UNDERMINING PHARMACEUTICAL PATENT POWER
The Need for State Attorneys General to Challenge Invalid Prescription Drug Patents

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INTRODUCTION

On August 2, 2006, the United States Court of Appeals for the Federal Circuit announced an important decision regarding the validity of a patent held by pharmaceutical giant Pfizer.¹ The Court held that Ranbaxy Laboratories, an Indian drug company, had infringed Pfizer’s patent for the cholesterol-reducing prescription drug Lipitor, the “best-selling pharmaceutical product of any kind in the world.”² Although the Court’s holding was somewhat confusing, affirming-in-part and reversing-in-part the ruling of the United States District Court for the District of Delaware, the ultimate result of the decision is clear. Pfizer’s patent for Lipitor, United States Patent Number 4,681,893 (the “‘893 patent”), is valid, and Pfizer will continue to control the market for cholesterol-reducing prescription drugs for a number of years.

The case started when Pfizer sued Ranbaxy Laboratories, claiming that Ranbaxy’s application to the Food and Drug Administration ("FDA") for approval of a cholesterol-reducing drug infringed upon Pfizer’s patent, in violation of 35 USCS § 271(e)(2). Pfizer claimed that the active ingredient in Ranbaxy’s drug was covered by two patents. In response, Ranbaxy filed a counterclaim, challenging the validity of Pfizer’s Lipitor patents upon grounds of double patenting, obviousness, and anticipation.

Patent disputes among major pharmaceutical companies, such as this, are not a rare occurrence. However, their outcomes can have huge implications for the entire pharmaceutical industry in the United States. A decision invalidating a major pharmaceutical company’s patent for a certain drug can open the door to generic competition much earlier than expected, creating

¹ 79 U.S.P.Q.2d (BNA) 1583.
opportunities for smaller companies to enter the market. On the other hand, a decision upholding a patent’s validity can effectively grant a major pharmaceutical company the exclusive rights over a particular drug, preclude competition, and guarantee that company high profits for many years.

Although private drug companies often respond to claims of patent infringement by challenging the validity of a patent, private companies are not the only parties affected by invalid patents. Consumers, the government, and the public as a whole are greatly affected by invalid patents in a number of ways, including higher prescription drug costs for individuals and higher taxes because of rising Medicaid costs.3 Because of the dramatic public effects of invalid patents, some public interest groups have undertaken activities to challenge patents. The Public Patent Foundation (“PUBPAT”), for example, has been active in challenging allegedly invalid patents in the pharmaceutical industry.4 In September of 2004, PUBPAT formally requested that the United States Patent and Trademark Office (“USPTO”) review and revoke a patent held by Pfizer over Lipitor.5 PUBPAT claimed that the patent was “anticipated by earlier work of other inventors” and therefore should never have received a patent.6 Less than a year later, in June of 2005, the USPTO rejected the Lipitor patent based upon PUBPAT’s request for patent

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3 See generally Lear v. Adkins, 395 U.S. 653 (discussing the harm caused by invalid patents).


6 Id.
reexamination. Finally, in November of 2005, Pfizer agreed to narrow its patent for a specific form of atorvastatin, the active ingredient in Lipitor. According to PUBPAT’s Executive Director, Dan Ravicher, revoking the patent was “a critical step towards providing American consumers with access to atorvastatin at a fair price, which will not only provide substantial economic benefit, but will also improve public health,” as more Americans will have access to the cholesterol-reducing drug.

Although PUBPAT was successful in challenging Pfizer’s patent for Lipitor, public interest groups alone can not be expected to fully protect the public from higher prescription drug costs. Individual private groups acting in the public interest may not have the strength or effect that a more centralized, organized, formal public actor may have. Given the strong public interest involved and the overwhelming and confusing area of patent law, it may be necessary for state attorneys general to engage in activities aimed at invalidating unlawful patents.

State attorneys general have many responsibilities, but arguably the most important role they play is that of public advocate. Attorneys general have the opportunity to use the power of their office to make and influence policy, to direct initiatives, and perhaps most importantly, to bring legal claims against private parties and public entities in order to protect the public interest, ultimately protecting the rights of their respective states’ citizens. In recent years, one of the fastest-growing threats to the public interest has been the skyrocketing costs of prescription

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8 http://www.pubpat.org/LipitorPatentNarrowed.htm
9 http://www.pubpat.org/LipitorPatentRejected.htm
10 Professor James Tierney, Lecture before Fall 2005 Columbia Law School Class Multi-State Litigation: The Role of State Attorneys General, September 8, 2005.
As the average age of Americans increases and the baby boom generation retires, the need for low-cost health care will become an even more pressing issue facing the national and state governments. This issue must be addressed and recent legislative attempts to curb rising costs have been largely ineffective.

State attorneys general are in a unique position to protect citizens in a way that is essentially unavailable to legislators: they have the opportunity to take full advantage of the judicial system by pursuing offenders, both civilly and criminally. This is a very effective way to affect public policy and protect the public interest. If the problem of rising prescription drug costs is to be fully addressed, the problem must be attacked at its source: specifically, there must be stronger regulation of the pharmaceutical industry. Such a strategy will require the attention and action of state attorneys general. The most effective way to regulate the costs of prescription drug is to prevent giant pharmaceutical companies from taking advantage of loopholes in patent law.

This paper will address the possible role state attorneys general may play, as well as the possible effect their involvement may have, in protecting the public interest, by engaging in a variety of practices and strategies aimed at challenging invalid pharmaceutical patents. State attorneys general have the ability to challenge invalid pharmaceutical patents in a number of ways, including: investigations; reexamination requests; claims for violation of the marking statute; consumer fraud claims; and the utilization of political pressure. By engaging in these activities, state attorneys general would have the opportunity to greatly decrease the cost of prescription drugs, thereby benefiting the American public.

See MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 75, (Random House 2004) (noting that “Americans now spend a staggering $200 billion a year on prescription drugs, and that figure is growing at about 12 percent a year”).
Part I of this paper addresses the current problems with the United States pharmaceutical industry, focusing specifically on the practices employed by pharmaceutical companies to ‘game the system,’ effectively stifling competition and maintaining high drug prices. Part II briefly examines the USPTO and the FDA and their procedures for granting pharmaceutical patents, as well as the gap left by the federal government in addressing industry problems. Part III focuses on the numerous opportunities available for state attorneys general to get involved in this area, and how the use of investigations, reexamination requests, amicus briefs, political pressure, individual and multi-state litigation can have a profound impact on public welfare. There are various advantages that may be derived from a strong presence of state attorneys general in the area of pharmaceutical patents; these advantages are examined in Part IV. Part V discusses the possible disadvantages and dangers of state attorney general involvement in this area, including the general arguments made by critics of state attorney general activism. Finally, the Conclusion explains that the advantages outweigh the disadvantages and hopefully creates an impetus for state attorneys general to consider protecting and promoting the public interest through activities related to the regulation of patents.

PART I: PROBLEMS WITH THE PHARMACEUTICAL INDUSTRY

The Lipitor patent problem is not an aberration; it is only one of many problems with the American pharmaceutical industry. These problems include a lack of funding for the research and development of new drugs, the disingenuous tactics drug manufacturers use in the field of patent law in order to preclude generic pharmaceutical companies from introducing cheaper alternative drugs, and most importantly, the consequence of the absence of generic competition: skyrocketing prescription drug prices. Through its work, the pharmaceutical industry has the
potential to greatly benefit the public, but these problems are preventing the industry’s ability to do so.

The first major problem with the pharmaceutical industry today is a lack of research and development, and as a result, limited scientific and technological discovery of new active ingredients. A minimal amount of research and development translates to limited pharmaceutical innovation.\textsuperscript{12} “[R]esearch and development (R & D) is a relatively small part of the budgets of the big drug companies—dwarfed by their vast expenditures for marketing and administration, and smaller even than profits.”\textsuperscript{13} Although major pharmaceutical companies claim that they have a difficult time merely breaking even on research and development costs for new drugs,\textsuperscript{14} for many years, “[the pharmaceutical] industry has been far and away the most profitable in the United States.”\textsuperscript{15} So why doesn’t the pharmaceutical industry spend more money on research and development of new, innovative prescription drugs? The answer is simple: profits.

