneer companies to appeal adverse decisions,⁹¹ and an administrative decision of validity might well prompt the opponent (and other generic competitors) to simply design around the patents, if possible. This is another benefit of the opposition proceeding—it will aid generics in targeting their scientific research and development to designing around strong patents. Nevertheless, alleged infringers will not want to lose invalidity as a defense during to infringement and would likely chose not to use opposition proceedings if they feel compelled to appeal an adverse administrative decisions.

On the other side of the balance, eliminating collateral estoppel should not have much impact on subsequent infringement suits. If the concern is giving a single generic competitor too many bites at the invalidity apple, attorney fees could automatically be imposed against a generic company that files an infringing ANDA on patents upheld in an opposition proceeding initiated by the same generic company. Alternatively, Hatch-Waxman could be amended to preclude awarding the 180-day exclusivity for paragraph IV challenges

⁹⁰If the Federal Circuit heard appeals of an AOJ directly, then such findings would obviously have preclusive effect against same generic in a later suit.

⁹¹FTC Study, *supra* note 12, at 18, noting that brand-name companies appealed nearly 90 percent of the cases in which they obtained an adverse district court opinion, but that generics appealed less often.

to patents that have survived an opposition. Also, if additional evidence of invalidity (such as previously undiscovered prior art) has surfaced, competitors should be able to litigate fully an invalidity claim, based on all prior art. If no additional evidence surfaces, the fact of the administrative proceeding may enable a court to render a validity decision on summary judgment. Finally, if the concern driving estoppel is to prevent harassment of patentees through oppositions,⁹² this can be achieved through the threshold requirement that a challenger must raise a substantial issue of patentability based on one or more of the statutory bars. The statute could simply give the director of the PTO authority to deny an opposition request with no appeal.

(2) *Adjusting Hatch-Waxman's Provisions to Promote Opposition Proceedings*

Persuading generic manufacturers to utilize patent oppositions to a substantial degree might require shortening, if not eliminating, the 30-month stay. The 30-month stay would operate as a bar to generic entry in cases in which an AOJ renders a decision of patent invalidity. If the patent is not de-listed from the Orange Book until after the appeal, then a generic company who files an ANDA with a paragraph IV certification on the patent would still be enjoined from marketing the drug—even though the patentee would almost surely be denied a preliminary injunction on the merits. Moreover, shortening the length of the stay might give generic companies an incentive to use opposition proceedings to challenge validity of the most marginal patents on a drug. Even if they will face infringement claims for other patents, generic companies might use the proceeding to remove additional patents from the litigation, which can be expected to shorten the overall duration of the Hatch-Waxman litigation.

Making oppositions a viable alternative to litigation would also likely require repealing the 180-day exclu-

⁹²Shi, *supra* note 265, at 450.

sivity bounty.⁹³ Otherwise, generic drug manufacturers will always choose to file a paragraph IV ANDA challenge over instituting an opposition. It may very well make sense to replace this “bounty” with a more permissive system for awarding fees during litigation and opposition proceedings. Engelberg asserts that the original purpose of the 180-day exclusivity provision “was to insure that one generic competitor would not get a free ride on the litigation effort of another . . . until [the party] had a fair opportunity to recover litigation costs.”⁹⁴ “Free riding” occurs largely because offensive collateral estoppel prevents patent owners from asserting a patent held to be invalid against other competitors, and there is arguably no threat of free riding when the outcome of litigation is a finding of validity and non-infringement.⁹⁵ Thus, allowing for more frequent fee shifting when a generic competitor wins on validity would fulfill this original goal, in both litigation and in an opposition proceeding. It would also be a more efficient alternative to the current system, which will certainly prompt more exclusivity-battles among generics and thus litigation against the FDA and could require a rulemaking to add substance to the term “substantially complete ANDA.” Finally, consumers would benefit from an even faster decline in drug prices when brand-name drugs go off-patent without the 180-day exclusivity provision.

Putting the *original* justification for the provision aside, the *current* benefit of the 180-day exclusivity has little to do with “replacing” attorney fees. Rather, it is a huge prize that generates vigorous competition among generics, which in turn benefits consumers. The enhanced generic competition therefore justifies having a period of oligopolistic pricing on a drug. Indeed, the 180-day exclusivity provision alone *could* be largely responsible for spurring growth in the generic drug industry.⁹⁶ On the other hand, the impact of the exclusivity period on generic behavior may be overstated. In fact, paragraph IV challenges are still a

⁹³The grant of 180-day exclusivity could *also* be shifted to reward third parties that prevail in opposition proceedings. This might *also* be a satisfactory solution, although it might prompt too many oppositions (over-harassment).

