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DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT, 1984 AND THIRTY-MONTH STAY PROVISION

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ABSTRACT

The Hatch-Waxman act of 1984 has been quite successful in increasing the availability of generic drugs, but closer analysis reveals that the Act's provisions relating to patent certification actually delay approval of generic drugs. The following paper addresses the problems arising from the thirty-month stay provision of the Hatch-Waxman Act, evaluates the legitimacy of the provision under accepted philosophical justifications for intellectual property, and suggests possible alternatives for addressing the failures of this provision. This article interprets the complicated Act and examines it with respect to the different theories of intellectual property. The numerous problems caused by the thirty month stay provision, 'evergreening' and 'trip-wire' patenting are also discussed at length. The legal implications of litigation including ethics and anti-trust law are examined. In conclusion, we authors recommend various remedial steps to be taken to exploit the Act to its fullest such that generic drug approval is not unnecessarily delayed.

Keywords: New drug application, Federal trade commission, ANDA: Abbreviated new drug application, FDA.

INTRODUCTION

Brief from the history of 1962, ages of only safety would be the criteria of approving the drug for customers in U.S, and where it was only days of innovator ruling the country. Patent law and the Federal drug approval laws are both rather arcane and complex. The intersection of these two areas in the Hatch-Waxman Act is particularly complicated, and this perhaps explains the failure of the Act to consistently comply with core philosophical principles for supporting the modern intellectual property regime. The following paper addresses the problems arising from the thirty-month stay provision of the Hatch-Waxman Act, evaluates the legitimacy of the provision under accepted philosophical justifications for intellectual property, and suggests possible alternatives for addressing the failures of this provision.

CERTIFICATION PROCEDURE

The Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act, have been quite successful in increasing the availability of generic drugs to consumers. By 1996, forty-three percent of the prescription drugs sold in the United States were generic compared to just nineteen percent in 1984[1], and at present it is 70% of prescription drugs. Despite the Act's overall success in promoting increased availability of generic drugs, the Act's provisions relating to patent certification actually delayed approval of generic drugs.

When a party files a new drug application ("NDA") the Food and Drug Administration ("FDA") may require submission of certain patents. According to CFR §314.53;

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An applicant shall submit information on each patent that claims the drug or method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For purposes this part, such patents consist of drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents. Process patents are not covered by this section.

Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book," is compiled by the US FDA and lists all approved drugs along with official and proprietary names of the drug.[2] When patent information is submitted for a new drug application in accordance with CFR § 314.53, the patent information is included in the Orange Book.[3]

Through the abbreviated new drug application ("ANDA") process, a party may obtain FDA approval of generic drugs without clinical trials if the drug is a bioequivalent of a drug previously granted NDA approval. ANDA approval requires that an applicant make a patent certification "with respect to each patent issued by the United States Patent and Trademark Office that, in the opinion of the applicant and to the best of its knowledge, claims the reference listed drug or claims a use of such listed drug for which the applicant is seeking approval.[4]

Certification requires the ANDA applicant to state that:

- The NDA holder submitted no patent to the FDA
- Any patent submitted has expired
- The date the applicable patent expires
- That "the patent is invalid, unenforceable, or will not be

infringed by the manufacture, use, or sale of the drug product for which the abbreviated application is submitted.[5]

If an ANDA applicant certifies a patent is invalid, unenforceable, or not infringed (a "paragraph IV certification"), the applicant must notify the NDA holder of the certification.[6] After being notified of paragraph IV certification, a NDA holder may sue the ANDA applicant for patent infringement by utilizing 35 U.S.C. § 271(e) (2) (A).[7]

Normally, patent infringement only occurs when an infringer makes, uses, offers for sale, sells, or imports an invention into the United States 35 U.S.C. § 27(e) (2) (A), however makes submission of ANDA application on a patented drug an act of an infringement which cannot be the basis of damage claims but can result in injunctive relief which prevents approval, sale, or use of the generic drug until after the NDA holder's patent expires.[8]

If the NDA holder files suit within forty-five days of paragraph IV certification, the thirty-month stay provision is triggered so that the ANDA application will not be approved for thirty months.[9] The delay is statutory and automatic. The NDA holder does not need to show any likelihood of success on the merits (Recent amendments made after 2003, to approve only single 30-month stay for 'n'-number of patents listed in orange book).

The statute provides limited opportunities for the ANDA applicant, to gain approval before thirty-months passes. First, the court can extend or reduce the thirty-month delay if either party fails "to cooperate in reasonably expediting the action [the patent litigation].[10] A court reduction in the thirty-month stay period is probably unlikely barring serious abuse of the litigation process, for example discovery stall tactics.