In reality, “[t]he prices drug companies charge have little relationship to the costs of making the drugs and could be cut dramatically without coming anywhere close to threatening R & D.”\textsuperscript{16} Rather than funding research and development to discover new active ingredients and invent new prescription drugs, major pharmaceutical companies spend the bulk of their resources

\textsuperscript{12} See MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 75, (Random House 2004). “[I]n the five years 1998 through 2002, 415 new drugs were approved by the Food and Drug Administration (FDA), of which only 14 percent were truly innovative.” Id.

\textsuperscript{13} Id. at xv.

\textsuperscript{14} See Bruce N. Kuhlik, Colloquium: The Assault on Pharmaceutical Intellectual Property, 71 U. CHI. L. REV. 93, 94 (Winter, 2004). “The average cost of developing a new drug has been estimated at $802 million. Only three out of every ten marketed drugs generate revenues that match or exceed average research and development costs.” Id. But see ANGELL, supra, note 13, at 38–41 (refuting the argument that $802 million is an accurate assessment).

\textsuperscript{15} ANGELL, supra note 13, at xv.

\textsuperscript{16} Id.
developing minor changes to already existing drugs. These minor changes in the drugs, very few of which actually improve the effectiveness of the active ingredients, can be patented by companies, thereby reducing competition and increasing brand-name profits. This process of making minor changes in drugs in order to extend patent life is known as “evergreening,” and the practice has become such a problem that some organizations have been established solely for the purpose of combating its effects.

One prime example of evergreening in the pharmaceutical industry today is Pfizer’s attempt to protect the high cost of its drug Lipitor. Discuss fact that Pfizer has 5 patents listed for Lipitor in the FDA Orange Book. Explain how evergreening leads to extra exclusivity. Explain that exclusivity is provided by the FDA, and generics can’t enter the market if they don’t receive FDA approval.

The second problem plaguing the pharmaceutical industry is the combination of disingenuous tactics used by industry giants to prevent competition by generic companies. By

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17 ANGELL, supra note 13 at 75. “Seventy-seven percent of the pharmaceutical industry’s output consisted of leftovers.” Id.

18 See ANGELL, supra note 13 at 75. Seventy-seven percent of the drugs approved by the FDA between 1998 and 2002 were “classified by the agency as being no better than drugs already on the market to treat the same condition.” Id.

19 See id. at 177.

20 April 27, 2006 Interview with Daniel Ravicher, Executive Director of the Public Patent Foundation. “Most typically, patent evergreening is alleged when brand-name manufacturers block generic drug manufacturers from entering the market with less expensive products by filing allegedly bogus patent infringement suits.”

21 The Prescription Access Litigation Project (PAL) was established in 2001 “to make prescription drugs more affordable for consumers by using class action litigation and public education to bring an end to illegal pharmaceutical price inflation.” About the Prescription Access Litigation Project (2005), available at http://www.prescriptionaccess.org/index.php?doc_id=567.

22 April 27, 2006 Interview with Daniel Ravicher, Executive Director of the Public Patent Foundation.
stifling this competition, major pharmaceutical companies are able to maintain high prescription drug prices. “Instead of investing more in innovative drugs and moderating prices, drug companies are pouring money into marketing, legal maneuvers to extend patent rights, and government lobbying to prevent any form of price regulation.”23 Patents are granted to inventors of new drugs for one major purpose: they are designed to give an innovator a period of exclusive rights to the product in order to allow the innovator to recoup its research and development investment.24 The exclusivity periods provided by the FDA are claimed to be a necessary incentive because they promote drug companies to invest in research and development in order to create innovative products.25 The story goes that exclusivity is essential to the developer of the pioneer drug; once the period of exclusive marketing rights expires, generic companies enter the market with copies and the drug’s price falls dramatically.26 Eventually, sales of the brand name plummet because generic prices fall to as little as 20 percent of the cost of the brand-name drug.27

23 Id. at 19.


25 See Bruce N. Kuhlik, Colloquium: The Assault on Pharmaceutical Intellectual Property, 71 U. Chi. L. Rev. 93, 99 (Winter, 2004). Major drug companies argue that a short period of patent protections would “be inadequate to attract anything approaching the current level of investment in pharmaceutical research and development.” Id. at 96. Note that some critics argue such incentive is unnecessary. See Carlos M. Correa, Patent Law, TRIPS, and R&D Incentives: A Southern Perspective, COMMISSION ON MACROECONOMICS AND HEALTH WORKING PAPER N. WG2: 12 at 18 (November 2001), available at http://www.cmhealth.org/docs/wg2_paper12.pdf (arguing that “the assumption that patents and licensing will maximize the social returns of public investment in R & D underestimates the effectiveness of publication and other means of knowledge diffusion that may enable society to benefit more than under a system of appropriation and restrictive licensing”).

26 See ANGELL, supra note 13 at 9.

27 See id. at 74.
Once the period of exclusivity expires, there is an understanding that other drug companies should have the opportunity to enter the market in order to compete and drive down prices.\textsuperscript{28} However, pharmaceutical giants do not always play by these rules because extending patents and exclusivity periods gives them market power and increased profits. “Because delaying the entry of a generic drug for even 1 year can result in a billion dollars of profits, drug companies have huge incentives to use the legal system to delay generic competitors from legitimately entering the market.”\textsuperscript{29}

Major patent-holding pharmaceutical companies use tactics to take advantage of loopholes in patent law in order to lengthen their exclusivity periods, thereby maintaining high prices on prescription drugs. In many instances, industry giants use patents as a device to prevent innovation by smaller companies, safeguarding their research and intimidating smaller companies by threatening infringement suits. The cost of litigation to pharmaceutical giants is very small in comparison to the increased profits from delayed generic competition, therefore “pioneer drug manufacturers may be tempted to ‘game the system’ to prolong the patent period.”\textsuperscript{30} Moreover, in most cases it is not in small generic drug manufacturers’ interest to litigate against pharmaceutical giants. \textbf{Explain the threat of patent infringement suits and}

\textsuperscript{28} See Eugene Trogan, \textit{Balancing The Need for Innovative Drugs While Providing Lower Cost Alternatives to Consumers: Hatch-Waxman Reviewed}, 24 MED. & L. 355, 359 (noting that “[o]ne of the main purposes of a patent is that the public will eventually enjoy the benefits of full disclosure of the patented material and be able to use that material freely after the statutory period of exclusivity”).


how it keeps generic companies out of the market. Because of the patent-holders’ threats, smaller companies often agree to delay introducing generic drugs.\(^{31}\)

Two examples of ‘gaming the system’ by pharmaceutical giants are tying and double-patenting. Tying occurs “when a drug manufacturer forces a patient to buy an un-patented drug or medical product in order to have the right to purchase a patented one.”\(^{32}\) Essentially, the patent-holding brand-name pharmaceutical company creates a combination pill in order to increase profits and prevent generic competition.\(^{33}\) Consumers are forced to “buy the tying party’s non-exclusive drug in order to get the patent protected component. This forcing destroys what would otherwise be a fully competitive market for the non-exclusive drug.”\(^{34}\)

Double Patenting, alternatively, occurs when major pharmaceutical companies attempt to extend their exclusivity periods by either illegally re-listing the patent with the FDA, or by evergreening, creating a slight variation in the original drug, and applying for a new patent.\(^{35}\) Such devices “shock one’s sense of justice”\(^{36}\) because they allow original inventors to ‘game the system’ and force consumers to continue to pay high prices.

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\(^{33}\) See id. at 16 (explaining the process of tying drugs for patent purposes).

\(^{34}\) Id. at 16.


\(^{36}\) Id. at 1386. “It would shock one’s sense of justice if an inventor could receive a patent upon a composition of matter…and then prevent the public from making any beneficial use of such product by securing patents upon each of the uses to which it may be adapted.” Id.
Pharmaceutical giants use these tactics in tandem to create the biggest prescription drug industry problem: skyrocketing prices for consumers. Because of the high cost of prescription drugs, many sick and elderly individuals cannot gain access to the medicine they so desperately need. “The pharmaceutical industry involves a delicate balance between the need for innovators to recoup research and development expenditures and the desire for consumers to pay affordable prices for drugs.” When brand-name companies ‘game the system’ and take advantage of patent law loopholes, the consumers are the ultimate losers.