⁹⁴Engelberg, *supra* note 31, at 423.

⁹⁵*Id.* This may not be entirely true, because the Markman hearing (on claim construction) might be available as a reference that would shorten subsequent infringement suits.

⁹⁶Wharton reports that the FDA did not grant 180-day exclusivity to any applicants between 1992 and 1998, but has since granted 180-day exclusivity for thirty drug products. Wharton, *supra*, n.21 at 1034.

minority (20 percent) of all ANDA applications,⁹⁷ and the swift entry of additional competitors after the 180-day exclusivity period suggests that generic competition would remain strong even without the 180-day bounty. The exclusivity period cannot be the only thing pushing generic competitors' product decisions, otherwise there would be many fewer generic products on the market. In addition, experience with antibiotics suggests that generics will compete with branded drug products *and* initiate patent challenges even without the 180-day exclusivity bounty to develop generic products and even to engage in patent challenges.⁹⁸ The *primary* benefit of the Hatch-Waxman scheme to generic manufacturers would remain—which was significantly decreasing the costs of *safety and efficacy tests* as a barrier to generic entry.

In addition, pioneer companies are finding new ways to cut into the benefits of the 180-day exclusivity period, which reduces its incentive value. Specifically, innovators have begun entering into deals with generic companies that cut into a first-to-file generic's 180-day exclusivity period. These can be straight corporate deals or settlements⁹⁹ in which the brand-name pharmaceutical company supplies its drug to a generic company, which sells the (unbranded) drug and directs royalties on the sales back to the brand-name company. The generic company's rights are triggered by market entry of any other generic version of its drug (i.e., the entry of the first-to-file generic ANDA challenger), and it avoids the ANDA process altogether because the drug is already approved for sale by the FDA—it *is* the brand-name drug without the brand-name. These deals allow an innovator pharmaceutical company to recoup revenues it would otherwise lose after the onset of generic competition.¹⁰⁰

Glaxo utilized this strategy to thwart second early potential Paxil competitor, Pentech Pharmaceutical. Apotex was the first generic ANDA filer and was entitled to the 180-day exclusivity period pending resolution

⁹⁷FTC Study *supra* note 12, at 10.

⁹⁸*See* Engelberg, *supra* note 31, at 425 (stating an opinion that there are few, if any circumstances in which not awarding the 180-day exclusivity would be grossly unfair to a generic challenger).

⁹⁹These deals may *also* arise in settlement negotiations between an innovator company and a generic that has filed paragraph IV challenges on a drug, which now must be reported to the FTC. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173, §§ 1111(a)(1)-(a)(2)

¹⁰⁰Abboud, *supra* note 7.

of the Hatch-Waxman litigation. Pentech had also filed a paragraph IV ANDA, but dropped the resulting litigation and instead entered into a settlement agreement with Glaxo. Under the settlement, Glaxo supplies Paxil (for free) to Pentech, who in turn distributes the drug—unbranded—and remits a “hefty royalty” on its sales to Glaxo. The settlement structured the agreement to begin as soon and as long as “any other generic version of paroxetine hydrochloride” remained in the U.S. market.¹⁰¹ In other words, the settlement ensured that Pentech would commence competition with Apotex *during* its 180-day exclusivity, if Apotex prevailed the infringement suit. Indeed, when Apotex finally began marketing its generic version of Paxil in September 2003 after spending five years and \$13 million researching and developing its generic version of the drug it was not alone—Pentech launched its authorized version on the same day.¹⁰²

The Glaxo-Pentech agreement has prompted antitrust claims—by Asahi Glass, the would-be supplier for Pentech’s generic version of Paxil,¹⁰³ and by Apotex in the ongoing litigation in the Eastern District of Pennsylvania.¹⁰⁴ The legal status of these deals is currently unresolved. This particular agreement could be considered anticompetitive, but if similar types of agreement can be implemented without violating the antitrust laws they will clearly frustrate the competition-inducing effect of the 180-day exclusivity period. In summary, a strong case can be made to revoking both of these special Hatch-Waxman provisions, either independently or in conjunction with initiating patent oppositions.