Second, the thirty-month period will expire if a court issues a final order determining that the patent is invalid, unenforceable, or not infringed[11] Presumably, a "final order" includes a summary judgment or trial verdict on the merits. Unfortunately for ANDA applicants, summary judgment or a trial verdict on these issues is unlikely until after a *Markman* hearing has occurred in order to determine the scope of the NDA holder's patent.[12] A *Markman* hearing typically requires full-blown discovery, use of experts, and other extensive trial preparations.[13]

Even after a *Markman* hearing, summary judgment may not be available. In this case, the stay period will not expire until after a complete and lengthy jury trial on the merits of patent validity and infringement. Therefore, as long as a NDA holder is unwilling to settle, the ANDA holder cannot expect that their ANDA application will be approved quickly.

ANDA STAY PROVISION AND PRELIMINARY INJUNCTION PRACTICE

The scope of exclusivity granted by the FDA's thirty month stay provision under 21 C.F.R. § 314.107(b)(3)(i)(A) has the same effect as a preliminary injunction because the provision prevents the ANDA applicant from producing, selling, or using its applied for drug product until a trial decision is made in the ANDA applicant's favor. Because of the statute has a similar result to a preliminary injunction, it is useful to compare the differences in how these to results are obtained.

A patent holder seeking a preliminary injunction against an alleged infringer must demonstrate:

- a reasonable likelihood of success on the merits;
- irreparable harm if an injunction is not granted
- a balance of hardships tipping in its favor
- the injunction's favorable impact on the public interest.[14]

The factors taken individually are not dispositive; instead, a district court in its discretion "must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested.[15]

Showing the first two factors, likelihood of success and irreparable harm, are essential if a preliminary injunction is to be granted.[16] The preliminary injunction should not issue if the alleged infringer raises an infringement or invalidity defense that the plaintiff cannot prove "lacks substantial merit.[17] For example, if the defense puts forth evidence of invalidity insufficient to prove invalidity on summary judgment yet "presents a serious challenge to validity" to be assessed at trial, the preliminary injunction will not be granted.[18]

In contrast to the requirements for issuance of a preliminary injunction, the FDA's thirty-month stay provision under 21 C.F.R. § 314.107 takes effect regardless of likelihood of success or irreparable harm. If a NDA holder files suit, the ANDA applicant's entry into the market is delayed for thirty months or until the ANDA applicant receives a favorable verdict even where the NDA holder has a very small chance of success on the merits of the suit. The ANDA applicant's barrier to entry remains absolute even where the ANDA holder presents powerful defenses that either tend to show non-infringement or presents serious challenges to validity of the NDA holder's patents. Further, the stay provision is effective even though the only harm of ANDA approval to the NDA holder may be monetary so that no threat of irreparable harm exists.

NDA holders gain a scope of protection on their patents allowing immediate injunctions against competition even if the patents are likely to be found invalid or to narrow to cover the ANDA applicant's product. No other patent holders enjoy this broadened scope of preliminary protection. Instead, other patent holders must seek preliminary injunctions that are available only when the relevant patent is likely to be found valid and where infringement is likely. Without being able to make these showings, the patent holder can only seek damages after the fact of infringement and cannot prevent the competitor from making, using, or selling the patented product during the lengthy trial process.

TACTICAL USE OF THE THIRTY-MONTH STAY PROVISION

Because the thirty-month stay provision takes effect automatically, NDA holders have a very significant incentive to file suit against ANDA applicants even where the merits of the case are weak. Additionally, the power of the thirty-month stay provision provides incentive for NDA holders to list as many patents as possible in the Orange Book in order to ensure that competitors will need to make a paragraph IV certification even after a primary patent covering the NDA product has expired. The practice of prosecuting and listing secondary patents is referred to as "evergreening" or "trip wire" listing of patents.[19]

In recent years, NDA holders have often brought suit against an ANDA applicant where the cases have had little merit, yet initiating the litigation nonetheless triggers the

thirty-month stay period and delays ANDA approval. For example, a NDA holder may engage in a strained legal argument for extending the life of a patent in order to sustain a lawsuit for a period of time.