Pharmaceutical giants are not the only companies to blame for the skyrocketing drug prices, however; generic companies also ‘game the system’ in their own way. Go into greater detail about the ability of small generics to litigate against giant companies, but they refuse because they, too, are out to increase profits for their shareholders. Explain how generic companies ‘game the system’ by engaging in reverse payment schemes. Because the drug companies are motivated by profits, and not the public interest, it is up to the government to enforce policies that keep costs low, while still offering incentives for drug manufacturers to research and develop new medicines. “Government policies that promote the discoveries of new drugs must be balanced with the encouragement of providing a competitive generic drug market in order to curb the rising cost of caring for a growing elderly population.” Unfortunately, as described in Part II, the federal government has failed in its effort to effectively encourage a competitive market.

37 See Angell, supra note 14 at xii (noting that “Americans now spend a staggering $200 billion a year on prescription drugs, and that figure is growing at about 12 percent a year”).


PART II: THE GOVERNMENT’S FAILURE TO REGULATE PATENTS

The pharmaceutical industry is not the only party to blame for its failure to adequately serve the public. There are two primary government agencies which regularly act with pharmaceutical companies in creating patents and prescription drug exclusivity rights, the United States Patent Office (“USPTO”) and the Food and Drug Administration (“FDA”). These two federal agencies, however, have failed to effectively regulate the pharmaceutical industry. Additionally, federal legislators in Congress have neglected their duty to regulate the major companies.

The USPTO is the governing body that grants patents to designers and inventors in order to “promote the progress of science and the useful arts by securing for limited times to inventors the exclusive right to their respective discoveries.” However, the Patent Office has not successfully accomplished this goal. The USPTO grants invalid patents at an alarmingly high rate, and these invalid patents lead to high social costs, especially in the pharmaceutical industry. One important reason for the Patent Office’s failure to effectively distinguish between valid and invalid patent requests is a lack of resources. When the USPTO considers a patent request, it essentially relies on the information provided by the applicant. This occurs because


41 See Joseph Scott Miller, Building A Better Bounty: Litigation-Stage Rewards for Defeating Patents, 19 BERKELEY TECH. L. J. 667, 689. “The Patent Office…appears to grant many patents that, when carefully scrutinized, fail to meet basic patentability standards.” In his article, Miller argues that a litigation stage bounty for patent challengers would be socially beneficial. See id.

42 See id. at 738. “The Patent Office grants invalid patents at a high rate. And invalid patents impose high social costs.” Id.

43 See Mason, supra note 37 at 101. “The PTO grants a patent primarily on the basis of the representations of the applicant[.]” Id.
the Office lacks the resources and funding to fully investigate patent requests.\textsuperscript{44} Such limited information makes it much easier for the USPTO to grant patents than to deny them. “The result is that nowadays nearly anything—including new uses, dosage forms, and combinations of old drugs, even coatings and colors of pills—can be patented.”\textsuperscript{45}

The FDA is the second step of pharmaceutical patent regulation, but it too has failed to protect the public. After a patent is granted by the USPTO and the pioneer drug manufacturing company concludes its clinical safety tests, the company turns to the FDA in order to list its patent in the Orange Book.\textsuperscript{46} Once a patent is listed in the FDA’s Orange Book, the FDA grants the patent-holder a period of exclusivity during which to market the drug. This exclusivity is different from that awarded by the USPTO, however, because it is granted when the drug is approved for marketing.\textsuperscript{47} Although they are separate exclusivity grants, the USPTO and FDA’s procedures act in tandem to protect developers of new drugs for a certain time period because pioneer drug developers usually receive both a patent and FDA exclusivity grant.\textsuperscript{48} The patents listed in the Orange Book, and therefore granted exclusivity, are supposed to be limited to those patents over the original drug and its approved use.\textsuperscript{49} However, the FDA does not prohibit drug

\textsuperscript{44} See id. (noting that the USPTO “has limited resources to investigate and litigate validity of the patent applied for”).

\textsuperscript{45} ANGELL, supra note 13 at 177.

\textsuperscript{46} See id. at 28. “Drug companies usually obtain a patent on a new drug before clinical testing begins.” Id. The Orange Book is the governmental listing of all FDA approved prescription drugs. See United States Food and Drug Administration Center for Drug Evaluation and Research Website at http://www.fda.gov/cder/ob/faqlink.htm.

\textsuperscript{47} ANGELL, supra note 13 at 177. See also United States Food and Drug Administration Center for Drug Evaluation and Research Website at http://www.fda.gov/cder/ob/faqs.htm#What%20is%20the%20difference%20between%20patents%20and%20exclusivity?. “Patents and exclusivity work in a similar fashion but are distinctly different from one another.” Id.

\textsuperscript{48} See ANGELL, supra note 13 at 178 (noting that “generic competition can be held off by either a relevant patent or an FDA grant of exclusivity, or both”).

\textsuperscript{49} See id. at 249.
companies from listing secondary patents—even those that are frivolous—in the Orange Book.\footnote{See id.}

Pfizer’s five patents on the active ingredient in Lipitor is a prime example of the FDA’s inability to restrict entries in the Orange Book. Although the United States Court of Appeals for the Federal Circuit found the ‘893 patent for Lipitor valid, the invalid patent that Pfizer recently agreed to limit was also listed in the Orange Book. The FDA clearly does not scrutinize patents, nor does it prevent secondary patents from being included in the Orange Book. “Of course, if patent law were strictly enforced, so that patents were granted only for discoveries or inventions that are truly useful, novel and non-obvious, there wouldn’t be so many secondary patents.”\footnote{ANGELL, supra note 13 at 249.} The combination of neglect by the USPTO and the FDA has allowed brand-name pioneer drug manufacturers to take advantage of the system and maintain control over the market, keeping drug costs as high as possible.

Congress has also failed to create legislation to regulate the tactics of pharmaceutical giants. One reason for this lack of success is the strength of the drug industry in Washington. “Drug companies have the largest lobby in Washington, and they give copiously to political campaigns. Legislators are now so beholden to the pharmaceutical industry that it will be exceedingly difficult to break its lock on them.”\footnote{Id. at xx.} Go into greater detail about drug company special interest donations.

Even when legislators do create laws designed to lower prescription drug prices and promote competition in the pharmaceutical industry, the results are not entirely successful. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, in order to “stimulate the foundering generic drug industry by short-
circuiting some of the FDA requirements for bringing generic drugs to market.” Essentially, the law permits generic drug companies to file an Abbreviated New Drug Application ("ANDA") in order to receive FDA approval for their copies of pioneer drugs before the pioneer drug patent expires. Under the new procedure, in order to receive FDA approval, a generic company only needs to demonstrate that its product is “bioequivalent” to an already approved brand-name drug; this is a much easier and less expensive process for generic companies.

Under law, before a drug is approved by the FDA, the manufacturer must prove that it is reasonably safe and effective based upon clinical tests and trials. Hatch-Waxman reduces this burden on generic companies because if the generic drug is, in fact, bioequivalent to an already approved drug, requiring the generic company to run the drug through the same battery of tests would be a waste of time and resources.

By allowing generic companies to spend less money in the drug-approval process, and to receive approval for generic drugs prior to the expiration of the brand-name pioneer drug’s exclusivity period, the Hatch-Waxman Act makes it easier for generic drugs to enter the market. The Act was supposed to stimulate the generic drug industry in order to create a

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53 Id. at 9–10. See also Trogan, supra note 26 at 359–60. “The Act was intended to strike a balance between maintaining the inducements necessary to bring about pioneering research and development of new drugs while enabling generic drug manufacturers to bring very similar drugs to the market at a lower price.” Id.

54 See Trogan, supra note 26 at 360.

55 See Trogan, supra note 26 at 360 (noting that “[p]roof of bioequivalence is much easier to establish compared to extensive requirements of an NDA”). See also ANGELL, supra note 13 at 28–32.