(3) The Potential for Oppositions to Reduce Hatch-Waxman Litigation

Addressing issues of pharmaceutical patent validity through administrative proceedings, particularly for sequential patents, could reduce the burden of pharmaceutical patent litigation on the district courts and

¹⁰¹For a discussion of the settlement agreement, *see* *Asahi Glass Co., v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d 986, 989 (N.D. Ill. 2003); *see also* *SmithKline Beecham Corp. v. Pentech Pharmaceuticals, Inc.* 261 F.Supp.2d 1002, 1004 -1005 (N.D. Ill. 2003) (Granting SmithKline’s motion to dismiss its suit against Pentech).

¹⁰²*See also* Par’s press release, “Par Pharmaceutical Provides Update On Paroxetine Sales,” available at http://www.parpharm.com/html/nf/PR_20030930.html. (last visited April 5, 2004). This company press release indicates that par expected sales of paroxetine ranging from \$90 million to \$95 million for the third quarter ending September 2003.

¹⁰³*See* *Asahi v. Pentech*, 289 F. Supp. 2d 986 (dismissing Asahi’s claim *seeking* a declaration of patent invalidity and its antitrust claims but upholding breach of contract and tortious interference claims against Pentech.)

¹⁰⁴*See* Torpharm’s Corrected Memorandum in Opposition to Pentech Pharmaceuticals, Inc. and Par Pharmaceuticals, Inc.’s Motion to Dismiss and to Strike, 3/15/04 (Civil Docket #2:01-cv-02169-RBS).

save judicial resources. An administrative outcome revoking a patent would *prevent* an infringement suit in district court, or at least would reduce the total number of patents involved in subsequent litigation over the same drug product. Moreover, an administrative ruling upholding or amending a patent might deter generic competitors from ever filing a paragraph IV challenge. Instituting opposition proceedings could also save the parties money. Median litigation costs for are estimated at nearly \$800,000 through the end of discovery, and \$1,503,000 through trial and appeal for *each* party.¹⁰⁵ The actual extent of cost savings to the judicial system and individual parties would depend, however, on the extent to which opposition proceedings allow generic competitors to challenge *all* of the patents listed in the Orange Book for a drug. For example, if pharmaceutical patentees file additional patents on a drug immediately before expiry of basic patents, an opposition proceeding would not avoid Hatch-Waxman litigation. In addition, the cost savings to the parties would depend on the extent to which the duration of infringement litigation is reduced by removing invalidity claims from the suit. Thus, an empirical analysis would be necessary to properly weigh the costs of instituting pharmaceutical (or general) patent oppositions against the cost savings from avoided litigation. Opposition proceedings would yield other benefits, in addition to possibly reducing the costs of Hatch-Waxman litigation. Consumers would benefit from faster access to generic drugs, at least to the extent that generic competitors face fewer delays to market entry posed by improvidently granted sequential patents. Pharmaceutical companies would have greater confidence in their patent portfolios, as succeeding in an opposition should add barriers to future generic companies that challenge the validity of the patents.¹⁰⁶ This would allow pioneer manufacturers more certainty in predicting total revenues on their most profitable products.

¹⁰⁵Lemley, *Rational Ignorance*, *supra* note -, at 1502.

¹⁰⁶See Graham, et al., *supra* note -, at 84-85 (noting that the Federal Circuit has indicated that claims confirmed through a reexamination, in practice, add barriers to subsequent contests, and that juries tend to give added weight to reexamined patents.)

Shifting to opposition procedures could also confer significant timing advantages that are unique to the pharmaceutical industry. Clearing up which drug patents are actually valid early on, particularly where the patents are for sequential improvements that may be listed in the Orange Book on an existing drug, would aid generic companies and consumers. Generic companies often begin preparations to compete with pioneer companies about seven years before the patent expires or exclusivity ends.¹⁰⁷ Excising invalid patents from the Orange Book earlier in this process would prevent generic companies from wasting resources trying to design around invalid formulation, dosage, or composition patents. Moreover, an opposition proceeding could clarify the limits of other patents, such as those claiming alternative crystalline forms of the basic compound. This would facilitate the development of non-infringing, bioequivalent generic drug products. At the same time, the danger of conferring this timing advantage on competitors is mitigated somewhat in the drug industry, due to the five- and three-year exclusivity provisions.¹⁰⁸ Even if generic companies were better prepared to win in *infringement* litigation upon filing the initial ANDA application, it likely would not shorten the process of gaining FDA approval for the generic version of a drug.

