IDEA: The Journal of Law and Technology

1999

39 J.L. & TECH. 389

SPECIAL PATENT PROVISIONS FOR PHARMACEUTICALS: HAVE THEY OUTLIVED THEIR USEFULNESS?

A POLITICAL, LEGISLATIVE AND LEGAL HISTORY OF U.S. LAW AND OBSERVATIONS FOR THE FUTURE

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I. Introduction

The Drug Price Competition and Patent Term Restoration Act of 1984 n1 ("the '84 Act") was an unprecedented attempt to achieve two seemingly contradictory objectives, namely, 1) to make lower-costing generic copies of approved drugs more widely available and 2) to assure that there were adequate incentives to invest in the development of new drugs. According to a recent study released by the Congressional Budget

[*390] Office n2 ("CBO"), by 1996 forty-three percent of the prescription drugs sold in the United States were generic, as compared to just nineteen percent in 1984. Moreover, substitution of generic drugs for brand-name counterparts saved consumers roughly $ 8 to $ 10 billion in 1994. Although not mentioned in the CBO study, the size and wealth of the research-based pharmaceutical industry has grown enormously since 1984. Financial publications abound with reports that sales and earnings in the industry are at record highs, and annual returns on equity and profitability continue to reach levels that far exceed the returns in other industries. n3 Most importantly, the re-investment of those profits in research, both in total dollars and as a percentage of sales, are at their highest points in history. Innovation is also being spurred by an enormous and rapidly growing federal expenditure for health- related research that now exceeds $ 10 billion and is headed for $ 20 billion per year over the next several years.

The '84 Act includes several modifications to conventional patent law including:

Provisions allowing for the extension of the normal term of a patent for up to five years to compensate a patent owner for the marketing time allegedly lost in satisfying government regulations requiring proof that a drug is safe and effective before it can be marketed. n4

A novel statutory exemption from claims of patent infringement for those acts of making, using, or selling a patented invention which are reasonably related to seeking FDA approval to market a drug, provided that no commercial use of a patented invention occurs before the patent expires. n5

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Special procedures for challenging the validity or infringement of drug patents which, in effect, guaranteed the patent owner a statutory preliminary injunction for a period of thirty months unless the adjudication was completed in a shorter time. n6

A "bounty" for challenging patent validity, infringement or enforceability in the form of 180 days of market exclusivity to the first generic applicant to file a patent challenge against any approved drug. n7

It is tempting to conclude that these unprecedented changes in patent law were responsible for producing an economic miracle in which the explosive growth in availability of generic drugs coexists with record profits and record investment in innovation by major pharmaceutical companies. Thus, until now, Congress has avoided revisiting the '84 Act on the theory that it was a delicately balanced compromise which was working well. However, Sen. Hatch (R-Utah), a critical sponsor of the '84 Act, has now joined the chorus of voices questioning the effectiveness of one or more of the patent provisions n8 and has promised congressional action during this session of the 106th Congress. This promised legislative initiative comes at time when 1) the Canadian version of the Bolar exemption is under formal attack before the World Trade Organization as an alleged violation of the patent exclusivity guarantees embodied in the intellectual property agreement (TRIPs) of the Uruguay Round of the GATT Treaty and 2) the Federal Trade Commission is investigating alleged misuse of the thirty-month statutory preliminary injunction by pharmaceutical patent owners and the 180-day generic exclusivity provision by generic drug manufacturers.

Each of the patent provisions of the '84 Act was born as part of a unique legislative process which, in reality, was a congressionally supervised negotiation between the generic and brand-name pharmaceutical industries in which the parties were compelled to reach a compromise by the legislature. Not surprisingly, a combination of mutual mistrust and fears about the uncertain economic impact of making generic drugs more readily available led to the creation of a law which was inelegantly

[*392] drafted n9 and extremely complex. n10 Over the last fourteen years, this law has created an economic boom for lawyers specializing in pharmaceutical issues who have parsed the vague language of the '84 Act and reconstructed or reinvented legislative intent in order to achieve desired economic results in particular cases.

For all of the foregoing reasons, this is a particularly appropriate moment to revisit the history of the negotiations leading to the '84 Act in order to provide a clear picture of how and why the patent provisions of the '84 Act were created, and what they were intended to accomplish. It is also the right time to examine whether these provisions are, in fact, responsible for maintaining an environment which simultaneously fosters investment in innovation and the widespread availability of generic drugs. In this author's view, such an examination leads to a rather surprising conclusion, namely, that the patent provisions of the '84 Act are not relevant to the current economic environment in the pharmaceutical industry and should be repealed.

Patent-term extensions and the Bolar exemption are self-canceling provisions which, taken together, have no net effect on the length of the exclusive marketing period of most new drugs. The patent certification procedures are being abused by both sides and produce no public benefit that would not otherwise occur. International differences in pharmaceutical patent law are causing the migration of pharmaceutical manufacturing to developing regions of the world where it is more difficult to maintain control over quality. There is mounting evidence that the real spurs to investment in innovation are 1) the loss of profits from old drugs which accompanies the expiration of patents and 2) the potential for earning the enormous profits which accompany the development of a new blockbuster drug that is a true advance in treating a disease and that can easily achieve sales in excess of $ 1 billion per year.

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II. U.S. Law and Drug Development Prior To 1984

A. The Notion That A Patent Entitles Its Owner To a Guaranteed Period of Marketing Time Was Contrary To Existing Law

Patent law does not provide a positive grant of the right to commercially exploit an invention for the life of a patent. Rather, a patentee is only granted the right to exclude others from making, using, or selling the claimed invention during the life of the patent. Whether or not the patent owner derives a commercial benefit from that exclusion is a matter that is totally divorced from the patent system. Commercial success actually depends upon a multitude of other factors including the commercial practicality of the invention, the state of development, the existence of a market and the existence of other federal and state laws which regulate the conditions under which products or services may be offered for sale. For example, since 1962 federal law has required pharmaceutical manufacturers to establish that their products are safe and effective before they can be marketed.

A patent can only be obtained if the invention described is useful. n11 Accordingly, after the food and drug laws were amended to require proof of safety and efficacy in 1962, the United States Patent Office took the position that a patent which asserted that a compound had therapeutic utility would not be granted absent proof that the compound was both safe and effective. n12 This position was quickly overruled by the Court of Customs and Patent Appeals which held that an invention could be "useful" within the meaning of the patent law even though it might not be commercially saleable under other laws. n13 The court noted that a fundamental purpose of the patent grant is to stimulate the capital investment necessary for further development and marketing of an invention. n14 Thus, for patent purposes, a compound was deemed to have utility based solely on a showing of activity in laboratory animals. n15

[*394] This, of course, made it common practice to file patent applications covering potentially useful therapeutic compositions many years before anyone knew whether the drug would be safe and effective in humans. To do otherwise would have resulted in the intolerable risk that the information would become generally known and thereby preclude the grant of any patent at a later date. More importantly, the early issuance of a patent containing broad claims serves to discourage potential competitors from investing in research involving similar compounds.

These basic principles of patent law and the practices that arose pursuant to these principles made it clear that there was no legal or logical relationship between the life of a patent and the commercial life of any product claimed in a patent. This, of course, did not prevent skillful lobbyists for the pharmaceutical industry from convincing legislators who lacked a basic knowledge of patent law that government regulations requiring proof of safety and efficacy were depriving inventors of exclusive marketing time to which they were entitled as amatter of law. The argument gained easy acceptance because it was consistent with the conventional wisdom that government "red tape" is a root cause of most business problems. Moreover, disguising corporate welfare as "remedial" legislation gives legislators the opportunity to assert that they are motivated by fairness rather than the influence of political benefactors.

B. The Weight of Legal Authority Supported the Belief That the Non-Commercial Activity Involved in Generic Drug Development During the Life of a Patent Was Not Infringement

Under U.S. patent law prior to 1984, there was ample authority for the proposition that a party who makes and uses a patented product or process does not infringe if the use is for purposes of research or experimentation and not for profit. n16 This so-called "experimental use" doctrine is simply an extension of the equitable concept that a court will not redress a de minimus use of a patented invention. Therefore, to support a finding of infringement, the law required the alleged infringer to derive a benefit at the expense of the patentee, i.e., to encroach on the patentee's commercially valuable use of the patent. n17

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It was common practice, prior to 1984, for generic drug companies to seek FDA approval to market generic versions of patented drugs before the relevant patents expired, even though it was necessary to make and use the patented invention and thus commit acts amounting to literal infringement as part of the process of seeking FDA approval. Yet there are no reported cases in which a patent owner sought to prevent such activities. To the contrary, in a 1975 case, Hoffman-LaRoche, Inc. v. Zenith Laboratories, Inc., n18 involving VALIUM - then one of Roche's most commercially successful products - Roche acknowledged that it did "not seek to interfere with Zenith's legitimate activities in seeking FDA approval" n19 for VALIUM. Roche apparently did not believe that its patent gave it the right to prevent Zenith from developing a generic copy of the patented drug during the life of the patent, even though the development was solely in preparation for post-expiration competition.