56 See ANGELL, supra note 13 at 27.

balance between small generic drug producing companies and pharmaceutical giants.\textsuperscript{58} Although generic companies have fared better following passage of the Hatch-Waxman Act, the provisions of the Act have also had some undesired and unintended consequences.

The Act requires that the ANDA applicant notify the patent-holder of its intention to receive FDA approval for the generic copy, and the patent-holder is given 45 days to challenge the ANDA by bringing an infringement claim.\textsuperscript{59} If the patent-holder brings an infringement suit, it is given a thirty-month stay on FDA approval of the generic product.\textsuperscript{60} Industry lawyers have manipulated this provision by filing secondary patents in the FDA’s Orange Book. This allows the patent-holder to “institute infringement actions for multiple patents on a single drug, each qualifying for a thirty-month stay.”\textsuperscript{61} By manipulating this loophole,\textsuperscript{62} patent-holding pharmaceutical companies, in the past, have been able to obtain numerous stays of the thirty month exclusivity period.\textsuperscript{63} These loopholes allowed pharmaceutical giants to “restrict competition beyond what the Hatch-Waxman Amendments intended”\textsuperscript{64} because as long as

\textsuperscript{58} See ANGELL, supra note 13 at 178--179.

\textsuperscript{59} See Trogan, supra note 26 at 361--62. When a generic company files its ANDA request, under a Paragraph IV Certification, it “can either challenge listed patents validity or certify that their generic equivalent will not infringe upon the patent held by the pioneer drug company…” Id. If the exclusivity holder brings an infringement suit, it is essentially challenging the Paragraph IV Certification’s claim. See id.

\textsuperscript{60} See id.

\textsuperscript{61} Trogan, supra note 26 at 364.


\textsuperscript{63} See ANGELL, supra note 13 at 181.

litigation on the infringement claim continued, the thirty-month stays barred generic manufacturers from the market. “These stays in many instances provided brand name companies at least two years of additional market exclusivity, during which the derived profits from the extended exclusivity far outweighed the litigation costs.”\textsuperscript{65}

Although the loophole allowing for multiple thirty month stays has been removed, the original procedure granting the patent-holder one thirty month stay is still in existence. This means that if a generic manufacturer notifies the patent-holder that it plans to file an ANDA, the patent-holder merely needs to file an infringement claim, and the generic manufacturer will be prevented from entering the market for at least 30 months, even if the patent infringement suit is a frivolous claim. Although Congress passed the Hatch-Waxman Act with good intentions, the regulatory failures of the USPTO and FDA have allowed pharmaceutical giants and generic drug companies to circumvent the law’s purpose.

Given the federal government’s failure to prevent manipulation of the patent law by pharmaceutical giants, challenges in court may be the only successful avenue for protecting the public from the anti-competitive practices of the pharmaceutical industry. Litigation is a viable option because “[a]lthough an issued patent carries a presumption of validity, because companies have incentives to obtain multiple patents on an approved drug to prevent generic competition, some patents issued covering a pioneer drug may press the limits of eligibility and may be judicially determined to be invalid as an attempt to improperly extend the drug’s monopoly.”\textsuperscript{66}

\textsuperscript{65} Trogan, \textit{supra} note 26 at 364.

\textsuperscript{66} Mason, \textit{supra} note 37 at 101.
Patent litigation is worth the resources in many cases because “roughly half of all issued patents later challenged in litigation are proven to be invalid.”

Because there are two methods through which major drug companies can gain monopoly rights over a particular drug (USPTO patents and FDA exclusivity rights), there are also two possible methods to challenge these rights. The first method is directed at the patent; it is a request for patent reexamination by the USPTO. A request for reexamination is filed by any party based upon a claim that the patent is for “prior art.” If, upon reexamination, the USPTO determines that the patent is invalid, the invalid patent-holder is given the opportunity to propose amendments to the patent or distinguish it from the prior art. The advantage to this method is that it is available to anyone; any person can file a reexamination request. Within the category of reexamination, there are two distinct procedures: ex partes reexamination, and interpartes reexamination. 

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67 John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. J. 185 (1998) (describing that 46% of all litigated patents are determined to be invalid). See also United States Patent Litigation Statistics, University of Houston Law Center, available at www.patstats.org/2003.html (noting that of the patent validity decisions made in 2003, the patent was invalidated 58% of the time).

68 See ANGELL, supra note 13 at 9.


71 See 35 U.S.C. § 305 (2005). “In any reexamination proceeding under this chapter, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited…” Id.


73 April 27, 2006 Interview with Daniel Ravicher, Executive Director of the Public Patent Foundation.
the advantages and disadvantages of each, and why one is only applicable in certain situations.

The second method of challenging a patent attempts to de-list a patent included in the FDA’s Orange Book. Basically, the challenger claims that a patent included in the Orange Book is not an approved drug. Under the Medicare Prescription Drug Improvement and Modernization Act passed in 2003, ANDA applicants have the ability to file a counterclaim “seeking an order requiring the…patent owners to delete a patent from the Orange Book[.]” This method has a major disadvantage, however. Under the law, “the delisting action can only be brought as a counterclaim in a patent infringement suit, not as an independent cause of action[.]” This severely limits the utility of this method of challenge because any interested party that has not filed an ANDA has no claim, meaning that public interest and good government groups may not file such an action. Additionally, the only remedy for this counterclaim is the removal of the patent from the Orange Book. Because there are no monetary damages, many ANDA applicants will not file counterclaims because the cost of intellectual property litigation may be prohibitive. Explain the other problem with removal of patent from Orange Book: patent still exists, and an infringement claim may still be brought; therefore, generics won’t take the risk of placing the drug on the market anyway because they’ll face the prospect of paying damages to the patentee.

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74 See Trogan, supra note 26 at 366.

75 Trogan, supra note 26 at 366.

76 Green, supra note 28 at 335.

77 See id (stating that “the only remedy is the removal of the patent from the Orange Book” and that the “provision does not allow the generic applicant to collect any money damages”).
PART III: OPPORTUNITIES FOR STATE ATTORNEYS GENERAL TO ACT

There are myriad opportunities for state attorneys general to act where the federal government has failed to do so, in order to protect the public from invalid pharmaceutical patents. Many state attorneys general are already active in protecting the public from pharmaceutical companies in consumer protection and antitrust work. In 2001, for example, 29 states sued pharmaceutical giant Bristol-Meyers Squibb, “alleging the company made false statements to federal regulators to extend its patent” on a particular drug. Even more recently, in 2003, a number of state attorneys general, including those from Michigan and Arizona, sued various pharmaceutical companies for alleged anticompetitive activity. The door to the pharmaceutical industry and its effect on the public interest has already been opened, but in order to fully step through, state attorneys general need to address the major sources of the problem. By challenging and invalidating improper prescription drug patents in the early stages of exclusivity, state attorneys general can prevent pharmaceutical companies from falsely inflating the prices of the prescription drugs that are so important to millions of Americans. As discussed in Part I, one of the major problems with the pharmaceutical industry is the leverage that major patent-holding companies exert over generic competitors. This power imbalance often leads to back-room dealing between major companies and generic competitors, leading to

78 See Angell, supra note 13 at 229. “In just the past couple of years, the pharmaceutical industry has faced a tidal wave of investigations and lawsuits brought by federal prosecutors, state attorneys general, company whistleblowers, and a host of consumer groups and individuals.” Id. “State attorneys general have also become very active in prosecuting drug companies for defrauding Medicaid.” Id. at 231.

79 Andrew Caffrey, Scott Hensley & Russell Gold, States Go to Court in Effort to Rein In Costs of Medicine, WALL STREET JOURNAL, May 21, 2002.


81 Interview with Eben Moglen, Professor of Law, Columbia Law School, in New York, NY (Nov. 3, 2005).

82 See Correa, supra note 29 at 8–9.
agreements regarding the time of release and the costs of specific drugs. The validity of these arrangements under antitrust law is often questionable.\footnote{See id.} If state attorneys general were to challenge the validity of certain patents, it would reduce the power that major patent-holding pharmaceutical companies exert over generic competitors.\footnote{Interview with Eben Moglen, Professor of Law, Columbia Law School, in New York, NY (Nov. 3, 2005).} Explain that, by eliminating this power, it will also eliminate the generic companies’ desire to enter into reverse payment schemes, etc.