A further benefit administrative proceedings is that they may yield a greater degree of uniformity and consistency in validity outcomes, both because a dedicated panel of “experts” would hear validity claims, and because shifting to administrative proceedings would reduce forum shopping. The FTC study suggests that forum shopping is occurring in Hatch-Waxman litigation—pioneer companies initiated litigation in just five federal judicial districts in 62 percent of the cases brought against first and second generic ANDA applicants.¹⁰⁹ The FTC views this as a virtue because “these courts have more experience with ANDA patent infringement litigation.”¹¹⁰ Indeed, forum shopping may have enhanced the efficiency of Hatch-

¹⁰⁷Findlay, *supra* note 1, at 229.

¹⁰⁸Moreover, a proposal to institute opposition proceedings could be traded-off against an increase in the term of initial marketing exclusivity.

¹⁰⁹FTC Study, *supra* note 12, at 21.

¹¹⁰FTC Study, *supra* note 12, at 21.

Waxman litigation by creating ANDA-specialized courts.¹¹¹ On the other hand, forum variation increases the unpredictability of outcomes overall, which might undermine the value of drug patents as a financing tool. Finally, to the extent that forum shopping favors patentees, it increases the perception that the patent system is unduly skewed in favor of pioneer drug companies.¹¹² Indeed, a more skeptical view is that pioneer companies chose these forums because they are generally more favorable to them, *see* Table 1., despite their lower overall success rate in Hatch-Waxman litigation.

Table 1. Outcomes in Federal Districts Most Utilized in Hatch-Waxman Litigation*

	Patentee	
District		Win-rate
S.D. Fla.	63 %	
S.D.N.Y.		63 %
D.N.J.	61 %	
N.D. Ill.		48 %
Overall Rates	58 %	

¹¹¹Moore, *supra* note 157, at 924-926.

¹¹²*See* Moore, *supra* note 157, at 917-920. Moore concludes that forum shopping has a major impact on litigation and that lack of uniformity in outcomes creates unpredictability that is problematic. Her data *also* show that “win rates” vary significantly by jurisdiction and that as a result, forum shopping does confer an advantage to parties.

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Developing an administrative proceeding could be a practicable replacement to litigating invalidity claims. The study by Graham, et al., found that oppositions involving a biotech or pharmaceutical patent resulted in revocation of the patent in 31.5 percent of the cases (this was slightly lower than the 35.1 percent rate of revocation for all patent challenges).¹¹³ Although the U.S. and European systems are not analogous, this matches up fairly well with the FTC Study finding a rate of invalidity for 28 percent of drug products litigated.¹¹⁴ Thus, patent oppositions could prove to be a viable forum for “litigating” the validity of pharmaceutical patents. Additional empirical analysis would be necessary, however to determine (a) whether there are a sufficient number of patent validity claims filed in the district courts to justify establishing an administrative opposition, and (b) whether those claims are filed long enough *before* basic drug patents expire to allow an AOJ sufficient time to render a decision on validity.

D. Would Reforming Hatch-Waxman Decrease Incentives for Innovation?

What impact would all, or any, of these changes have on the delicate balance achieved by Hatch-Waxman? *Would* clarifying patent quality earlier on in the life of a drug, enhancing the availability of damages for antitrust violations, or eliminating the 30-month stay cause the demise of the pharmaceutical industry in the U.S.?

(1) *What Type of Innovation Should Hatch-Waxman Promote?*

First, it is worth considering exactly what we mean when we talk about “innovation.” Some commentators

¹¹³*Id.* at 111, 113.

¹¹⁴FTC Study, *supra* note –, at 20.

view the surge in patenting as a characteristic of a flawed intellectual property system,¹¹⁵ and patent evergreening in particular as exemplifying a dearth of innovation in the drug industry. The pharmaceutical industry argues that robust patent rights are needed for sequential, as well as initial patents.¹¹⁶ While sequential drug improvements are important and beneficial to consumers, they are not the type of innovation that the public should be concerned with when it comes to assessing the level of patent protection to afford prescription drugs.