In Smith, Kline & French Laboratories v. A.H. Robins Co., n20 Smith, Kline & French ("SK&F"), moved to strike a claim of patent infringement, as a matter of law, on the ground that the manufacture or use of a patented drug product for the purpose of conducting tests to obtain FDA approval is an experimental use and not an infringement. n21 The SK&F motion was denied only because the court lacked evidence as to whether the FDA approval process involved any distribution of the patented drug, which, arguably, might constitute a commercial activity. n22

The 1982 decision in Pfizer, Inc. v. International Rectifier, Inc. n23 is the first reported case which arguably supports the proposition that the use of a drug for purposes related to seeking FDA

[*396] approval is an act of infringement that is not entitled to protection under the experimental use doctrine. In Pfizer, an injunction had previously been granted because the defendant was engaged in clearly commercial activities with respect to the patented drug. n24 That injunction contained broad language barring any manufacture or use of the patented drug. n25 In a subsequent action for contempt of the injunction, the defendant was unsuccessful in arguing that the injunction did not extend to activities related to seeking FDA approval to market the patented drug. n26 Since the Pfizer decision involved the literal violation of a pre-existing court order, its value as precedent on the drug development exemption was questionable.

The October, 1983 decision by the district court in Roche Products, Inc. v. Bolar Pharmaceutical Co. n27 was consistent with earlier precedents and common practice. The court embraced the notion that the activities involved in seeking FDA approval to market a patented drug did no economic harm to the patent owner during the life of a patent and were exempt from a claim of infringement as a de minimus activity. In the court's view:

the court can not find a basis for holding that Bolar's limited experimental use of flurazepam hcl [sic] would constitute infringement. First, Bolar realizes no benefit during the term of the patent; its activities are in no way connected with current manufacture or sale here or abroad. Nor do its activities lessen Roche's profits during the patent's term. Second, post-expiration delay in competition unintentionally imposed by FDA regulation is not a right or benefit granted by the patent law. This court will not act to protect the right or benefit that is without legal basis. Third, Roche can point to no substantial harm it will suffer from Bolar's FDA studies before the patent expires. Bolar's threatened activity is at best de minimus and will not support an action for infringement. n28

Although an appeal of the lower court's Bolar decision seemed certain, on the eve of the negotiations which led to the '84 Act, the weight of judicial authority and common industry belief and practice supported the view that it was not an act of patent infringement to make or use a patented drug solely for the purpose of seeking approval to market a generic copy of the patented drug.

C. There Was No Established Process for Approving Generic Drugs

The 1962 amendments to the food and drug law, which required proof that a drug was safe and effective before it could be approved for marketing, n29 contained no provisions for a separate approval process for drugs which were identical to drugs which had been previously approved. Thus, a party seeking approval to market a generic version of an existing drug was compelled to file a New Drug Application ("NDA") and to

[*397] independently prove that the drug was safe and effective. n30 Many drugs were approved based on a so-called "paper" NDA in which the applicant relied upon published data concerning the safety and efficacy of the previously approved drug as the proof that its own, identical product was safe and effective. However, such data were not readily available for all approved products. Moreover, nothing in the FDA regulations prevented the Agency from requesting additional, expensive clinical studies to deal with safety or efficacy questions that may have arisen from adverse reaction reports or other published information pertaining to the approved product between the time of its approval and the time of the paper NDA filing. Often, the paper NDA applicant lacked the financial resources or expertise required to respond to such requests.

For the foregoing reasons, by the early 1980s the approval of generic versions of existing drugs was an uncertain process. The patents on many important drugs had expired or were about to expire, and the prospect of competition in the sale of those products and of inevitably lower prices for consumers was dim.

III. The Political Environment Leading to the '84 Act

During the first session of the 97th Congress (1980-82) legislation was introduced in both the U.S. Senate (S. 255) and the House of Representatives (H.B. 1937) which would have provided patent-term extensions of up to seven years in duration for pharmaceutical patents in order to compensate pharmaceutical patent owners for marketing time allegedly lost due to government delays in determining that a drug was safe and effective. The Senate version of that legislation was passed, with minor amendments, in July, 1981. n31 Subsequently, in February, 1982, the House of Representatives held hearings on the issue, at which time various studies on effective patent life conducted by private sources representing the Pharmaceutical Manufacturers Association ("PMA") and by the Congressional Office of Technology Assessment were the subject of scrutiny. n32

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On September 15, 1982, in the closing days of the 97th Congress, an amended version of the 1981 Senate bill, H.R. 6444, was placed before the House under an expedited procedure for non-controversial legislation which required a two-thirds majority for passage. n33 There were 250 votes in favor of passage, but the bill fell five votes short of the required two-thirds majority. n34 Rep. Henry Waxman (D-Cal.) and Rep. Albert Gore, Jr. (D-Tenn.) were credited with mustering the critical "no" votes needed to prevent passage. n35 But for their efforts, patent-term extensions for pharmaceuticals would have become the law of the land without any infringement exemption for generic drug development or any streamlined procedure for approving generic drugs.

In the 98th Congress, which commenced in January, 1983, the momentum had clearly begun to shift in favor of generic drugs. In July, 1983, Rep. Waxman, Chairman of the House Subcommittee on Health of the Committee on Energy and Commerce introduced new legislation (H.R. 3605) to reform the FDA's generic drug approval process in order to expedite approvals and stimulate competition which would lead to lower drug prices for older drugs. n36 Although the patent-term extension proposals from the previous session of Congress were also reintroduced, it was apparent that the extension proposals would go nowhere without the support of Chairman Waxman. By the Fall of 1983, the stage was set for a compromise involving a blending together of patent-term extension legislation with a new expedited FDA approval process for generic versions of previously approved drugs. By sheer coincidence, the negotiations between Rep. Waxman and representatives of the brand-name and generic drug industries began at about the same time (October, 1983) that the district court rendered its decision in Roche. n37

IV. The Events Leading to the Enactment of the '84 Act

By late January of 1984, Rep. Waxman had reached an agreement in principle with representatives of the PMA and the Generic Pharmaceutical Industry Association ("GPIA"). The agreement was based on an outline of a proposed new law which would amend the food and drug law

[*399] to provide for an expedited generic drug approval process n38 and amend the patent law to provide for patent-term extensions. For the next several months, the staff of Mr. Waxman's subcommittee conducted intense negotiations on the detailed language of the proposed legislation with representatives of the GPIA and the PMA. Early on, this author, acting as patent counsel to the GPIA, urged that the proposed patent- term extension law should codify the district court decision in Bolar. n39 It was my contention that a reversal by the Court of Appeals for the Federal Circuit ("Federal Circuit") would amount to a two-to-three-year extension of market exclusivity for patented drugs beyond their patent expiration date thereby reducing, if not entirely eliminating, the need for any patent-term extension legislation. Fortunately, the PMA negotiators were of the view that the district court decision in Bolar did not change existing law and that codification of that decision merely preserved the status quo. Accordingly, the first draft of the Waxman legislation, which was released on April 4, 1984, contained Section 202 which read:

Section 271 of title 35, United States Code, is amended by adding at the end the following:

"(e) It shall not be an act of infringement to make, use or sell a patented invention solely for experimental use in connection with the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." n40

Although the April 4 draft left several important areas of controversy unresolved, it did not produce any immediate protest with respect to the Bolar exemption. Rather, the major unresolved patent controversy related to how the new ANDA procedure would function, if at all, if a generic drug manufacturer believed that a patent covering the innovator's compound was invalid or not infringed. This was a topic of major concern to pharmaceutical patent owners because most generic drug manufacturers were quite small and could not afford to pay significant damages if they were found to be liable as infringers. n41 During the next

[*400] several weeks, representatives of the GPIA and the PMA hammered out a tentative agreement, which included the following key elements:

(a)If a generic manufacturer seeks approval for an ANDA and intends to challenge a patent, it would be required to notify the patent owner and NDA holder.

(b)Either party could file a declaratory judgment action at any time after notice.

(c)The patent owner would be entitled to seek a preliminary injunction. In any such proceeding, the fact that ANDA approval was being sought would satisfy the requirement for irreparable harm and the presumption of validity would be proof of the patent owner's likelihood of success. Therefore, the burden would be on the generic manufacturer to prove by clear and convincing evidence that it was likely to prevail on the ultimate merits of the case. Otherwise a preliminary injunction would be granted.