In 1995, Geneva and Noropharm filed ANDA applications to produce generic terazosin hydrochloride[20] Abbott Laboratories sued each of these applicants on the basis of a patent that rather clearly expired on October 15, 1994[21] Abbott used a strained legal argument (asserting that the twenty-year patent term should start from the filing date of the divisional application rather than the original parent application) to claim that the patent really would not expire until January 21, 1997 in order to list the patent's expiration in the Orange Book as that date and in order to bring suit against the ANDA applicants thus triggering the ANDA stay provision.[22]

The district court dismissed Abbott's case pursuant to FRCP 12(b)(6) on March 16, 1996, and the Federal Circuit affirmed this dismissal in a succinct January 14, 1997 opinion[23], Here, the ANDA applicants had a clear cut case (clear enough to win the case on a motion to dismiss), but the barest legal argument as to why Abbott's patent should have expired in January 21, 1997 allowed Abbott to trigger the thirty-month stay provision and perpetuate the monopoly on its NDA product for over a year past the expiration date of their patent. The problem is exacerbated by the FDA's apparent lack of review or understanding of the patent laws in that it blindly accepted for the Orange Book Abbott's assertion that its patent would expire in 1997 and used this assertion to deny ANDA approval to two competitors.

In addition to triggering the ANDA stay provision by arguing for extended patent terms, NDA holders trigger the stay provisions by suing based on unsustainably broad readings of their patents. Elan Corporation submitted an ANDA for a high blood pressure medication on April 30, 1997.[24] The SSA (surface area per weight) of Elan's product was 6.15 m^2/g while Bayer intentionally changed its patent during the course of prosecution so that it covered ranges from 1.0 to 4 m^2/g instead of 1.0 to 6 m^2/g.[25] Nonetheless, Bayer brought suit triggering the thirty-month stay provision.

The Federal Circuit upheld summary judgment in favor Elan and found that Bayer's patent could not possibly cover Élan's product literally or under the doctrine of equivalents because Bayer had "made statements of clear and unmistakable surrender of subject matter outside the claimed SSA range of 1.0 to 4 m^2/g.[26] Despite the fact that Bayer's patent clearly did not cover Elan's product, Bayer's strained argument for a broad scope of its claims triggered the thirty-month stay provision and delayed Elan's ANDA application at least until March 16, 1999 when the district court granted summary judgment in Elan's favor.[27] Bayer thus extended the monopoly on its NDA product for nearly two years by keeping a product not covered by its patents out of the marketplace.

Many other lawsuits have been filed triggering the ANDA thirty-month stay provision based on an argument for an unsustainably broad reading of patent claims. The litigation over a secondary Marrion Merrell Dow patent covering Seldane (the primary Seldane patent expired before Norton filed an ANDA application) lasted thirty months before Baker Norton was granted summary judgment on the issues of literal infringement and infringement under the doctrine of equivalents[28] Thus, Marrion used a "trip wire" patent to gain the entire benefit of the thirty-month stay provision even though the case for infringement was not even strong enough to withstand a motion for summary judgment.

The possible scenarios and tactical litigation moves that can arise are further complicated by the fact that the first ANDA applicant to make a paragraph IV certification is granted 180 days of exclusive production before a second ANDA applicant can gain approval for its application[29] *Mova Pharmaceuticals v. Shalala* illustrates the kind of situation that may arise[30] Mova filed an ANDA application to produce a generic diabetes drug in December 1994.[31] The NDA holder, Upjohn, filed suit to trigger the thirty-month stay provision.[32] Eight months later, a third company, Mylan Pharmaceuticals Inc. filed its own ANDA, and Upjohn did not challenge the certification by Mova within forty-five days so the thirty-month stay provision was not triggered.[33]

The FDA granted the one hundred eighty day exclusivity period to Mylan instead of Mova since Mylan had not yet "successfully defended" itself against Upjohn.[34] Mova challenged this decision and ultimately prevailed in April 1998 when the D.C. Circuit held that the FDA's successful defense requirement was unsustainable based on Congress's statutory language.[35]

The complicated statutory construction issues surrounding the 180-day exclusivity period addressed by the D.C. Circuit obscures the overall picture of what happened in this case. Upjohn sued Mylan in February 1997, and the trial court ruled that Upjohn's patent was *invalid* and not infringed on March 31, 1998.[36] At least two generic drug manufacturers wanted to compete with Upjohn, but one competitor ANDA approval was delayed from December 1994 to June 1997 because the thirty-month stay period was triggered on the basis of a patent that was ultimately found to be invalid and entitled to no legal weight whatsoever. Upjohn, in deciding whether or not to use an invalid patent to sue a particular ANDA applicant making a paragraph IV certification within fifteen days of notification, wielded the incredible power of determining who, if anyone, it would compete with.