Issues of standing present the biggest procedural barriers to exclusivity challenges by state attorneys general. As discussed in Part II, only a party who is engaged in, or fears an imminent infringement suit can seek a declaratory judgment ruling a patent listed in the FDA’s Orange Book invalid.\footnote{See Green, supra note 28 at 335.} Explain the possibility of such claims before an infringement suit is actually filed, thereby allowing the generic company to engage in a preemptive strike against the patentee. However, also explain that, even with such rulings, the generic won’t enter the market because of the fear of high damages owed. In other words, declaratory judgments of patent invalidity may only be used as a defensive measure by a generic company preparing to infringe upon a patent-holder’s exclusivity right.\footnote{See Green, supra note 28 at 335 (noting that “the delisting action can only be brought as a counterclaim in a patent infringement suit, not as an independent cause of action”).} A claim of infringement is a condition precedent to declaratory relief adjudging a patent to be invalid.\footnote{See id.} The law precludes non-private entities from fulfilling the proper standing requirements to challenge a patent in this

\[83\] See id.

\[84\] Interview with Eben Moglen, Professor of Law, Columbia Law School, in New York, NY (Nov. 3, 2005).

\[85\] See Green, supra note 28 at 335.

\[86\] See Green, supra note 28 at 335 (noting that “the delisting action can only be brought as a counterclaim in a patent infringement suit, not as an independent cause of action”).

\[87\] See id.
manner. However, any party is permitted to bring a reexamination claim before the USPTO, such as the request filed by PUBPAT for a review of Pfizer’s Lipitor patent. 88

Acting on behalf of both the state and the general public interest, state attorneys general could bring reexamination claims in front of the USPTO. 89 Such claims would have three related effects. First, by challenging allegedly invalid patents, state attorneys general would create time periods during which the patent-holder would be engaged in reexamination. 90 Discuss how forcing patent-holders to engage in reexamination can force holder to make claims that force patent to be either limited or broad. Therefore, the second effect would be to prevent pharmaceutical giants from exerting power to threaten generic manufacturers into agreements, thereby increasing competition. 91 Finally, if enough reexamination hearings were held, the competition from generic companies would be so widespread that there would be a market-wide reduction in prescription drug prices 92

In addition to filing reexamination claims through parens patriae power, state attorneys general may also protect the public interest in more informal ways. A less formal method of protecting the public interest would be to act as co-counsel for generic competitor defendants in infringement suits. 93 As explained above, private parties lack standing to challenge the validity of a patent (aside from reexamination requests) unless they are first sued under an infringement


89 Id.

90 Id.

91 Id.

92 Id.

93 Telephone Interview with Patrice Jean, Associate, Kenyon & Kenyon LLP (Oct. 25, 2005).
claim, or have a reasonable anticipation of suit.94 Once a generic competitor is sued for allegedly infringing a patent (or reasonably anticipates such a suit), however, the generic company has the opportunity to defend itself by claiming the patent to be invalid.95 If a state attorney general believes the allegedly infringed-upon patent to be invalid, he or she may want to direct resources toward assisting in the defense of the lower cost generic drug manufacturer. By acting as co-counsel on behalf of a private patent-challenger, state attorneys general would further the public interest without being forced to expend the resources necessary to file formal lawsuits. This more informal method of involvement would allow state attorneys general to receive some of the credit for the lower cost of drugs while avoiding many of the procedural hurdles and high costs of filing a formal lawsuit in the name of the state.

Another more informal way for state attorneys general to act in the public interest is to write amicus curiae briefs in private cases. By writing amicus briefs, state attorneys general could again play an important role in influencing and directing public policy.96 Because state attorneys general play an important role in shaping public policy, simply writing amicus briefs or minimally engaging on behalf of private litigators would, at the very least, alert the public to the problem by drawing attention to it, thereby magnifying the issue in a way that might prompt collective action throughout the branches of state government.

There are two major methods by which state attorneys general could carry out the above-mentioned activities. The first method is traditional state attorney general litigation. In this form of action, a single state’s attorney general, acting individually as a single plaintiff, litigates

94 See Green, supra note 28 at 335 (noting that “the delisting action can only be brought as a counterclaim in a patent infringement suit, not as an independent cause of action”).

95 Interview with Eben Moglen, Professor of Law, Columbia Law School, in New York, NY (Nov. 3, 2005).

96 Interview with Eben Moglen, Professor of Law, Columbia Law School, in New York, NY (Nov. 3, 2005).
against private parties, or takes other action discussed above, on behalf of his or her own state’s citizens. However, there are disadvantages to this approach. First, resources are scarce, especially in the complex and specialized practice of patent law which would be new terrain for state attorneys general. Not only do most state attorney general offices lack the in-house expertise to challenge a pharmaceutical patent, but most state attorneys general, acting individually, likely lack the money, clout, and other resources necessary to acquire outside assistance that would provide the specialized knowledge.

Additionally, even if an individual state’s office had the resources necessary to litigate against a large pharmaceutical company, such litigation would probably not have the desired effect. The pharmaceutical industry is a multi-billion dollar per year business. While each state attorney general presumably protects the public interest of his or her own state’s citizens, it would be very difficult for litigation brought by an individual state’s office to have any deterrent effect on the national pharmaceutical industry’s patent practices. These barriers make the prospect of successful individual state attorney general action very unlikely.

The second way to accomplish these goals would be to engage in multi-state litigation and coordination. In multi-state litigation, the attorneys general of many states “prosecute their cases jointly, sharing with each other legal theories, discovery materials, court filings, litigation


98 Telephone Interview with Patrice Jean, Associate, Kenyon & Kenyon LLP (Oct. 25, 2005).

99 Id.

100 See ANGELL, supra note 13 at xii (noting that “Americans now spend a staggering $200 billion a year on prescription drugs, and that figure is growing at about 12 percent a year”).
expenses, and even staff." State attorneys general are often more successful in this manner because they can “coordinate their enforcement litigation on an interstate basis, simultaneously pursuing the same causes of action in different states against the same private parties.”

Multi-state litigation is controversial because many critics argue that, by engaging in it, state attorneys general infringe upon the power of the legislature by attempting to regulate business practices through litigation; critics argue that regulation should remain in the domain of legislative bodies because legislatures are more efficient. Despite critics’ claims, however, the legislative branches in both state and federal government seem ill-equipped to regulate and address pharmaceutical patent problems, as discussed above.

There are advantages to the, albeit more controversial, method of coordinating litigation amongst many state attorneys general: separate offices can combine individuals’ expertise, thereby reducing the knowledge gap between state attorneys general offices and pharmaceutical companies; greater and more widespread media coverage can generate more public attention than individual offices alone. Additionally, “coordinated settlement reduce[s] the resources necessary to litigate, joint retention of expensive experts and joint discovery” reduce costs to state taxpayers, and there is “added momentum in settlement discussions because states can offer a global peace.” All in all, multi-state litigation allows for many state attorneys general to pool their expertise, information, and resources in order to increase efficiency and promote more 

102 Id.
103 Professor James Tierney, Lecture before Fall 2005 Columbia Law School Class Multi-State Litigation: The Role of State Attorneys General, November 10, 2005.
104 See supra Part II at 12.
successful public protection. One individual state’s office of the attorney general would have a very difficult time litigating against a major pharmaceutical company before the USPTO, especially given the nuances of, and the specialized expertise required to litigate, patent law.\textsuperscript{106} Pharmaceutical companies have entire legal departments devoted to applying for patents;\textsuperscript{107} without combining resources, it would be very difficult for state attorneys general to successfully counteract this industry advantage. Multi-state litigation creates such an opportunity.

The National Association of Attorneys General (“NAAG”) would play a vital role in coordinating the work of state attorneys general to form multi-state litigation in this area. NAAG is an “organization comprised of federal, state, and regional attorneys general that work together to ‘facilitate interaction among Attorneys General, thereby enhancing their performance…to respond effectively to emerging state and federal issues.’”\textsuperscript{108} In an area as complex and specialized as patent law, NAAG’s involvement would be essential because it would put the necessary people, with the requisite knowledge and expertise, in contact with one another.