(d)No ANDA could be approved for one year in order to provide sufficient time for adjudication of a preliminary injunction motion.

(e)Damages for commercial infringement by the ANDA holder would be the lost profits of the NDA holder.

By April 24, sufficient progress had been made on the outstanding issues to cause the president of the PMA, Lewis Engman, and his outside counsel, Peter Barton Hutt, to commit themselves to "sell" the compromise to the executive committee of the PMA and to the full board, both of which were scheduled to meet later that month. At almost the same moment, the Court of Appeals for the Federal Circuit handed down its

[*401] decision in Roche Products, Inc. v. Bolar Pharmaceutical Co. n42 The Federal Circuit concluded that the ultimate commercial purpose underlying the development activities necessary to seek FDA approval for a generic drug made such activities an act of infringement. Therefore, it reversed the district court and held that the development of the data to support an ANDA could not begin until a patent expired. n43

Not surprisingly, the unexpected Bolar reversal caused a major rift at the highest levels of PMA. Those representatives directly involved in the negotiations, who had previously agreed to codify the lower court's decision in Bolar, could not credibly withdraw from that agreement without also agreeing to a drastic reduction in the proposed length of patent term extensions. On the other hand, the CEOs of the major pharmaceutical companies quickly recognized that the proposed legislation had become a terrible bargain. In their view, the combination of: 1) the creation of an expedited generic drug approval process, 2) the Bolar exemption, and 3) the provisions allowing for challenges to the validity of pharmaceutical patents more than offset any possible gain which would be realized from the highly restrictive patent-term extensions which had been proposed. n44 Therefore, the major pharmaceutical patent owners believed they would be better off with no legislation of any kind. The stage was set to kill the legislation before it was even formally introduced.

On May 3, 1984, in an attempt to pressure the PMA Board of Directors to accept the compromise, Rep. Waxman and Sen. Hatch, who had by then committed to sponsor a Senate version of the Waxman draft legislation, wrote a joint letter to the PMA threatening to enact the

[*402] proposed ANDA approval process for generic drugs without any patent- term extension provisions unless the PMA agreed to the compromise. That letter had its intended effect. It caused a fragmented PMA to generally endorse the Waxman draft over the objection of several of its largest members. Nevertheless, the PMA continued to express strong objections to the patent challenge procedures, particularly the proposed declaratory judgment and expedited litigation procedures. The PMA also made clear that it would not support any legislation that did not provide its members with a clear opportunity to fully adjudicate a patent claim before a generic drug could be marketed.

For a brief period of time, the PMA's patent litigation demands appeared to present an insurmountable obstacle to agreement since both parties recognized that the federal courts were not compelled to either hear or expedite declaratory judgment actions. However, by mid-May, the GPIA's patent counsel had conceived and proposed a solution to the impasse that contained all of the elements relating to patent challenges that were ultimately enacted into law. The centerpiece of that solution was the creation of an "artificial" act of patent infringement, which would compel the courts to take jurisdiction. Specifically, it was proposed to create an exception to the Bolar infringement exemption in those instances where an applicant for an ANDA declared an intent to seek immediate FDA approval for marketing without regard to the expiration date of a patent. n45 The certification procedure contained the following elements:

Each holder of an approved NDA would file a list of product and method-of-use patents that might be infringed if a generic drug was marketed before the patent expired. This list of patents would be published by the FDA in its list of approved products, i.e. The Orange Book. n46

An applicant filing an ANDA would be required to make a certification of its intent with respect to each listed patent. In those instances where the patent was not being challenged, the certification would state that the approval was being sought as of the expiration date of the patent. If the patent was being challenged, the ANDA applicant would certify that

[*403] it believed that the patent was invalid or would not be infringed and would request immediate approval. n47

If a certification challenged a patent, the ANDA applicant was required to serve a formal notice on the patent owner and NDA holder setting forth the specific grounds for the assertion. n48 The patent owner would then have forty-five days from the date of the notice to commence an action for infringement. n49

If a patent infringement action was commenced, the FDA was prohibited from approving the ANDA for eighteen months, n50 thereby assuring the patent owner of sufficient time to either fully adjudicate the patent issues or obtain a preliminary injunction.

In short, patent owners received statutory assurance that there would be no generic competitor on the market unless and until their patent rights were adjudicated. The generic drug manufacturers received several benefits as an inducement to accept these patent limitations, including assurances that 1) the ANDA giving rise to the patent challenge would be preserved for approval upon patent expiration even if the challenged patent was found to be valid and infringed n51 and 2) no damages could be awarded for infringement unless there were commercial acts. n52 Most important, the patent challenge compromise included a "bounty" provision that prohibited the FDA from approving a second ANDA until the earlier of 180 days after 1) the first ANDA applicant who asserted a patent challenge commenced marketing or 2) the entry of a judgment declaring the challenged patent to be invalid, not infringed or unenforceable. n53 This provision was requested by the generic drug manufacturers to insure that the successful challenger of a patent would have an opportunity to recoup its litigation costs before other generic manufacturers

[*404] could take advantage of the elimination of the patent as a barrier to competition. The PMA apparently did not recognize that this provision was a significant incentive to challenge patents and, therefore, it voiced no objection to this provision.

With a compromise in place, Rep. Waxman convened an open session of the Committee on Energy and Commerce, Subcommittee on Health and Environment on June 12, 1984 and offered the compromise as a substitute for H.R. 3605. n54 The substitute bill and the Committee report pertaining thereto were published on June 21, 1984. n55 On June 12, Sen. Hatch introduced identical legislation referred to as "The Drug Price Competition and Patent Term Restoration Act of 1984" (S. 2748).

Although the proposed legislation was endorsed by the PMA, many of its larger and more influential members, including Merck, Squibb, Johnson & Johnson, Hoffman LaRoche and American Home Products, immediately formed a coalition in opposition to the legislation. In a paper released on June 16, 1984, these companies expressed strong opposition to the Bolar exemption, the patent certification procedures, and the restrictive rules relating to the availability of patent-term extensions. On June 25, 1984, the New York Times entered the fray with an editorial endorsing the Waxman-Hatch compromise and noting that the dissenting coalition stood to profit if the compromise failed to be enacted into law. n56 The battle lines were clearly drawn and the likelihood of achieving a compromise before Congress adjourned for the 1984 elections seemed slim.

The first skirmish in the battle took place on June 27, 1984 when the House Committee on the Judiciary, Subcommittee on Courts, Civil Liberties and the Administration of Justice held a hearing on H.R. 3605. These hearings and subsequent hearings and mark-ups of H.R. 3605 did not produce any significant changes in the proposed law but did provide the dissident pharmaceutical companies with an opportunity to present their objections to the legislation. The centerpiece of that opposition was the assertion that the Bolar exemption amounted to an unconstitutional taking of the property of a patent owner without due process of law n57 - a position that was urged by two noted constitutional scholars

[*405] retained by the major pharmaceutical companies, Professor Norman Dorsen of NYU School of Law and Professor Larry Tribe of Harvard Law School. n58

By early August 1984, it had become clear that no law would be enacted unless a compromise could be negotiated directly between the generic and brand-name factions. Accordingly, Sen. Hatch placed heavy pressure on representatives of the two sides to reach agreement and ultimately acted as a referee and arbitrator on the final points of disagreement. The compromise left the Bolar exemption intact. It did, however, make the following major changes (and several more minor changes) that benefited the brand-name drug industry:

The elimination of many of the restrictive rules relating to patent-term extensions. Although the compromise allowed only a single patent to be extend a single time in connection with the first approval of a new chemical entity, n59 it gave the patent owner a choice as to which patent could be selected for extension. n60

A provision barring the FDA from approving an ANDA for thirty months (previously eighteen months) in the event of patent challenge litigation. n61

The addition of several exclusive marketing provisions that were not based on patents - 1) a provision barring the filing of an ANDA for five years from the time of first approval of an NDA for a new chemical entity, n62 2) a provision prohibiting the approval of an ANDA for three years following any NDA approval for a new use or new dosage form that was based on new clinical tests n63 and 3) a provision granting two years of exclusivity for those NDAs approved between January 1, 1982 and the date of enactment that were not already

[*406] entitled to the ten years of exclusivity accorded to NDAs for new chemical entities as part of the Act. n64

A provision stating that if any provision of the legislation is declared unconstitutional, the remainder of the law would survive. This provision was designed to facilitate a challenge to the Bolar provision on constitutional grounds.