The problematic interaction between the thirty-month stay provision and 180-day exclusivity period is illustrated by a footnote in the *Mova* case.[37] An *amicus* brief by Biovail Corporation reveals that it was the second applicant to file a paragraph IV certification for a heart medication.[38] The first ANDA applicant was sued the NDA holder for patent infringement, and Biovail claimed that the NDA holder was paying the ANDA holder $10 million per quarter in exchange for the first applicant agreeing not to sell its product after the 30-month stay provision expires.[39] Thus, both the first applicant and NDA holder had incentive to drag out the patent litigation in order to keep Biovail out of the market. Although antitrust law may be available to deter this kind of behavior[40], the situation illustrates that the ANDA 30-month stay provision combined with the 180-day exclusivity provision can create situations which neither further the intellectual property regime's role in providing innovation incentives nor further the Hatch Waxman's goal of expediting generic drugs to the marketplace.

The incentive of NDA holders to list as many patents in the Orange Book as possible ("land mine" patents) exacerbates thirty-month stay provision problems. Regulations allow "drug substance (ingredient) patents,

drug product (formulation and composition) patents, and method of use patents" to be listed in the Orange Book.[41] Thus, pharmaceutical companies often list "unapproved uses, special crystalline forms of the active ingredient, specific formulations, tablet shape or other subject matter.[42] A patent on narrow subject matter such as a special crystalline form or tablet shape would not cover an ANDA applicant's proposed use of the same drug unless the applicant was using the exact same special form or shape.[43] Nonetheless, if an ANDA applicant certifies against these narrow patents, the NDA holder may sue the ANDA applicant to trigger the thirty-month stay provision.

In one article, Terry G. Mahn, a partner at Fish & Richardson, P.C., explicitly recommends that patent prosecutors practice "evergreening" and "trip wire" listing of patents.[44] Chemical intermediates of a NDA drug and even things loosely associated with the drug, like a patent on adhesive for a transdermal patch, can be listed in the Orange Book thus allowing the NDA holder to file suit and trigger the ANDA stay provision.[45] Mahn acknowledges that this kind of bootstrapping "may not be fair; however, it is allowed" since the FDA has never sanctioned anyone for listing something in the Orange Book improperly and there has never been a proceeding brought for an unauthorized filing.[46]

OPTIONS AVAILABLE TO ANDA APPLICANTS

An ANDA applicant who wants to avoid the thirty-month stay provision and faces patents listed in the Orange Book which do not cover the NDA drug itself but instead cover narrow forms of the drug or irrelevant uses for the drug (unapproved uses) has a very limited number of undesirable legal options available to it. The applicant either must argue to the FDA or to a court that paragraph IV certification should not be required or must certify against all the patents listed in the Orange Book and hope to have the inevitable lawsuit by the NDA holder dismissed on the merits as soon as possible to end the thirty-month stay.

The ANDA regulations require that certifications be made only against patents "which claims the reference [Orange Book] listed drug or that claims a use of such listed drug.[47] To "claim" the drug, according to the patent law definition of "claim," a patent's claim section would have to include every element directed at the drug and no other elements. For example, a patent having claims that include elements of the drug and elements of packaging does not "claim" the drug.[48] The code suggests that the term "drug" includes only drug products (dosage forms) and drug substances (active ingredients).[49]

In cases where a patent's claimed elements include more than dosage form or active ingredient (for example, the patent may include packaging elements or crystalline form elements irrelevant to the active ingredient), an ANDA applicant might be able to convince the FDA or a court that it does not need to certify against patents even though they are listed in the Orange book because the patents "claim" more than the drug, not the drug itself. Alternatively, the ANDA applicant may argue that the patents should be removed from the Orange Book because the patent does not claim the drug, and that once removed, the patents need not be certified against. Each of these approaches presents difficulties.

FDA regulation interpretations indicate that, in the FDA's view, an ANDA applicant must certify against every patent listed in the Orange Book. The FDA has "determined that 'Congress intended that an ANDA applicant need only consult the Orange Book to determine the existence of an applicable patent claiming the listed drug or use of the listed drug.[50] The FDA has explained that "[t]he Orange Book 'provides notice to potential ANDA applicants of the patents which may protect the pioneer drug product, thus allowing them to provide appropriate certification under the act.[51]

The FDA's view is supported by the regulations' mechanism for challenging disputed patent.[52] Existence of a formal procedure for disputing an Orange Book listing implies that third parties would have a reason, such as required certification, to dispute a listing. The FDA statements quoted by the *Abbott* court combined with the formal procedure for ANDA applicants to challenge the relevancy of information listed in the Orange Book indicates that the FDA is likely to interpret the code as requiring certification against all patents listed under a drug in the Orange Book.