Both generic and pioneer manufacturers will always have an incentive to develop improvements to drug products—they should be rewarded with a presumptively valid patent *only when* the improvement is truly innovative.¹¹⁷ Pioneer companies currently direct significant resources towards “improvement” patents only because the current system significantly rewards them *regardless of* whether the sequential patent is actually valid, so long as it makes it through the PTO. According to PhRMA, innovator pharmaceutical companies allocated about 80 percent of research and development expenditures to new drug products from 1998 to 2000, while the remaining 20 percent went to “significant improvements and/or modifications to existing products.”¹¹⁸ For 2001, this corresponds to roughly \$6 billion dollars of research activities that could have been directed at researching new cures for diseases. Moreover, sequential patents should not restrict consumer choice between an old-but-cheaper product and a new-and-improved version of a drug.

The key question is whether profits *improperly gained* by procuring invalid sequential (or basic compound) patents are essential to maintaining the status of the American pharmaceutical industry as the world leader in pharmaceutical innovation.¹¹⁹ If so, then this could independently justify affording pharmaceuticals significantly stronger patent protection than for other industries,¹²⁰ even if the system often yields inequitable

¹¹⁵Glasgow, *supra* note 3, at 257, (Quoting former Chairman of the FTC Robert Pitofsky).

¹¹⁶PhRMA White Paper, *supra* note 4, at 27.

¹¹⁷Moreover, the pioneer drug company will have a head-start over generic competitors on finding patentable improvements if generic experimentation directed at generating sequential patents does not fall within Hatch-Waxman’s safe-harbor exception to *Bolar*.

¹¹⁸PhRMA White Paper, *supra* note 4, at 7.

¹¹⁹PhRMA White Paper, *supra* note 4, at 3.

¹²⁰Rai, *supra* note 5, at 179.

results. I believe the evidence for this proposition is not strong enough to justify the inequitable extension of patent rights that result from weaknesses in the patent institutions and the Hatch-Waxman Act.

(2) Sequential Patents May Not be as Critical to Appropriating Returns on Pharmaceutical Research Investments

Patents are considered particularly strong in the pharmaceutical industry. In other industries, patents are not viewed as a highly effective means of encouraging innovation.¹²¹ A study by Levin et al. reported that, “in only one industry, drugs, were product patents regarded by a majority of respondents as strictly more effective than other means of appropriation,” (i.e. securing returns sufficient to make the investment worthwhile).¹²² They attribute the effectiveness of patents in chemical industries to the fact that relatively clear standards can be applied to assess validity and to defend against infringement. “The uniqueness of a specific molecule is more easily demonstrated than the novelty of, for example, a new component of a complex electrical or mechanical system. Similarly, it is easy to determine whether an allegedly infringing molecule is physically identical to a patented molecule.”¹²³

In contrast to basic compound patents, the value of sequential patents on drugs for protecting investments and appropriating returns is arguably much lower. This would be true if rates of invalidity are higher for sequential patents or if they are easier for generic competitors to design non-infringing products around. Given the high rate of generic success in Hatch-Waxman litigation, there is some support for both these propositions. Therefore, it is quite possible that innovator pharmaceutical companies have already adjusted to the greater uncertainty of sequential patents, and may not view them as much more than a potential means to secure windfall profits when they *have* “hit the lottery” and discovered a blockbuster drug. Thus, in exchange for preventing at least some unjust enrichment of pioneer companies, opposition proceedings

¹²¹Allison & Lemley, *supra* note 89, at 185, 189.

¹²²Levin et al., *supra* note 5, at 783, 796.

¹²³Levin et al., *supra* note 5, at 798

would provide the benefit of clarifying *which* of their sequential patents are more reliable. This enhanced certainty would facilitate planning and enable companies to better plan to transition from one income source to others, rather than rendering a pioneer company (or its investors) surprised by an unfavorable court ruling.