Beyond question, the five-year non-patent exclusivity, which effectively guaranteed that every new drug would have an exclusive marketing period of about seven years (counting the usual time required to obtain approval of an ANDA) whether or not it enjoyed any patent protection was the key to the compromise. This provision assured innovators of a reasonable opportunity to recoup development costs and to make a profit irrespective of the existence of patents. n65 It did not deprive generic manufacturers of any important economic right since there is no real incentive to develop a generic drug until a market has been established and any post-approval issues of safety and efficacy have been resolved by broad use in the general population. Although some might argue that the establishment of monopoly rights outside the boundaries of the patent system is unconstitutional, the grant of such rights had already been established for pesticides as a means of compensating innovators for the disclosure of safety and efficacy data upon which generic manufacturers would subsequently (indirectly) rely in seeking marketing approval from the Environmental Protection Agency. n66

The compromises in the summer of 1984 did not make any change in the two-year limit on patent extensions for "pipeline" drugs, i.e. drugs that were already under development. Nor was any such change actually sought by the dissident pharmaceutical manufacturers. The short-term economic needs of the brand-name drug companies were protected by a ban on the use of the abbreviated new drug application process for ten years with respect to new drugs which had been first approved between January 1, 1982 and the date of enactment of the new law. In any event, Congress "established different maximum periods of

[*407] extension to provide greater incentive for future innovations." n67

The incorporation of these negotiated changes into H.R. 3605 and S. 2748 led to their immediate approval by the House and Senate in September 1984. The Drug Price Competition and Patent Term Restoration Act of 1984 was signed into law by President Ronald Reagan in a Rose Garden ceremony on September 24, 1984.

V. Controversies Relating to the Patent Provisions of the '84 Act After 1984

A. The Bolar Exemption in the Courts

Despite the attempt by the major pharmaceutical companies to derail the '84 Act by claiming that the Bolar exemption was unconstitutional, the constitutionality of that provision has never been challenged. Yet there have been numerous reported cases in which the interpretation of that provision has been critical to the outcome of a controversy. Moreover, since 1984, hundreds of ANDAs have been given actual or tentative approval by the FDA prior to the expiration of a patent. Apparently, the arguments presented to Congress were merely part of an attempt to defeat the enactment of the Bolar exemption and were not based on a serious belief in the merit of the constitutional argument.

In any event, the United States Supreme Court has construed the Bolar exemption in an analysis that would appear to undermine any notion that an attack on constitutional grounds would ever have succeeded. In Eli Lilly & Co. v. Medtronic, Inc., n68 the Federal Circuit held that the 35 U.S.C.

271(e)(1) exemption for use reasonably related to the development and submission of information under federal laws regulating the manufacture, use or sale of "drugs" is not limited to drugs, but it also extends to medical devices that are subject to FDA approval. The Supreme Court granted certiorari and affirmed. n69

In his opinion for a majority of the Court, Justice Scalia concluded that the 1984 Act "was designed to respond to two unintended distortions of the seventeen-year patent term produced by the require-

[*408] ment that certain products must receive premarket regulatory approval." n70 Justice Scalia went on to explain, stating:

First, the holder of a patent relating to such products would as a practical matter not be able to reap any financial rewards during the early years of the term. When an inventor makes a potentially useful discovery, he ordinarily protects it by applying for a patent at once. Thus, if the discovery relates to a product that cannot be marketed without substantial testing and regulatory approval, the "clock" on his patent term will be running even though he is not yet able to derive any profit from the invention.

The second distortion occurred at the other end of the patent term. In 1984, the Court of Appeals for the Federal Circuit decided that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement, even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval. Since that activity could not be commenced by those who planned to compete with the patentee until expiration of the entire patent term, the patentee's de facto monopoly would continue for an often substantial period until regulatory approval was obtained. In other words, the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term.

The 1984 Act sought to eliminate this distortion from both ends of the patent period. Section 201 of the Act established a patent-term extension for patents relating to certain products that were subject to lengthy regulatory delays and could not be marketed prior to regulatory approval. . . .

The distortion at the other end of the patent period was addressed by

202 of the Act. That added to the provision prohibiting patent infringement the paragraph at issue here, establishing that "[I]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." This allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to gain regulatory approval. n71

Justice Scalia also correctly and precisely characterized the relationship between the Bolar exemption of 35 U.S.C.

271(e)(1) and the new act of infringement described in 35 U.S.C.

271(e)(2) in the following manner:

The function of [Sections 271(e)(2) and (4)] is to define a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications. As an additional means of eliminating the de facto extension at the end of the patent term in the case of drugs, and to enable new drugs to be marketed more cheaply and quickly,

101 of the 1984 Act amended

505 of the FDCA, 21 U.S.C.

355, to authorize abbreviated new drug applications (ANDAs), which would substantially shorten the time and effort needed to obtain marketing approval. An ANDA may be filed for a generic drug that is the same as a so-called "pioneer drug" previously ap-

[*409] proved, or that differs from the pioneer drug in specified ways. The ANDA applicant can substitute bioequivalence data for the extensive animal and human studies of safety and effectiveness that must accompany a full new drug application. . . .

These abbreviated drug-application provisions incorporated an important new mechanism designed to guard against infringement of patents relating to pioneer drugs. Pioneer drug applicants are required to file with the FDA the number and expiration date of any patent which claims the drug that is the subject of the application, or a method of using such drug. ANDAs and paper NDAs are required to contain one of four certifications with respect to each patent named in the pioneer drug application: (1) that such patent information has not been filed, (2) that such patent has expired, (3) the date on which such patent will expire, or (4) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

This certification is significant, in that it determines the date on which approval of an ANDA or paper NDA can be made effective, and hence the date on which commercial marketing may commence. If the applicant makes either the first or second certification, approval can be made effective immediately. If the applicant makes the third certification, approval of the application can be made effective as of the date the patent expires. If the applicant makes the fourth certification, however, the effective date must depend on the outcomeof further events triggered by the Act. An applicant who makes the fourth certification is required to give notice to the holder of the patent alleged to be invalid or not infringed, stating that an application has been filed seeking approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent, and setting forth a detailed statement of the factual and legal basis for the applicant's opinion that the patent is not valid or will not be infringed. Approval of an ANDA or paper NDA containing the fourth certification may become effective immediately only if the patent owner has not initiated a lawsuit for infringement within 45 days of receiving notice of the certification. If the owner brings such a suit, then approval may not be made effective until the court rules that the patent is not infringed or until the expiration of (in general) 30 months, whichever first occurs.

This scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement. And that was precisely the disability that the new

271(e)(1) imposed, with regard to use of his patented invention only for the purpose of obtaining premarketing approval. Thus, an act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by

271(e)(2) - the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent. Not only is the defined act of infringement artificial, so are the specified consequences, as set forth in paragraph

(e)(4). Monetary damages are permitted only if there has been "commercial manufacture, use, or sale." Quite obviously, the purpose of (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend. n72

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Unfortunately, the language of

271(e)(1) was not limited to activites related to seeking an approval for a generic drug, but rather broadly protected activities which are "solely" for purposes "reasonably related" to the development and submission of information under any federal law that regulates the manufacture, use or sale of drugs. n73 This broad language has been the subject of much dispute and judicial interpretation. As Chisum has noted,

271(e)(1) is awkwardly worded and requires a two-pronged analysis to determine if an alleged activity is "solely" for uses "reasonably related" to the development and submission of information to the FDA. n74 Thus, a body of case law has developed that seeks to broaden the scope of the broad language of the Bolar exemption to cover situations where the alleged infringers' activities are not directly related to seeking approval for a copy of a previously approved drug. n75 A discussion of the limits of the Bolar exemption as it relates to research and development activities unrelated to generic drugs is beyond the scope of this article.

B. The Impact of the Bolar Exemption on International Treaties and Trade

The European Union has asserted that the Bolar exemption is a violation of the exclusive rights conferred on a patent owner under Article 28 of theTRIPs Agreement. This argument is totally lacking in substance and appears to represent an attempt by the multi-national pharmaceutical industry to use the European Union in an effort to

[*411] undermine the compromise that led to the '84 Act. Article 30 of the TRIPs agreement specifically recognizes that "Members may provide limited exceptions to the exclusive rights conferred by a patent. . . ." n76 There is ample evidence that this provision was designed and intended by the United States to preserve the Bolar exemption.

In a letter of March 9, 1993, while the TRIPS treaty was still being negotiated, Sen. David Pryor (D-Ark.) requested that the U.S. Trade Representative take steps to insure that the international treaties not only preserve the Bolar exemption but also promote its adoption by U.S. trading partners so as to enhance the availability of active ingredients required for generic drug development efforts. The PMA, which represents the multi-national pharmaceutical industry in the United States, immediately wrote to the U.S. Trade representative to oppose Senator Pryor's attempt to internationalize the Bolar exemption.