The FDA's stance on the issue is critical if an ANDA applicant hopes to receive approval without an extended delay due to a court challenge of the FDA's position. A suit challenging the FDA's requirement that a certain Orange Book patent be certified against could itself take thirty months to resolve, thus being useless in preventing delay. Further, if an ANDA applicant argued in court that it need not certify against a patent listed in the Orange Book, the FDA's stance carries substantial weight because "an agency's construction of a statute it is charged with enforcing is entitled to deference if it is reasonable and not in conflict with the expressed intent of Congress.[53]

Because the FDA is likely to rule that an ANDA applicant must provide certification against any patent listed in the Orange Book without evaluating whether or not the listed patent claims the drug or drug product, an ANDA applicant may wish to remove a patent from the Orange Book before refusing to certify against the patent. The Supreme Court in dicta stated that "ANDA's and paper NDA's are required to contain one of the four certifications with respect to each patent named in the pioneer drug application" thus implying that no certification needs to be made against patents not included in the Orange Book.[54] Further, the FDA's interpretation states that an ANDA applicant should only need to consult the Orange Book in determining what certifications is necessary.[55]

Unfortunately for ANDA applicants, it is rather difficult to have a patent removed from the Orange Book. The regulations allow ANDA applicants to dispute "the accuracy or relevance of patent information.[56] Under this regulation, a party disputing a patent listing must inform the FDA of its grounds of disagreement with the patent's inclusion.[57] The FDA then requests the NDA holder to withdraw or amend its patent information.[58] If the NDA holder refuses, the Orange Book remains unchanged and the ANDA applicant must certify against every listed patent[59], since the regulation puts NDA patent listing entirely at the control of the NDA holder, the procedure provides no hope of relief for ANDA applicants who feel a patent is listed improperly.

A district court may however issue a declaratory judgment that a NDA holder must remove a patent from the Orange Book.[60] In *Ben Venue Laboratories, Inc. v. Novartis Pharmaceutical Corp.*, the court gave the FDA's listing of a patent some deference since the FDA has rejected patents in the past.[61] However, the Court held that an Orange Book

listing creates no presumption that the patent is listed correctly because the FDA lacks resources and expertise to properly review submitted patents.[62] Therefore, an ANDA applicant could perhaps avoid the thirty-month stay provision by challenging, in court, a patent's inclusion in the Orange Book. However, lawsuits are often lengthy processes, and a lawsuit challenging an Orange Book listing could delay ANDA approval almost as much, or perhaps even more, than the thirty-month stay provision.

Strategies involving refusal to certify or removal of a patent from the Orange Book rely on the argument that the patents do not claim the NDA approved drug or use. If the patents claim legitimate variants of the drug or drug use, there is no way an ANDA applicant can argue that they need not certify against these patents even if the patents claim variants which are not useful or are irrelevant to ANDA applicant's proposed product.

If an ANDA applicant is unable to reasonably argue that it need not certify against a NDA holder's patent or is unwilling to go through what may be a lengthy court battle to have a patent removed from the Orange book, the only option is to certify against the NDA holder's patent, wait for the NDA holder's lawsuit to trigger the thirty-month stay provision, and try to get the lawsuit dismissed as quickly as possible. The problem with this situation is that the stay provision acts like a preliminary injunction entered against the ANDA applicant regardless of the merits of the NDA holder's case or of the lack of irreparable harm the NDA holder would suffer.[63] To avoid the injunction, the ANDA applicant must obtain dismissal by showing that the NDA holder's suit could not be successful even if all facts are favorable to the NDA holder, where under a normal preliminary injunction standard the NDA holder would have the burden of showing a likelihood of the suit's success on the merits.

INCENTIVES OF PATENT LAW

Exclusive rights granted for the originator of an invention or creative work, intellectual property rights, are well recognized in the modern laws of nearly every nation.[64] In fact, the Constitution specifically allows Congress "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.[65] The primary question when formulating intellectual property regimes is, "How much exclusivity should be granted and for what period of time?"

A number of principle philosophical foundations for privileging intellectual property rights exist. The foundations can help inform policy makers on what extent of intellectual property rights should be granted. Specifically, the ANDA thirty-month stay provision can be evaluated on the basis of how well the provision furthers the goals addressed by these philosophical foundations.

The United States patent law regime, according to most courts, is primarily concerned with providing an economic incentive for invention. The U.S. Supreme Court has stated that, "The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge.[66] People are more likely to invent new products if they get an award in the form of the exclusive right to sell the product because the exclusive right to sell often translates into the ability to charge significant royalties for the invention compared to the price that would be charged if competition existed.