Although individual litigation and multi-state litigation lie at opposite ends of the procedural spectrum, there is one other potential strategy state attorneys general could use in order to protect the public from invalid pharmaceutical patents. This strategy combines the benefits of multi-state coordination with the simplicity of individual state action in order to take advantage of the USPTO’s reexamination procedure. As explained above, reexamination forces patent-holders to make preclusive statements about their patents; this

\textsuperscript{106} Telephone Interview with Patrice Jean, Associate, Kenyon & Kenyon LLP (Oct. 25, 2005).

\textsuperscript{107} Id.

essentially creates “open season” to take advantage of brand name drug manufacturers with invalid, or soon to be invalidated, patents.\textsuperscript{109}

Because reexamination before the USPTO is a system anyone can participate in, and ex parte reexamination claims can be brought over and over again, there is an opportunity for individual state attorneys general to repeatedly challenge the validity of a single patent.\textsuperscript{110}

**Explain the effects of repeated challenges: the estoppel effect of evidence and statements made by patentees during ex parte reexamination procedure.**

The procedure for reexamining patents is a system that state attorneys general can use to their advantage. Rather than bringing one single multi-state claim, each individual state attorney general could bring a claim on behalf of his or her state’s citizens before the USPTO. And although reexamination claims would be brought by individual states, NAAG could be utilized to coordinate the claims in an efficient and effective manner, causing the invalid patent-holders to suffer “death by a thousand cuts.”\textsuperscript{111} **Remember, this “death by a thousand cuts” is not an inability to bring an infringement claim, but rather a combination of hundreds of statements which make the patent requested too explicit for a typical defense that the patent defined is ambiguous. Explain this.** The reexamination procedure creates a system which grants state attorneys general vast power to frustrate invalid patent-holders’ tactics. By coordinating individual state claims on a national scale, state attorneys general can take full advantage of the patent reexamination system in order to protect the public interest.

**PART IV: ADVANTAGES OF ATTORNEY GENERAL INVOLVEMENT**

\textsuperscript{109} Id.
\textsuperscript{110} Interview with Eben Moglen, Professor of Law, Columbia Law School, in New York, NY (Nov. 3, 2005).
\textsuperscript{111} Interview with Eben Moglen, Professor of Law, Columbia Law School, in New York, NY (Nov. 3, 2005).
There are a multitude of public policy advantages to state attorneys general engaging in pharmaceutical patent litigation to challenge invalid patents before the USPTO. These benefits include lower health care costs for the state, cheaper prescription drug prices for consumers, increased competition in the pharmaceutical industry, and perhaps most importantly, greater innovation of life-altering prescription drugs by major pharmaceutical companies. Although this paper has focused primarily on the parens patriae powers of state attorneys general to sue private parties in order to protect the public interest, a more well-known role of the attorney general is to litigate on behalf of his or her state. The first benefit of a state attorney general’s action to challenge invalid pharmaceutical patents is the effect it will have on his or her own state’s budget.

Every single state’s attorney general has a legitimate interest to protect the state from invalid patents because the high prescription drug prices that are a result of patent exclusivity are a terrible burden on each state’s budget, particularly through the Medicaid program. Medicaid is a “joint federal-state program that purchases health services for the poor” and “provides coverage for outpatient prescription drugs.” Although prescription drug coverage is optional under federal Medicaid guidelines, every state in the nation offers the coverage to Medicaid enrollees. Prescription drug purchases for the Medicaid program account for a large

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112 Professor James Tierney, Lecture before Fall 2005 Columbia Law School Class Multi-State Litigation: The Role of State Attorneys General, September 8, 2005.

113 Interview with James Tierney, Lecturer-in-Law, Columbia Law School, in New York, NY (October 27, 2005).


115 See Dawn M. Gencarelli, One Pill, Many Prices: Variation in Prescription Drug Prices in Selected Government Programs, National Health Policy Forum Issue Brief No. 807 at 5, August 29, 2005, available at www.volunteersinhealthcare.org/pdfs/DrugPricing_08-29-05.pdf. “All state Medicaid programs offer prescription drug coverage to their Medicaid enrollees even though it is an optional benefit.” Id.
percentage of pharmaceutical company profits. 116 “In 2004, the Medicaid program alone had annual outpatient drug expenditures of $30.6 billion, making it the single largest payer of prescription drugs in the United States.” 117 Because Medicaid is a program shared between federal and state government, states covered $12.2 billion of this amount. 118 The rising cost of Medicaid creates budget crises for many states. 119 It is, therefore, only natural that one solution to rising state budget deficits is to limit Medicaid spending through a reduction in prescription drug expenditures. However, state legislatures have, thus far, been unsuccessful in curbing the increase of prescription drug prices and the corresponding Medicaid costs.

In New York, for example, “[t]otal state government expenditures on prescription drugs are expected to exceed $5 billion dollars” in the 2005-2006 fiscal year, including $4.5 billion for Medicaid beneficiaries. 120 “Almost one fourth (23%) of the total increase in New York’s Medicaid expenditures since 1997 can be attributed to increasing expenditures for prescription drugs and supplies.” 121 Moreover, there is no end in sight to the rising health costs; “[i]f left unchecked, New York’s Medicaid program, already the most expensive in the nation, will

116 See Richard G. Frank, Perspective Election 2004: Prescription Drug Prices, 351 NEW ENG. J. MED. 1375, 1375 (Sept. 30, 2004) In 2002, for example, the United States spent $162.4 billion on prescription drugs; government purchases account for 22% of this spending through the Medicaid program. Id.


118 See id.

119 See ANGELL, supra note 13 at 227. “One of the biggest drains on state budgets is Medicaid, and the fastest-growing component of that is prescription drug spending. States also have to foot the bill for prescription drugs for state employees, and, in some states, for some of the uninsured as well.” Id.


121 Id.
exceed $47 billion in 2005-06.” 122 New York State payments for Medicaid were more than 35% of all state revenue-financed state spending in 2003. 123 Given that one of the greatest challenges facing New York State government is the budget shortfall, 124 reducing the costs of prescription drugs would be very beneficial to the state.

New York is not the only state facing the problem of high prescription drug prices; states all over the country are attempting to address similar Medicaid-related issues. 125 States do not have unlimited budgets, and the only options for funding increased Medicaid costs are either to raise taxes or cut other services and programs. 126 Neither of these choices would be beneficial for any state or its citizens. Every state attorney general, therefore, has a valid reason to litigate, in the interest of his or her state, to reduce the high cost of prescription drug prices. Challenging the validity of pharmaceutical patents is the most viable option to accomplish this goal.

Of course, challenging the validity of certain pharmaceutical patents would not only benefit the state as an entity. Any action in this area by state attorneys general would also be

122 National Education Association of New York, 2005-2006 New York State Education Highlights Proposed by Governor George Pataki, NEA Website, January 27, 2005, available at http://www.neany.org/page.asp?ParentSectionId=35&PageID=259&SectionID=83&NodeId=P259. “A surge in prescription drug spending, a growing elderly population in need of Long Term care services and the increased use of all health care services are combining to drive unprecedented annual Medicaid cost increases.” Id.


very beneficial to the public interest.\textsuperscript{127} One benefit that citizens of a state would gain if an attorney general were to take action would be a reduction in taxes. The possibility of increased taxes to cover the rising costs of Medicaid for states should be a concern for every citizen. If taxes are increased to cover the high cost of prescription drugs, citizens are worse off; state attorneys general could play a major role in preventing the further increase of Medicaid-induced taxes.

Moreover, individuals who are not covered by the Medicaid program do not have the support of fellow taxpayers; many people need to pay for their own prescription drugs. Rising drug costs take more money out of the pockets of consumers. By challenging invalid patents, thereby increasing competition by generic manufacturers, state attorneys general will successfully cause the market price of prescription drugs to fall, or at the very least prevent the costs from rising higher. This might be promoted as a form of consumer protection by state attorneys general, or it might be considered an entirely separate sphere of work; however it is touted, a decrease in prescription drug costs is a valid public interest because it benefits consumers.