Referring to the draft version of Article 30 in the Dunkel text of what later became the TRIPs agreement, the president of the PMA stated:

PMA remains troubled by the language in Article 30 in that the conditions for exceptions may be met provided that they do not "unreasonably conflict" with the normal use of the patent and "unreasonably prejudice" the patent owner's interest. There is concern that the combination of "unreasonably conflict" and "unreasonably prejudice" could be abused by some developing country governments in such a way as to go beyond Bolar-type exemptions and violate patent rights. Nonetheless, we understand that Article 30 is included in the Dunkel text precisely to preserve the Bolar amendment in U.S. law. Clearly any country can also include such exemptions to its patent law if it determines them to be in their national interest. n77

Not surprisingly, the official Statement of Administration Action by the President of the United States, which accompanied the GATT Implementing legislation, n78 states (with respect to the scope of patent rights):

The Agreement permits limited exceptions to the exclusive rights conferred by a patent if certain conditions are met. United States law contains some

[*412] such exceptions, such as those set out in section 271(e) of the Patent Act *(35 U.S.C. 271*(e)). n79

The TRIPs Agreement was designed and intended to be a major step toward the harmonization of international intellectual property law. It is unfortunate that the multi-national pharmaceutical industry sees the process as nothing more than an opportunity to recapture the concessions it willingly made in the United States in order to get the benefit of patent-term extensions. Fortunately, neither the U.S. Trade Representative nor the U.S. Congress has shown any willingness to abandon the Bolar exemption based on such tactics. In any event, the Bolar exemption, and comparable international safe harbor provisions, appear to fall squarely within the plain language of the exemption language of Article 30 of the TRIPs agreement since they do not impinge on any significant economic interest of the patent owner. Under the circumstances, it seems highly unlikely that the European Union will ultimately succeed in its attempt to challenge national patent laws which contain such provisions.

It is becoming increasingly clear that the international business of developing and manufacturing generic drugs will soon exist only in those countries which recognize safe harbor provisions unless uniform international rules are developed. As the U.S. experience demonstrates, in the typical case, a generic drug will be approved and available for distribution on the day that patent rights expire. Moreover, as international reciprocity between health authorities becomes the norm, pre-existing FDA approval will result in expedited local approval. Therefore, unless the European Union wins its legal battle against the Bolar exemption or adopts safe harbor provisions, it cannot expect to maintain a viable domestic generic drug industry. Drug products developed and manufactured in safe harbor countries will clearly be on the market in European countries years before domestic counterparts can legally be developed. The economic incentives to develop generic drugs locally will ultimately disappear and so will the jobs related to such activities.

Notwithstanding the foregoing, the adoption of laws permitting generic drug development during the life of relevant patents does not guarantee domination of generic drug development and manufacturing activities in the international market place. This is due to the fact that the development of pharmaceuticals is critically dependent on the availability of the active chemical entity in a drug product. Few, if any, active pharmaceutical ingredients are manufactured by the makers of generic drugs in the United States. For many years, such active ingredients were readily available from European countries whose laws did not

[*413] permit patents on chemical entities. In recent years, those sources have dried up due to changes in the patent laws, leaving developing nations in Asia and Eastern Europe as the primary sources for newer active ingredients. Unfortunately these sources are sometimes of questionable value due to their inability to comply with FDA quality control procedures. U.S. companies could, of course, develop active ingredients under the Bolar exemption but thus far have not demonstrated any significant desire to do so.

The production of raw material in Country A in aid of product development in Country B is not protected if a safe harbor exemption is narrowly drafted so as to permit only those acts carried out in pursuit of a domestic health authority registration. Thus, for example, the current U.S. Bolar exemption does not permit a U.S. manufacturer to produce and sell experimental quantities of a raw material to a foreign entity engaged in the development of an application to register a drug in its home country. The only exempted activities are those which relate to seeking a drug registration in the United States. Therefore, those nations which seek to dominate worldwide commerce in the manufacture and sale of both raw materials and finished drug products must enact a Bolar exemption which permits the making, using or selling of a patented invention for all uses reasonably related to seeking a registration in any nation and not merely a registration in their own country. Israel has recently enacted such legislation. It would provide an exemption from patent infringement for the export of research quantities of patented raw materials in aid of drug development activities in a country, such as the United States, which recognizes a Bolar exemption. Ultimately, in the absence of international harmonization of patent-term extension provisions and safe harbor provisions, the efforts of TRIPs to provide for a system in which patents expire more or less simultaneously around the world will be inapplicable to pharmaceutical patents. The end result is that countries, such as Israel, which permit generic drug development to begin before relevant patents expire and which also limit the length, if any, of patent-term extensions will "own" the business of developing and manufacturing generic drugs. Clearly, the intent of the laws providing for patent-term extensions was to insure the existence of adequate incentives to produce pharmaceutical innovations and not to deprive countries of viable domestic competition after those patents expire. Therefore, the time is ripe for the nations that have enacted lengthy patent-term extension provisions without safe harbor provisions to revisit those laws and find other ways of providing incentives that do not undermine the existence of a viable domestic generic drug industry.

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C.

Patent Challenges and Generic Exclusivity

No area of the '84 Act has caused more controversy than the special provisions pertaining to the enforcement of patents, i.e., the provisions of the '84 Act relating to the listing of patents claiming approved drugs, the procedures for challenging a patent, and the provision giving the first applicant to challenge a patent to a 180-day headstart in the marketplace before other ANDAs can be approved by the FDA. Largely as a result of ongoing uncertainty as to how to deal with the many new patent issues created by vague provisions in the '84 Act, it took the FDA more than ten years to enact "final" regulations. n80 It is now clear that the patent provisions of the '84 Act, particularly the provisions creating 1) a statutory thirty-month, non-adjudicated, preliminary injunction for any pharmaceutical patent listed in the Orange Book and 2) a 180-day period of exclusivity for the first ANDA applicant to challenge any listed patent, had many unintended consequences. A significant number of lawyers now devote their full time to the manipulation of the statutory language and regulations relating to these subjects for the purpose of creating economic benefit for individual brand-name and generic drug manufacturers - usually without regard to the question of whether any public benefit is produced.

The '84 Act required the holders of NDAs to identify all patents claiming an approved drug product or a method of using such a product as to which a claim of patent infringement might reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use or sale of the approved drug. An applicant seeking approval for an ANDA must either wait until all listed patents expire or file a so-called "Paragraph IV" certification asserting that a listed patent is invalid, unenforceable or would not be infringed. However, if a Paragraph IV certification is filed, the patent owner can automatically keep the ANDA from being approved for thirty months merely by starting an action for infringement. n81 The purpose of that provision, as previously noted, was to create a system in which the rights of the patent holder would be adjudicated before any economically damaging competition would occur. Unfortunately, the Act naively presumed good faith on the part of patent holders in selecting the patents that would be listed. Therefore, it provided no guidance whatsoever as to what patents should or should not be listed and no mechanism for determining if a patent was properly or

[*415] improperly listed. Moreover, the drafters of the Act failed to recognize that the automatic thirty-month injunction inadvertently created a powerful incentive for the holder of an NDA to list any and every patent related to a drug product irrespective of whether such patent was a significant barrier to legitimate competition. Thus the '84 Act automatically enables a patent owner to prevent competition irrespective of the merits of the patent being asserted and without any meaningful penalty for a wrongful assertion save for the possible award of the opposing party's legal fees. These fees are nominal as compared to the hundreds of millions of dollars in monopoly profits that can be earned during the thirty months a competitor is held off the market.

Not surprisingly, the opportunity to extend market exclusivity by merely listing a patent in the Orange Book has encouraged brand-name drug companies to seek, obtain, and, ultimately list a great variety of patents of little scope or merit except for their ability to delay legitimate competition. A cursory inspection of the FDA Orange Book's patent and exclusivity listings will reveal that most approved products have more than one listed patent. Sometimes, there are five or six listed patents for a single product. Some of these patents claim unapproved uses, special crystalline forms of the active ingredient, specific formulations, tablet shape or other subject matter which can easily be circumvented while still producing an equivalent generic version of an approved drug. These patents nevertheless prevent competition for at least thirty months.

In those circumstances where the patent challenge is filed simultaneously with the filing of the ANDA, there would, of course, be no generic competition in any event until the FDA reviews and approves the ANDA - a process which normally consumes anywhere from nine months to two years. However, the '84 Act does not prevent an NDA holder from listing a newly acquired patent on the eve of an ANDA approval and there have been instances where a new patent first appears in the Orange Book shortly before the basic patent protection for an approved drug expires thereby delaying the onset of generic competition.