The ability of the patent law to encourage development of knowledge through incentives must be weighed against the harm caused by the "patent monopoly.[67] Ultimately, the inventor's royalty results in higher prices for consumers of the invention and perhaps a reduced output of production of the invention.[68] Higher cost and lower output of the invention may mean that the public resorts to inefficient alternatives or in some cases goes without the utility the invention would provide, and thus, the public utility may not be maximized.

Applying a utilitarian or economic standard to drug patents is an especially delicate balance. Obviously, for utilitarian and humanitarian reasons, the development of promising new drugs should remain a very high priority, and the government should maximize incentives for developing these new drugs. On the other hand, the costs of one inventor maintaining a monopoly on a drug are also quite high. Patient demand for a much needed drug is relatively inelastic, so the royalty on a drug monopoly can be very costly to consumers.

The ANDA thirty-month stay provision is problematic from an economic or utilitarian perspective for several reasons. First, an NDA holder may sue an applicant based on any patent listed in the Orange Book for which it can make even the most strained argument for infringement. Many of these patents cover "unapproved uses, special crystalline forms of the active ingredient, specific formulations, tablet shape or other subject matter[69]" which may or may not be truly useful or practical in a real world setting.[70] For drugs, efficacy in a laboratory experiment is sufficient to meet the utility requirement of patent law[71] even though efficacy in a laboratory experiment certainly does not mean the drug would be useful in a wide variety of human patients or could possibly be made commercially viable.

Thus, the thirty-month stay provision extends the patent monopoly on a drug sold by the NDA holder while potentially only encouraging the NDA holder to prosecute and file suit on patents that disclose inventions that really do not help society at all. In these cases, the stay provision clearly is not supported by an economic or utility maximizing approach to patent law since the provision does nothing to encourage useful drug development while society suffers all the costs of the patent monopoly.

Secondly, the thirty-month stay provision encourages drug companies to file suit against an ANDA applicant based on unsustainably broad interpretations of their patent claims. For example, Bayer was able to utilize the thirty-month stay provision to prevent Elan from selling a drug with a measured SSA of 6.15 m^2/g on the basis of a Bayer patent listed in the Orange Book which only claimed a range of 1.0 to 4 m^2/g.[72] Bayer's patent is the only legal instrument which documents what Bayer has invented and what knowledge Bayer has contributed to the world in exchange for a patent monopoly, and according to this document, Bayer did not invent any variant of the drug having a SSA greater than 4 m^2/g. Bayer may have drafted and amended its claims to avoid this greater range because another entity previously invented the drug in the higher SSA range, because it did not believe the drug would be useful in the higher range, or possibly because it did not know the drug was useful or possible to manufacture in the higher range.

Regardless, Bayer was able to exert a thirty-month monopoly over a product it never invented because of the

presumptive preliminary injunction effect of the thirty-month stay provision. The thirty-month stay provision triggered the negative patent monopoly effect of intellectual property law without society being able to reap any innovation. Additionally, Elan's product was kept from consumers even though it may have been more innovative that Bayer's patent if it is the case that Bayer never considered a high SSA range. The thirty-month stay provision could, in a situation like this, reduce the incentive for a company like Elan to develop new drug products.

Third, the thirty-month stay provision does not particularly encourage patents on the core commercial drug invention but instead encourages the practice of listing "evergreening" and "trip wire" patents.[73] In order to promote maximum utility and economic efficiency in society, it would be far better to encourage development on useful core drug inventions instead of encouraging drug companies to spend resources devising and identifying non-useful sub-inventions that may act as "trip wire" patents.

A fourth problem with the thirty-month stay provision from an economic or utility maximizing perspective is that it encourages drug company emphasis on profits through patents in general. One problem with patents is that their power to encourage invention is limited by the ability of consumers to pay monopoly rents. The patent system works very well in encouraging development of drugs that benefit, no matter how slightly, the part of the population that can afford monopoly rents (Viagra and Rogaine are examples). The patent law does very little to encourage development of drugs that will help people who cannot afford to pay for drugs even where the benefit for society as a whole is potentially very large (drugs to treat AIDs and malaria in the impoverished African nations for example).

The most economically efficient system would encourage that drugs be developed that will help society the most for the minimum research costs, rather than encouraging development of drugs that help the wealthy segment of the population slightly at greater research expense. To reach greater efficiency than the patent system allows, the public could, for example, divert funds from monopoly rents paid to patent holders toward direct government subsidies for drug researchers developing drugs which attack the most devastating diseases that affect the greatest number of people.