Some might argue that an additional, more abstract, benefit to attorney general action in this area is increased competition in the pharmaceutical industry. Most focus is placed on the tangible goals of increased money in the pockets of consumers, lower taxes, and reduced strain on state budgets, but for those who believe in a free and open market, increased competition may be an advantage in itself.

Finally, but perhaps most importantly, state attorneys general can generate greater innovation of life-altering prescription drugs by major pharmaceutical companies in the long-run by taking steps to challenge invalid patents today. Major drug manufacturers currently use teams

\textsuperscript{127} See Miller, \textit{supra} note 39 at 688. “A court judgment that a patent claim is invalid is a public good.” \textit{Id.}
of lawyers to take advantage of loopholes in patent law in order to extend exclusivity rights and prevent competition from generic companies.\textsuperscript{128} If state attorneys general were to challenge invalid patents and were successful in preventing these patent-extending tactics, perhaps, in the long-run, major pharmaceutical companies would begin to focus more time and energy on research and development. Although research and development costs are not as high as the major pharmaceutical manufacturers would like consumers to believe,\textsuperscript{129} they are often too high for small generic companies to cover. Research and development is often cost-prohibitive for small generic competitors.\textsuperscript{130} Therefore, the public relies on the major companies to develop new drugs. However, as discussed in Part I above, major pharmaceutical manufacturers have not developed innovative drugs at the rate the public expects.\textsuperscript{131}

If brand name companies were precluded from using their tactics to extend exclusivity periods because state attorneys general challenged their invalid patents, this would allow generic companies the opportunity to become competitive. In the long-run, this would reduce brand-name companies’ profit margins in re-selling old drugs; major manufacturers might then focus more of their resources on research and development, creating innovation through the use of more advanced research in science and technology. Prescription drugs are necessary in our society, but reproducing the same drugs over and over without innovation is not an efficient use of major pharmaceutical companies’ resources. If the market for already produced-drugs becomes competitive because of lower prices offered by generic companies, perhaps major brand-name companies will have more incentive to use their resources in a more beneficial way.

\textsuperscript{128} See Mason, supra note 27 at 99.

\textsuperscript{129} See ANGELL, supra note 13, at xv.

\textsuperscript{130} See Correa, supra note 29 at 8–9.

\textsuperscript{131} Supra, Note 18.
In addition to the public benefits gained from state attorneys general getting involved in the pharmaceutical patent-challenging area, the attorneys general may, themselves, benefit politically. In forty three states, attorneys general are elected by popular vote.\footnote{See Lynch, supra note 96 at 2002.} Therefore, many state attorneys general consider themselves to be politicians,\footnote{Professor James Tierney, Lecture before Fall 2005 Columbia Law School Class Multi-State Litigation: The Role of State Attorneys General, December 8, 2005.} and many, in fact, seek higher office in the future.\footnote{Id.} Generally, by fighting for lower taxes, state attorneys general will receive a great deal of public support. Whether citizens fully understand the complicated procedures of the patent challenge is essentially irrelevant from a political standpoint; the attorney general of a specific state could muster a great deal of name recognition and political support if he or she announces work that will successfully reduce taxes.

Perhaps even more important, politically, would be the decrease in drug prices. The largest population in need of prescription drugs is the elderly, and studies show that the elderly are the largest and most consistently active voting bloc.\footnote{See generally Michael G. Housman, Senior Power and the Medicare Trust Fund Crisis, 5 Harvard Health Policy Review 133 (Fall 2004), available at http://www.hcs.harvard.edu/~epihc/currentissue/housman.pdf. “The resentment among senior citizens is palpable, and they constitute a powerful voter bloc – a fact not lost on Congress or state legislatures.” Angell, supra note 13 at 15.} “Additionally, the elderly exhibit unrivaled levels of political participation such as contacting their elected officials, attending public meetings, and writing letters to newspapers.”\footnote{Michael G. Housman, Senior Power and the Medicare Trust Fund Crisis, 5 Harvard Health Policy Review 133, 133 (Fall 2004), available at http://www.hcs.harvard.edu/~epihc/currentissue/housman.pdf.} Moreover, the American Association of Retired Persons (“AARP”) is one of the most politically powerful organizations in the country.
With more than 35 million members, it is the nation’s largest membership organization.\textsuperscript{137} “With a single announcement in its Newsletter, the [AARP] can cause legislators to be flooded with more phone calls, telegrams and hand-written letters than any other organization in the country.”\textsuperscript{138} There is no reason to believe that state attorneys general would not receive similar attention if they were to focus on such an important topic. Individual state attorneys general could increase their chances of future political success by focusing on prescription drug prices, an issue that is so close to the hearts and wallets of such an influential group.

**PART V: DISADVANTAGES AND DANGERS OF STATE ATTORNEY GENERAL INVOLVEMENT**

Although there are numerous advantages and reasons for state attorneys general to get involved in pharmaceutical patent litigation, there are disadvantages and dangers that must be considered before such action is taken. There are two basic types of criticism that should be taken into account before a final decision is made as to the proper role of state attorneys general in this area: general opposition to activist state attorneys general, and disadvantages specifically associated with state attorneys general in patent litigation.

The first type of criticism is a generalized fear of state attorney general action. Some scholars claim that activist state attorneys general are dangerous for society. One of the most outspoken critics of the increasing role of state attorneys general is Richard Epstein, professor at The University of Chicago Law School.\textsuperscript{139} Epstein argues that the proper role of government is a limited one; he claims that for government, the most appropriate consideration is, “\emph{primum no

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\textsuperscript{138} Housman, \textit{supra} Note 138 at 133.

\textsuperscript{139} Professor Epstein is the James Parker Hall Distinguished Service Professor of Law and Director of the Law and Economics Program at The University of Chicago Law School (http://www.law.uchicago.edu/faculty/epstein/).
\end{footnotesize}
nocerum, or first, do no harm.” 140 This is a reasonable perspective when government is fulfilling its responsibility to protect its citizens and enforce its laws; however in many areas, including pharmaceutical patent law, the government is not protecting its citizens or enforcing its laws. As discussed above, the under enforcement of current patent laws permits major pharmaceutical companies to engage in monopolistic practices, which ultimately harm American people.

In many situations, certainly, the role of government should be limited; government should not be involved in every aspect of citizens’ lives. However, in some instances, the government needs to take a role in enforcing its laws and protecting citizens. The current practices of major pharmaceutical companies require such action by government. “When you say to government, ‘first do no harm, don’t intervene, don’t get too anxious,’ you have to assume things are going ok.” 141  Currently, at least in the area of health care, things are not ‘going ok.’ Given the skyrocketing costs of medicine, this is not the time to choose government officials “who walk through life without leaving footprints in the snow.” 142

Critics also challenge the work of state attorneys general from a federalism perspective. 143 They argue that when state attorneys general act to regulate major industries, the state actor extends his or her policies beyond the state’s border. 144  “When every state may regulate beyond its borders, national economic actors are subject to fifty overlapping and often conflicting regimes (as well as federal regulation)...the most aggressive state will dictate the terms of business conduct for all fifty states. State regulation will escalate.” 145 If state attorneys general are competing with each other and the federal government, they argue, this will lead to

141 Professor James Tierney, Epstein v. Tierney debate: Is Eliot Spitzer Good for America, Columbia Law School, January 2006
142 Id.
143 See Epstein and Greve’s papers.
144 See Greve’s paper.
145 Greve’s Paper pgs. 9-10.
regulation by “the loudest mouth,” and policy will be created and forced by whoever happens to be the most aggressive actor. Opponents of state attorney general activism argue that “[a] perceived necessity [by federal legislators and regulators] to out-demagogue rival decisionmakers is not a recipe for sound policy,” that it is the “antithesis of constitutional federalism.”