On its face, it would appear that the existence of so many listed patents is a major hindrance to generic drug manufacturers. Until recently, that was not the case. During the 1980s, many of the smaller generic manufacturers were relatively unsophisticated and simply accepted the patent expiration dates listed in the Orange Book at face value. This created an economic benefit for the more sophisticated generic companies since the cost and time involved in challenging a weak patent is insignificant as compared to the large profit windfall which results from being the first (and perhaps only) approved generic manufacturer able to compete for market share with a high-priced brand-name

[*416] product. n82 The wholesale price of a generic drug which is available from a single source is likely to be seventy percent or more of the price of the branded product. In contrast, when a generic drug is available from many sources, the wholesale price is likely to be thirty percent or less of the name-brand price. In these circumstances, all of the early challengers, in addition to the party receiving the 180-day exclusivity, gained the benefit of a smaller field of competitors and higher profit margins than would have existed if they had waited until the listed patent expired.

In recent years, the 180-day exclusivity provision has become a barrier to generic competition rather than the spur to competition which was intended by the '84 Act. Generic companies now routinely employ patent lawyers and screen every patent listed in the Orange Book looking for patents susceptible to attack on the ground of non-infringement or invalidity. As a result, multiple challenges to the same patent have become commonplace. Indeed, the listing of a weak patent of dubious coverage, e.g. a patent claiming a formulation, polymorph, metabolite, etc. in an attempt to extend market exclusivity after a basic chemical entity patent expires routinely provokes a challenge from several different generic companies almost simultaneously. n83 Under the '84 Act, the 180-day exclusivity belongs to the first ANDA applicant who simply files a Paragraph IV certification challenging a patent. There is absolutely nothing in the statute which requires that applicant to diligently 1) pursue a judgment with respect to the patent, 2) meet all technical requirements for approval of the ANDA, or 3) market a product once the ANDA approval is granted. Nevertheless, the Act prohibits the FDA from approving a subsequently filed ANDA until 180 days after one of two events occurs, namely, 1) the entry of a judgment declaring the challenged patent invalid, not infringed or unenforceable or 2) the actual entry into the market by the first ANDA challenger.

Experience has shown that the first ANDA applicant to file a patent challenge may never trigger the start of the 180-day period, thereby blocking the FDA from granting approval to any generic product. More often than not, the first generic challenger will enter into a lucrative cash settlement with the patent owner that results in a judgment

[*417] in favor of the patent and prohibits the challenger from marketing a product under its ANDA until the patent expires. Therefore, the 180-day exclusivity period never starts. n84 And no subsequently filed ANDA can be approved unless a final judgment adverse to the patent is obtained by one of the subsequent applicants. n85 But even in that circumstance, the winning party would be compelled to wait 180 days before enjoying the fruits of its victory and would not receive any exclusivity of its own. This result is dictated by the fact that, under the language of the statute, the 180 days of exclusivity belong solely to the first challenger and not to the first winner.

The likelihood that a patent challenge will result in an actual judgment that triggers the 180-day exclusive period is, in fact, very small. Of the approximately two dozen or more patent challenges filed since 1984, only a handful have resulted in an actual judgment after a full trial. These include the unsuccessful challenge involving AZT (RETROVIR), successful challenges involving cyclobenzaprine (FLEXERIL), HCT/amiloride (MODURETIC), tenormin (ATENOLOL) and ranitidine (ZANTAC), and the challenge to tamoxifen (NOVALDEX) which was settled on appeal after the district court declared the patent to be unenforceable. The vast majority of patent challenges have resulted in a settlement involving either a cash payment to the challenger in exchange for an agreement to forego the challenge or the grant of a deferred license, i.e, a license which would allow the generic challenger to begin competition on an agreed-upon date before the actual expiration of the patent, typically six months or more. In a pending case involving a sustained release version of diltiazem, the patent owner (Hoechst-Roussel) is paying the challenger (Andrx) the sum of $ 10 million per quarter to refrain from entering the market unless and until a final judgment is entered in pending litigation even though more than thirty months have lapsed and Andrx is free to enter the market under its approved ANDA. Despite these self-help arrangements which produce little or no public benefit, the literal language of the '84 Act appears to

[*418] grant the generic manufacturer a 180-day exclusivity period despite the existence of an agreement between the patent owner and the generic challenger which upholds the patent.

In an effort to combat the foregoing inequitable result, the FDA has sought to non-literally construe the '84 Act so that the prize of 180 days of exclusivity would only be available to the first successful litigant rather than the first challenger, i.e., the first ANDA applicant who actually obtains a judgment disposing of the patent. While this approach has some merit it would deny exclusivity to the first challenger in those circumstances where the first challenger is never sued and, therefore, acquires the right to immediate approval. This was clearly not the intent of the statute and ignores the plain language of the statute. Accordingly, a series of judicial decisions have concluded that the FDA lacks the authority to enact regulations that are contrary to the plain language of the Act. n86 In June, 1998, the FDA issued formal guidelines in which it abandons any further attempt to prevent the misuse of the 180-day exclusivity rule. n87

In a public filing with the FDA in July, 1998, this author suggested that at least some of the unintended consequences of the misuse of the 180-day rule could be eliminated by the enactment of regulations which would require a generic challenger to amend its ANDA and withdraw the challenge as soon as any agreement is reached between the challenger and the patent owner. n88 This approach would at least insure that only a true challenger would get the benefit of the 180-day exclusivity although the benefit would only be available to the first such challenger. The FDA has not adopted this proposal, and recently granted Barr Laboratories a 180-day period of exclusivity for Tamoxifen despite its withdrawal of a patent challenge. n89

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VI. The Patent Provisions of the '84 Act No Longer Serve Any Useful Function

Armed with fourteen years of experience under the '84 Act, there are many who now argue that it is time to revisit the issues which gave rise to its existence, examine its impact, and make adjustments. A thoughtful analysis of those questions could well lead to the conclusion that all of the special patent provisions of the '84 Act should now be repealed. This would include patent-term extensions, the Bolar exemption, and the special patent certification and litigation procedures. n90 A careful examination of the facts reveals that these provisions no longer contribute to the original goals of the Act, namely, increasing the availability of generic drugs or stimulating investment in innovation.

A. The Bolar Exemption and Patent Term Extensions

The controversy over safe harbor exemptions masks the underlying central question, namely: "How much marketplace exclusivity should a drug enjoy before competition is permitted?" The available evidence strongly supports the notion that patent-term extensions and the Bolar exemption are self-canceling, i.e., their combined effect on the length of exclusive marketing periods is negligible. In July, 1998, the Congressional Budget Office of the Congress of the United States issued a report entitled How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry. n91 That report concludes, inter alia: "[t]he Act's provision for extending patent terms merely compensated for the loss of the average three-year delay between patent expiration and generic entry that existed before the act (in cases where generic entry occurred)." n92

The CBO report also concludes that "[t]he average length of time between when a brand-name drug enters the market and when its patent expires rose by more than two years - from an average of about nine

[*420] years before 1984 to 11 to 12 years." n93 That conclusion actually grossly understates the true period of market exclusivity being enjoyed by most new drugs because it wrongly assumes that market exclusivity ends when the extended patent expires. In actuality, many drug products have more than one patent listed in the Orange Book and the last patent to expire is not the patent that received an extension. Moreover, an analysis of recent patent-term extensions issued by the U.S. Patent and Trademark Office shows that the vast majority of new drugs are actually receiving an extension which results in fourteen years of patent life commencing with the date of FDA approval. n94

The situation with respect to blockbuster drugs demonstrates that brand-name drug companies know how to achieve lengthy exclusive marketing periods without government intervention when their vital economic interests are at stake. An examination of the top twenty-five selling drugs (Appendix) reveals that half of them have exclusive marketing periods greater than fourteen years without any patent extension whatsoever, and that most of them have multiple patents which will extend exclusive coverage well in excess of fourteen years. Indeed, only two products appeared to have exclusive market lives of less than fourteen years (11 and 13.5 years).

The CBO report correctly notes that "[t]he act tried to balance two competing objectives: encouraging competition from generic drugs while maintaining the incentive to invest in developing innovative drugs." n95 It has clearly done so. The CBO concludes that without the '84 Act, U.S. consumers would be paying in excess of $ 10 billion per year more in prescription drug costs. n96 Yet the market capitalization of the seven largest pharmaceutical companies has grown by an astounding $ 665 billion (536%) in the last eight years as a result of record sales and earnings. n97 More importantly, the portion of their income re-invested in research and development has never been greater. Apparently, the

[*421] swifter pace of development of new drugs more than offsets the loss of profit resulting from generic competition against older drugs. All of this is happening in an environment where, according to the CBO study, the patent-term extensions of the '84 Act have been wiped out by the Bolar exemption.