The thirty-month stay provision enhances the value of patents in a vague way by allowing the patent to be used to significantly delay ANDA approval regardless of whether the patent actually covers the ANDA drug as long as some argument for infringement can be made. By enhancing the value of patents, the stay provision encourages drug companies to focus on the kind of drugs that are made most valuable by patents, namely those drugs which are marketable to people have the money to pay monopoly rents. Since drugs that provide slight utility to wealthy people are not necessarily the drugs that provide maximum utility to the human population as a whole, the thirty-month stay provision, and patent law for new drugs generally, is not necessarily an efficient means for providing incentives for drug invention.

A fifth problem with the thirty-month stay provision is that any gains it may provide to a company are too unpredictable and speculative to be substantial incentive for research and development. The drug company's primary patent on a new drug protects the company's monopoly on the NDA product for at least twenty years from the date the patent is filed. "Evergreening" or "trip wire" patents which might trigger the thirty-month stay of ANDA approval would not have value until after the primary patent which prevents others from manufacturing and selling the drug has expired.

During the twenty-year life of the primary patent, a better drug or treatment technology could potentially be developed thus making the potentiality of a thirty-month stay of competing ANDAs worthless. The thirty-month stay provision could be rescinded or reinterpreted not to be triggered upon suits based on "trip wire" patents again making the stay provision worthless. After twenty years, there may be no need to exclude ANDA competitors as it could be that no significant competitor exists.

Since, ex ante, a drug company or inventor is likely to consider the potential gains from the thirty-month stay provision merely speculative rather than significant, the stay provision provides very little incentive for new drug manufacture. The stay provision is thus economically inefficient since it not likely to provide the public with the benefit of new drugs even though the public pays the full price of the thirty-month patent monopoly whenever a company triggers the stay provision.

There more efficient possibilities for encouraging research and development of new drugs rather than allowing new drug applicants to block ANDA applications based on patents which would not meet a preliminary injunction standard. One possibility, mentioned above, is that the public's payments toward patent monopoly rents could be shifted towards direct research for the most needed drugs. In this scenario, the thirty-month stay provision would decrease in importance as drug patents in general decrease in importance to drug companies.

Another possibility is an accelerated FDA review of new drug applications. Accelerated review of FDA new drug applications could greatly increase profits by allowing the NDA holder's product to get to market more quickly. Accelerated review is worth more to companies, and is thus a better incentive, than future delay of competition in the marketplace through the thirty-month stay provision. The value from future delay of competition may be several years away and thus any gains must be discounted against the time value of money.[74]

ANTITRUST LIMITATIONS (DJ & FTC)

Because a lawsuit brought in order to trigger the thirty-month stay provision is brought in order to maintain a monopoly, antitrust law is implicated. The FTC has filed complaints against NDA holders who conspire with an ANDA applicant to prevent generic products from reaching the marketplace. In reaching a settlement with Abbott Laboratories and Geneva Pharmaceuticals Inc., the FTC required the companies to stipulate that they will not enter contracts where an ANDA applicant agrees with a NDA holder not to waive or transfer exclusivity rights or produce a generic product. The settlement also requires any agreement during pending patent litigation involving payment of ANDA applicants by NDA holders to prevent production of generic drugs be approved by the court.[75]

The FTC's enforcement actions are attacking situations similar to those that arose in *In re Cardizem CD Antitrust Litigation.* In this case, the court held that drug companies

could be liable for violation of the Sherman Act because of agreements where a NDA holder pays an ANDA applicant not to market a generic product, even if the agreement is incidental to a patent suit.

Even if agreements between NDA holders and ANDA applicants are likely to give rise to significant antitrust issues as in *In re Cardizem CD Antitrust Litigation*, it is far less likely that the single act of an individual NDA holder suing a ANDA applicant implicates antitrust law. *Noerr-Pennington* doctrine generally gives antitrust immunity parties who engage in legitimate government petitioning activity even if some injury to competition results directly or indirectly. The *Noerr-Pennington* doctrine has extended antitrust immunity to "non-sham, pre-litigation threats of suit, demand letters, and communications about pending suits. This extension combined with an immunity extended to an antitrust defendant's refusal to settle, makes clear that invoking litigation itself is immune from antitrust liability even if there are anticompetitive results.

Noerr acknowledged however that petitions to the government are not immune when they are merely a "sham'' To determine if litigation is a sham, it must be "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. Secondly, in sham litigation, "the baseless suit conceals an attempt to interfere directly with the business relationships of a competitor.