Epstein argues that such a system, in which numerous actors compete to enforce the same laws, leads to “exuberant overenforcement” of the laws, and that “occasional underenforcement” is preferable. However, this theory relies on the assumption that the underenforcement of laws is, in fact, only occasional. In circumstances such as those which exist in the pharmaceutical industry, the problem is not merely occasional underenforcement; the problem is a complete lack of enforcement. When the federal government fails to protect citizens by enforcing its own laws, other regulators have a right, and even a duty, to ensure that the laws are not being broken. Critics argue that “[w]hile federal regulators do fall down on the job now and then, it is unlikely that all of them should do so, all the time, in all of the arenas where the AGs have released their ambitions.” However, in the circumstances when they do ‘fall down on the job,’ shouldn’t there be another regulatory and enforcement mechanism? “Competition in law enforcement is good, because we live in a world where laws are dramatically underenforced, and over time, that competition results in higher quality.” The gaps need to be filled, and state attorneys general are appropriate actors to complement federal enforcement.

146 Epstein, Tierney v. Epstein Debate.
147 Greve’s Paper at 22.
149 Epstein, Tierney v. Epstein Debate.
150 Greve’s Paper at 7.
151 Tierney, Tierney v. Epstein Debate.
Finally, critics argue that an increased role for state attorneys general threatens the separation of powers. Under the Federal Constitution, Congress is divested with “all legislative powers;”\textsuperscript{152} similarly, in states, the conventional wisdom is that the power to make laws belongs to the legislature, the governing body closest to the people.\textsuperscript{153} The executive branch, they argue, exists to enforce the laws enacted by the legislature, and state attorneys general are undermining this important distinction. They claim that state attorneys general are infringing upon the domain of legislators, creating their own policy, and enforcing this policy through litigation, a “government by indictment.”\textsuperscript{154} “Contrary to time-honored principles of representative government, which presume legislative control over taxing and spending decisions, the AGs’ ability to obtain lucrative settlements under open-ended laws means that they send money the legislature’s way, rather than the other way around.”\textsuperscript{155}

The response to this argument is similar to that of the other criticisms of state attorney general activism; the executive officials are merely enforcing the laws enacted by the legislature when other actors in the executive branch fail to do so. State attorneys general are not acting as quasi-legislatures; they are merely enforcing already existing laws in situations where a vacuum has been created by non-enforcement. If state attorneys general were to engage in pharmaceutical patent litigation, they would not be creating public policy; they would not be passing new laws. On the contrary, attorneys general would merely be enforcing the patent law that Congress has already enacted. There is no question that the authority to enact patent law is solely within the power of Congress; an individual state officer does not have the ability to create new laws in this federal realm. However, a state attorney general surely has the power to request

\textsuperscript{152} US Constitution, Article I, Section 1 
\textsuperscript{153} Find something from Federalist Papers. 
\textsuperscript{154} Greve Paper (title) 
\textsuperscript{155} Greve’s Paper, 29.
that the United States Patent and Trademark Office enforce its own laws. Therefore, specifically in the enforcement of patent law through pharmaceutical litigation, fears of undermining the separation of powers should not be a reason to limit the action of state attorneys general.

The second type of criticism launched at state attorneys general is specific to litigation aimed at challenging pharmaceutical patents. Rather than the generalized and somewhat abstract criticism of activist state attorneys general discussed above, this critique points to the inherent drawbacks of their involvement in patent litigation. These arguments are more beneficial to the public policy debate than the generalized, theoretical criticisms of those who simply oppose all state attorney general activism. Rather than resting on generalized theory, the critics who make specific policy arguments focus on the practical problems state attorneys general will face in this area, including procedural hurdles. Critics of state attorney general action in pharmaceutical patent litigation have specific concerns regarding the feasibility of such work, and their concerns are valid and worth discussion. The disadvantages of state attorney general involvement in pharmaceutical patent challenges include the possibility of wasted resources, the lack of an immediate or tangible monetary award, the short-term market disadvantage and possibly hostile public reaction to it, and the criticism and potential political consequences that state attorneys general may confront.

There is a strong possibility that engaging in pharmaceutical patent litigation could cause offices to squander resources that could be better used in other areas. Many state attorneys general offices have scarce resources; there is never enough funding or manpower to accomplish the goals that attorneys general hope to achieve. Any resources or efforts used to challenge invalid patents are necessarily taken from other worthwhile goals. Although coordinating action

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156 Professor James Tierney, Lecture before Fall 2005 Columbia Law School Class Multi-State Litigation: The Role of State Attorneys General, September 22, 2005.
between offices and merging resources and expertise is designed to limit the inefficiency problems associated with individual state attorney general claims, there is still the strong potential for inefficiency and wasted resources.

Moreover, the lack of any immediate reward for efforts in this area may have a number of negative consequences. First and foremost, the complexity of, and expertise needed for, patent law may require state attorneys general to seek the outside assistance of private firms. Private firms, however, may be very reluctant to assist state attorneys general because there is no immediate or tangible monetary reward from patent reexamination claims. The long-term benefits to the public may be immense, but without some form of immediate compensation, it is very difficult to attract the interest of private firms. Additionally, the lack of an immediate reward for the public may dissuade some state attorneys general from diverting resources from other areas such as consumer protection, environmental protection, and antitrust work where immediate monetary gains may be available. In patent reexamination claims, there is no communal award of damages to be utilized for government programs or to be dispersed amongst the effected population. The returns from successfully challenging an invalid patent are great, but they are long-term and therefore often less popular.

Major pharmaceutical companies will, of course, be negatively affected if state attorneys general challenge invalid patents and market exclusivity rights, however the brand name manufacturers are not the only inconvenienced parties. Individual shareholders of major patent-holding pharmaceutical companies, such as Pfizer, Merck, and Bristol-Meyers Squibb, will likely feel the brunt of the new policy. Competition from lower generic drug prices will probably cause brand name manufacturers’ stock prices to fall. Although this competition will

157 See generally Miller, supra note 39.
lead to more drug innovation and presumably increased profits for major companies in the long run, the short term effect will be a sharp decline in stock value.\textsuperscript{158} State attorneys general may be reluctant to sacrifice the funds of short term investors for the long term public interest, and the public will likely be even more reluctant.

Finally, the criticism aimed at state attorneys general for engaging in regulatory action at the federal level will likely increase, especially because the state actors would be challenging and intervening in the work of federal agencies like the United States Patent and Trademark Office and the Food and Drug Administration. Those individuals who object to current multi-state litigation will undoubtedly complain that these actions represent an even greater increase in the encroachment of federal and legislative power by state attorneys general. Such complaints are unlikely to directly alter the goals pursued by state attorneys general; however the criticism can lead to political consequences to which attorneys general are not immune.

As discussed in Part IV, many state attorneys general have political minds.\textsuperscript{159} If public opinion is at all dictated by media coverage, state attorneys general may choose to focus on other problems affecting their constituents. There are a number of more interesting (and less complex) issues that state attorneys general can address which are more ‘media-friendly’ and would likely garner more public support than patent litigation. Moreover, even the state attorney general who is term-limited or otherwise unconcerned with polls or future political aspirations may still face the daunting reality that his or her successor will not continue the effort; this may discourage current state attorneys general from expending the vast resources necessary to accomplish such long-term goals.

\textsuperscript{158} Interview with Eben Moglen, Professor of Law, Columbia Law School, in New York, NY (Nov. 3, 2005).

\textsuperscript{159} Professor James Tierney, Lecture before Fall 2005 Columbia Law School Class \textit{Multi-State Litigation: The Role of State Attorneys General}, December 8, 2005.
CONCLUSION

Although there are dangers to state attorney general involvement in pharmaceutical patent litigation, the benefits far outweigh the disadvantages. The cost of prescription drugs is out of control, and the federal and state governments have, thus far, failed to curb the rising prices. Today, as Americans are living longer, the need for low-cost prescription drugs is more vital than ever before. Skyrocketing prescription drug costs are a detriment to those who need prescription drugs and can’t afford them, and to society as a whole.

The American pharmaceutical industry has the potential to have one of the most beneficial impacts of any business on the interests of the public. Although major pharmaceutical companies currently fail to meet this potential, greater regulation and enforcement of patent law could be a major step toward improving the industry and its ability to serve the public. It is time for state attorneys general to play a role in benefiting society by enforcing pharmaceutical patent laws and promoting changes in the prescription drug industry.