(3) We Do Not Know What Drives Innovation

“Stronger appropriability [afforded by stronger intellectual property protections], will not always yield more innovation, and where it does, innovation may come at excess cost.”¹²⁴

In contrast to the unregulated system of the U.S., in price-regulated markets originator products receive lower prices during the patent term but retain higher sales after patent expiry because generic competition is weak.¹²⁵ Thus, the U.S. system is viewed as more favorable to innovation because in an unregulated market, companies can recoup their research and development costs faster, which yields higher rates of return on investments. Therefore, this suggests that changes in the patent system that effect a modest decline (or increase) in the expected length of a drug’s period of market exclusivity should not have a major effect on the expected net present value of investments.¹²⁶ Hence, reducing the potential to extent monopolistic drug pricing through invalid sequential should not significantly disrupt incentives for innovation, unless this independently has the effect of yielding *significantly* shorter average effective periods of market exclusivity. On the other hand, viewing the net present value of a drug as the major factor influencing incentives to invest in new research and development may be unrealistic. Returns to investment on individual drugs are highly skewed, reflecting the “blockbuster” nature of the pharmaceutical industry—for every ten drugs that make it to market, only three cover the average development costs for a new drug.¹²⁷ The probability that

¹²⁴Levin et al., *supra* note 5, at 816.

¹²⁵Danzon & Furukawa, *supra* note 11, at W3-524, 534

¹²⁶CBO Study, *supra* note 16, at 45-9.

¹²⁷PhRMA White Paper, *supra* note 4, at 9, citing Grabowski & Vernon, *Returns to R&D on New Drug Introductions in the 1980s*, 13 J. of Health Econ. 383 (1994). The PhRMA paper predicts that even fewer new drugs now cover their development costs than in the 1980s, based on increasing development time and costs and decreasing average returns.

any one patent will cover a drug compound that turns out to be lucrative is slim, leading one commentator to say, “during the prosecution phase, the Hatch-Waxman Act is similar to buying a lottery ticket: the odds are great, but if it hits, there is a big payout.”¹²⁸ Hatch-Waxman litigation centers on these “winners”—drug products in which patent litigation was brought pursuant to a paragraph IV ANDA challenge had median sales of \$190 million per year, while those in which no lawsuit was filed had sales of less than \$100 million in the year the generic applicant filed its application.¹²⁹

The drug industry characterizes revenues from these blockbuster drugs—not average expected returns on investments—as “providing the necessary incentive to promote further investment to support the research, development and refinement needed for future treatments and cures.”¹³⁰ Thus, benefits to innovation (and hence ultimately to consumers) may be attributable to the sometimes-inequitable outcomes observed in Hatch-Waxman suits. On the other hand, the blockbuster model itself may create barriers to investment in innovation, if indeed “it is the looming expiration of a patent that fuels innovation.”¹³¹ Overall, Mark Lemley has aptly summarized the dilemma: “[t]he problem is, quiet frankly, that we don’t have a clue how innovation works.”¹³² More importantly, we do not know how patent evergreening works to encourage true pharmaceutical innovation.

IV. Conclusion

¹²⁸ See Mahn, *supra* note 80, at 233 (citing a Wall Street Journal Article finding that only one in 2500 drug patents ever makes its way to market.)

¹²⁹ FTC Study, *supra* note 12, at 14.

¹³⁰ PhRMA White Paper, *supra* note 4, at 2, 9 (noting that blockbuster drugs support most R&D).

¹³¹ See Engelberg, *supra* note 31, at 421.

¹³² Lemley, *Reconceiving Patents*, *supra* note 6, at 139.

While addressing important shortcomings in the Hatch-Waxman statutory framework, the 2003 amendments to the Hatch-Waxman Act do not deter the significant incentive pharmaceutical companies have to protect drug products through patent evergreening. The cases discussed supra at Part II illustrate several instances in which improvidently granted patents on sequential aspects of drugs have delayed generic competition, harming consumers awaiting cheaper versions of life-saving medicines. Instituting a system for inter partes patent oppositions offers the potential for simplifying Hatch-Waxman litigation and would afford pioneer drug companies greater confidence in their patent portfolios.

Although additional empirical analysis is needed to determine the extent to which patent oppositions would offer a practicable and cost-saving alternative to litigation, as an initial proposition, the case for patent oppositions seems strong. In addition, the changing economic climate in the pharmaceutical industry suggests that the automatic 30-month stay and 180-day exclusivity period for generic competitors may no longer be warranted, although further increases to the patent term extensions available under Hatch-Waxman might be necessary to offset the impact of repealing these provisions.