The first prong in proving antitrust violation through sham litigation may be difficult, for many excluded generic drug manufacturers to prove when formulating an antitrust claim. Specific facts supporting an objectively baseless claim must be alleged.[76] In *In re Cardizem*, the State Law Plaintiffs alleged sufficient facts to state a claim by asserting that the generic manufacturer provided samples of the product to the NDA holder, Hoechst, for them to evaluate and confirm no infringement and that Hoechst prosecuted and listed in the Orange Book a second patent which has no significant change or improvement to the original product but instead was prosecuted and listed for the purposes of initiating litigation and triggering the thirty-month stay provision. In other words, the "trip wire" patents recommended by Terry Mahn[77] could give rise to antitrust liability if they are sought for the sole purpose of triggering the thirty-month ANDA stay provision.[78]

CONCLUSION

The statutory thirty-month stay of approval triggered by paragraph IV certification and subsequent patent infringement suit by the NDA holder is not efficient when evaluated under any of the prevalent norms justifying intellectual property regimes. The thirty-month stay provision allows NDA applicants to prevent generic drugs from entering the marketplace on the basis of expired patents, unsustainably broad readings of core patents on the NDA product, and "trip wire" or "evergreening" patents which do not reflect substantial change or improvement over an original patent but are prosecuted for the sole purpose of triggering the stay provision.

The problems created by Hatch-Waxman Act's creation of the thirty-month stay provision should be addressed at many levels. First and most obviously, Congress should repeal the certification requirement for ANDA applicants. NDA holders would still be able to protect their innovations through standard patent law enforcement just like any other inventors. NDA holders would simply no longer benefit from special treatment. Even if Congress does not act, other entities can minimize the problems created by the thirty-month stay provision.

The FDA should interpret Hatch-Waxman Act within statutory constraints in order to minimize the stay provision's effect. The FDA could reasonably interpret the Hatch-Waxman Act to only allow core patents directly covering the NDA product to be listed in the Orange Book, and rigorously review all patents submitted for inclusion in the Orange Book for suitability. Additionally, the FDA could evaluate the expiration of dates submitted to the Orange Book rather than simply taking applicants at their word. These two steps would eliminate the problem the stay provision being triggered by "trip-wire" patents and by expired patents.

Third, courts should more freely exercise their discretion under the Hatch-Waxman Act to modify the length of the stay based on the plaintiff or defendant's failure "to cooperate reasonably in expediting the action. Courts could potentially, under this provision, reduce the length of the thirty-month stay to zero where the plaintiff's action has such an extremely small chance on the merits that the NDA's filing of the suit or the NDA holder's failure to settle the action for a nominal amount constitutes failure to expedite the action. By utilizing available discretion in this manner, the courts can reduce the problems caused by thirty-month stay provision while discouraging frivolous and nearly frivolous actions in their court. A court utilizing this discretion brings might analyze the thirty-month stay provision using standards similar to those historically accepted for preliminary injunctions.

Fourth, the FTC and parties excluded from the generic drug market because of the thirty-month stay provision may seek remedies through antitrust laws in some cases. Although the burden of proving that a claim is objectively baseless may not be easy to overcome and the process of litigating an antitrust trial may take well over thirty months, the possibility of treble damages calculated on the basis of the generic drug manufacturer's lost profits during the thirty months could bring enough pressure on NDA holders that at least the most frivolous patent cases would be settled.

Finally, individual attorneys should refuse to pursue patent prosecution or litigation that has little merit even if the client desires to trigger the thirty-month stay provision. An attorney's interest in maintaining a professional reputation by advancing only positions with potential merit before the Patent and Trademark Office and before the Federal Courts along with the attorney's individual sense of morality and justice should serve, to some extent, to prevent the attorney from engaging in litigation and patent prosecution that is merely tactical. To best serve society, attorneys should aspire to substantively promoting justice and the state of the law of the law through client advocacy rather than invoking meritless suits merely because the suit serves a client's immediate interest such as triggering the thirty-month stay provision.

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63. See id. at 973 (quoting The Standard English translation of GRUNDLINIEN DER PHILOSOPHIE DES RECHTS is PHILOSOPHY OF RIGHT (T. Knox trans. 1942) at 45.

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65. A wealthy person is better equipped to survive if they lose their job or societal connections due to illness because they have saved capital. Second, a wealthy person can afford luxuries which may distract themselves from the sickness or otherwise make the sickness more tolerable.

66. Even if the case is decided on motion for summary judgment, it could easily be thirty months from the time the suit is initiated to the time summary judgment motions are decided. See, e.g., Marrion Merrell Dow Inc. v. Baker Norton Pharmaceuticals, Inc., 948 F.Supp. 1050 (S.D.Fla. 1996).

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