In short, the fear that the expedited ANDA process for approving generic drugs would undermine innovation has not materialized. To the contrary, corporate managers are acutely aware of the fact that their own financial futures are directly tied to the price of their shares and that price is determined by earnings. The precipitous drop in earnings which now accompanies the expiration of a patent on a blockbuster drug has created an environment which spurs the search for a new generation of products which begin to produce equal or greater profits as the prior patents expire. n98 In 1984, Congress believed that it was necessary to extend the life of patents in order to spur innovation. Today, a powerful case can be made for the notion that it is the looming expiration of a patent that fuels innovation. The uninterrupted growth in the sales and earnings of large pharmaceutical companies plainly supports the conclusion that the pharmaceutical industry is doing well financially and does not need additional patent-term extensions. Any such extensions would merely serve to fuel the growth of industry profits at public expense. Consumers need relief from high drug prices, and assuring generic competition at the earliest date is one way of achieving that goal. The simplest way for Congress to assure the public that pharmaceutical industry profits are the result of innovation rather than political favoritism is to eliminate the ill-advised concept of patent- term extension from U.S. patent law. No other industry enjoys such a government subsidy.

By also eliminating the Bolar exemption, yet another special legal privilege for pharmaceutical patents will disappear thereby taking Congress out of the business of using the patent law to regulate competition within an industry. Moreover, the elimination of these special patent law provisions for pharmaceuticals will enhance the ability of the U.S. Trade Representative to harmonize international patent law with respect to pharmaceutical patents. Such harmonization is of importance in insuring that the business of developing and manufacturing generic drugs is not limited to a handful of nations that maximize safe harbor exemptions and minimize patent-term extensions. The elimination of

[*422] the Bolar exemption is also likely to spur both innovation and competition in a manner that benefits the public. On the generic side, it will serve to encourage the swiftest possible development of a generic drug after a patent expires since those who are first to market are likely to profit the most. On the brand-name side, uncertainty as to when market exclusivity will actually end is likely to spur the development of innovative replacement products which are ready for market before generic competition for the product of a recently expired patent begins.

B. Patent Certification and Generic Exclusivity

Since 1984, the Federal Circuit has firmly established the principle that preliminary injunctions are available in meritorious patent cases just as they would be in any other type of case. The Federal Circuit requires an evaluation and balancing of four factors in determining whether a preliminary injunction against patent infringement should be granted in a particular case. They are: 1) reasonable likelihood of success on the merits, 2) irreparable harm, 3) the balance of hardships faced by the parties, and 4) the impact of the injunction on the public interest. n99 There is no reason why the same test should not apply to pharmaceutical patents.

A patent is presumed to be valid and the party attacking validity has the burden of proving invalidity by clear and convincing evidence. It is often presumed that infringement of a valid patent would result in irreparable harm and, in any event, doubt concerning the alleged infringer's ability to satisfy a judgment would be sufficient to prove actual irreparable harm. Therefore, if the automatic thirty- month injunction was eliminated from the '84 Act it is likely that in most closely contested cases, a preliminary injunction would still be available to the patent owner at the commencement of an action. Moreover, in those instances where the patent challenge begins when the ANDA was filed, no preliminary injunction is even necessary since there can be no commercially harmful infringement until the FDA actually approves the ANDA. That approval process normally takes at least a year, thereby leaving ample time for the parties to litigate the question of whether an injunction is warranted. Indeed, the absence of an automatic thirty-month injunction will serve to compel the parties to expedite the litigation process as a matter of mutual self-interest in getting an early definitive court ruling on the merits.

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The elimination of the automatic thirty-month injunction will do no harm to the owners of meaningful patents but will bring an end to the abuse of that provision to prevent or delay competition in non-meritorious cases. Surely, the practice of listing marginal patents and asserting them solely to delay generic competition will come to an end as soon as no benefit can be derived from that practice. In any event, there is absolutely no reason why the enforcement procedures for pharmaceutical patents should continue to differ in any respect from other patents. Unlike the situation which prevailed prior to 1984, patents are now vigorously protected by the Court of Appeals for the Federal Circuit - a court which was new and had essentially no track record in 1984; the generic drug industry has become big business and has the financial ability to pay damages for wrongful infringement, and, most importantly, fourteen years of patent litigation experience has demonstrated that the generic side prevails far more often than the patent owner when patent rights are asserted. Therefore, the public interest demands the elimination of special injunction rights for pharmaceutical patents.

It is now clear that the 180-day period of exclusivity for the first ANDA applicant merely to challenge a patent was ill-conceived. At the time it was hastily drafted and injected into the negotiations leading to the '84 Act, we foolishly believed that patent challenges would only arise in cases where the validity of a basic patent was at issue, that there was no realistic possibility that such cases could be settled, and that litigation would be expensive. We were wrong on all counts! Experience has demonstrated that a significant number of patent challenges arise from the fact that weak patents of questionable scope are commonly listed in the Orange Book and that generic manufacturers are now skilled at developing non- infringing products which are bio-equivalent. Moreover, a significant number of patent challenges have resulted in settlement agreements in which the potential generic manufacturer was handsomely rewarded for giving up the right to challenge a patent. Finally, even the cost and risk of patent validity challenges turned out to be far less than expected because some patent lawyers were willing to share the risks and the rewards of a patent challenge under a contingent fee arrangement. In any event, the potential profit from a successful challenge far exceeds the cost of litigation and risk can and has been minimized by careful selection of meritorious cases as well as the real possibility of settlement.

The entire purpose of the 180-day exclusivity provision, at the time it was drafted, was to insure that one generic competitor would not get a free ride on the litigation effort of another generic competitor until the party who had borne the cost and risk of litigation had a fair opportunity to recover its litigation costs. Obviously, if 1) there is no litigation or 2) the litigation does not produce a judgment that would

[*424] inure to the benefit of other generic manufacturers, there can be no free ride and, therefore, no reason to grant the exclusivity reward. Therefore, the FDA was theoretically correct in attempting to limit the exclusivity reward to a successful litigant who actually obtains a judgment which is adverse to the patent owner. That approach would at least prevent those parties who have settled litigation from reaping where they have not sown. But the remedy contrived by the FDA does not go far enough. The agency (and others) have failed to recognize that a judgment that a patent is not infringed (or, conversely, that it is infringed) does not inure to the benefit (or detriment) of anyone other than the defendant in that case. It is a fact-based decision that involves a comparison between the challenger's product and the claims of the patent. Thus, for example, one generic manufacturer's sustained- release product or polymorph may be made by using a technology which is vastly different from that of another generic manufacturer such that one product infringes a patent and the other does not. Therefore, there is no reason in logic or law that the fate of one party may be held hostage to that of another party, irrespective of the order in which the challenges were filed. Indeed, in the extreme case, the patent owner could elect to sue the first challenger for infringement and forego a suit against the second challenger based solely upon differences between the two generic products that spell thedifference between infringement and non-infringement. In short, the 180-day exclusivity rule should not apply in cases based on a judgment of non-infringement since the challenger produces a result which only benefits itself.

For similar reasons, no exclusivity benefit should be granted to the detriment of an ANDA applicant who filed a patent challenge but was never sued by the patent holder. In those cases where the patent owner, for whatever reason, fails to assert its rights against a legitimate challenger, it defies logic to assert that such a challenger's ANDA should be held hostage to litigation involving an earlier-filed ANDA. If the patent owner does not object to the approval, there is no free ride and no basis for a claim that the prior challenge produced any benefit that would support exclusivity as against the subsequent challenger.

Given the foregoing limitations, there remains only the question of whether a party who procures a judgment that a patent is invalid or unenforceable, i.e., a judgment which would prevent the patent owner from thereafter asserting the patent against anyone, is entitled to the exclusivity reward. The answer is unclear and depends on the circumstances. If there is more than one party challenging a patent on the ground of invalidity or unenforceability, it can not be said that a case of free-riding exists. There may also be cases where the first challenger is the last to judgment and vice-versa. Alternatively, it is possible that

[*425] independent challenges to the same patent will be consolidated under procedural rules thereby resulting in simultaneous judgments. In short, there are few, if any, conceivable circumstances in which the failure to award exclusivity to a successful patent challenger would be grossly unfair to the challenger. More importantly, it seems highly unlikely that the elimination of the 180-day provision would actually discourage generic manufacturers from engaging in patent challenges.

It is now reasonably clear that the 180-day rule has been abused and produces no real public benefit that would not occur in its absence. Indeed, in would be difficult to identify a single actual case in the last fifteen years in which an unfairness or hardship would have been visited on a patent challenger by virtue of the unavailability of the 180-day exclusivity. On the other hand, many cases can be identified where the existence of the exclusivity either made no difference whatsoever or actually delayed generic competition. Ultimately, the decision to challenge a patent is a business decision which the government should not directly or indirectly encourage or discourage. Therefore, it is time to repeal this provision.

VII. Conclusion

Given the experience of the last fourteen years and the available data, the announced plan of Congress to revisit the provisions of the '84 Act presents an ideal opportunity for deregulation. The evidence is clear that the patent-related provisions of the '84 Act are no longer necessary to achieve the policy of fostering innovation while insuring public access to older drugs at competitive prices. The elimination of patent-term extensions, the Bolar exemption and the special procedural barriers to challenging patents that are invalid or not infringed will make it easier to achieve international harmonization and allow the marketplace to achieve maximum efficiency.

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Appendix

This Appendix collects information on the patent extensions granted to various blockbuster drugs under the Drug Price Competition and Patent Term Restoration Act of 1984. The information is organized in descending order of sales volume, by dollar value. The first line in each entry lists the BRAND NAME, the generic name, and the dollar value of 1997 sales. The second line lists the initial date of FDA approval, the length of the extension, the extended patent's expiration date, the minimum period of exclusivity, the last listed patent's expiration date, and the actual period of exclusivity based on the last listed patent's expiration date.

[SEE TABLE IN ORIGINAL]

n1 Pub. L. No. 98-417, 98 Stat. 1585 (1984). At the time of its enactment, the '84 Act was commonly referred to as the "Waxman-Hatch Act." See F-D-C Reports, "The Pink Sheet," Sept. 10, 1984. In recent years, with Republican majorities in Congress, the Act is now often called the "Hatch-Waxman Act" despite the fact that the legislation originated with Rep. Henry Waxman (D-Cal.) and was first introduced into the House of Representatives as House Bill 3605 in June, 1984. H.R. 3605, 98th Cong. (1984). Sen. Orrin Hatch (R-Utah) agreed to sponsor the Waxman bill in the Senate, and his involvement was critical to the ultimate enactment of the law.

n2 How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry (v i s i t e d M a r . 2 3 , 1 9 9 9) <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0&from=1>.

n3 Since 1991 the market capitalization of the seven largest pharmaceutical companies has increased by $ 655 billion (536%). Will 1999 Be As Kind to Pfizer As 1998?, F-D-C Reports, "The Pink Sheet," Jan. 11 1999, at 7.

n4 See *35 U.S.C. 156* (1994). In recognition of the fact that some of the lost marketing time results from necessary development effort rather than government delay, the maximum extension was limited so as not to exceed a maximum of fourteen years of market exclusivity from the date of FDA approval.

n5 See *35 U.S.C. 271*(e)(1) (1994). This provision is commonly referred to in the United States as the Bolar exemption because it overruled the decision of the Court of Appeals for the Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858, 221 U.S.P.Q. (BNA) 937 (Fed. Cir. 1984)*. Internationally, this provision is called the "safe harbor" provision.

n6 See *21 U.S.C. 355*(c) (1994) & *35 U.S.C. 271*(e)(2)-(4) (1994). Collectively these provisions are commonly referred to as the "patent certification" procedures of the '84 Act.

n7 *21 U.S.C. 355*(j)(5)(B)(iv) (1994).

n8 144 Cong. Rec. S12846-03 (1998).

n9 This was noted by U.S. Supreme Court Justice Scalia in *Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 679, 15 U.S.P.Q.2d (BNA) 1121, 1130 (1990)* ("No interpretation we have been able to imagine can transform 271(e)(1) into an elegant piece of statutory draftsmanship.").

n10 *Id. at 669, 15 U.S.P.Q.2d at 1126* (explaining that the statute's language is "not plainly comprehensible on anyone's view").

n11 *35 U.S.C. 101* (1994).

n12 See, e.g., *In re Hartop, 311 F.2d 249, 135 U.S.P.Q. (BNA) 419 (C.C.P.A. 1962).*

n13 *In re Anthony, 414 F.2d 1383, 1396, 162 U.S.P.Q. (BNA) 594, 605 (C.C.P.A. 1969).*

n14 *Id. at 1460, 162 U.S.P.Q. at 606.*

n15 The position of the Patent Office was subsequently expressed as follows: "If there is no assertion of human utility, or if there is an assertion of animal utility, operativeness for use on standard test animals is adequate for patent purposes." U.S. Patent and Trademark Office, Guidelines for Considering Disclosures of Utility in Drug Cases, in Manual of Patent Examining Procedure 608.01(p) (3d ed. rev. 1973).

n16 5 Donald S. Chisum, Chisum on Patents 16.03[1][a] & [b], at 16-102 to 16-109 (rel. no. 61, Mar. 1997).

n17 *Kaz Mfg. Co. v. Cheesborough-Pond's, Inc., 211 F. Supp. 815, 818, 136 U.S.P.Q. (BNA) 65, 67-68 (S.D.N.Y. 1962).*

n18 No. 75-2221 (D.N.J filed Dec. 23, 1975).

n19 Id.

n20 *61 F.R.D. 24, 181 U.S.P.Q. (BNA) 12 (E.D. Pa. 1973).*

n21 *Id. at 34, 181 U.S.P.Q. at 18.*

n22 Id.

n23 *217 U.S.P.Q. (BNA) 157 (C.D. Cal. 1982).*

n24 *Id. at 158.*

n25 Id.

n26 *Id. at 162.*

n27 *572 F. Supp. 255 (E.D.N.Y. 1983).*

n28 *Id. at 258.*

n29 *21 U.S.C. 355*(b) (1994).

n30 See generally, Alan H. Kaplan, Fifty Years of Drug Amendments Revisited in Easy-To-Swallow Capsule Form, 50 Food & Drug L.J. 179, 188-89 (1995).

n31 Alan D. Lourie, Patent Term Restoration, *66 J. Pat. Off. Soc'y 526, 529 (1984).* This article provides a comprehensive summary of the legislative events relating to the efforts to enact patent- term restoration legislation.

n32 See, e.g., Patent Term Extension and Pharmaceutical Innovation: Hearing on H.R. 1937 Before the Subcomm. On Investigations and Oversight of the Comm. on Science and Technology, 97th Cong. (1982). A good summary of the arguments presented by the opposing sides was published in 1 Health Affairs (Spring, 1982).

n33 Lourie, supra note 31, at 532.

n34 Id.

n35 Id.

n36 Id. at 533.

n37 *Roche Prods., Inc. v. Bolar Pharm. Co., 572 F. Supp. 255 (E.D.N.Y. 1983).*

n38 The proposed new approval process eliminated the need for independent proof of safety and efficacy. Instead, an Abbreviated New Drug Application (ANDA) could be filed in which the applicant would prove that its product was chemically identical and bio-equivalent, i.e., that it produced comparable amounts of the active ingredient in the body.

n39 Letter from Alfred Engelberg, Patent Counsel to the GPIA, to David Beier, Counsel to the Subcomm. on Patents of the House Judiciary Comm. (Feb. 15, 1984) (on file with author).

n40 The draft was never published. A copy is on file with the author.

n41 Prior to the '84 Act, there were only a few patent infringement controversies between brand-name and generic drug manufacturers due to the difficulty of obtaining FDA approval to market a generic copy. Many of these cases resulted in settlements in which the generic infringer consented to a permanent injunction on the eve of trial in exchange for a waiver of damages for past infringement, thereby assuring the generic manufacturer a profit. This was a practical solution, from the patent owner's viewpoint, since the infringer lacked the financial ability to pay any significant damage award, and the risk of a declaration that a patent was invalid was high in many jurisdictions. The simplified ANDA approval process threatened to produce greater opportunities for this type of hit-and-run infringement and was a major concern to PMA.

n42 *733 F.2d 858, 221 U.S.P.Q. (BNA) 937 (Fed. Cir. 1984).*

n43 Nothing in the court's opinion was intended to prejudice the proposed exemption to its decision that was then pending before Congress. In fact, the court went out of its way to state: It is the role of Congress to maximize public welfare through legislation. Congress is well aware of the economic and societal problems which the parties debate here, and has before it legislation with respect to these issues. No matter how persuasive the policy arguments are for or against these proposed bills, this court is not the proper forum to debate them. Where Congress has the clear power to enact legislation, our role is only to interpret and apply that legislation. *Id. at 865, 221 U.S.P.Q. at 942* (citations omitted).

n44 The draft legislation generally limited the availability of a patent extension to the first approval of a product and to the first patent which claimed that product. The cumbersome provisions of the proposed legislation were designed to prevent patent

owners from "evergreening," i.e. using a series of related patents (divisionals, continuations) covering different aspects of the same basic product invention in combination with patent term extensions to unduly prolong the exclusive market period.

n45 As enacted, the Bolar exemption to infringement became *35 U.S.C. 271*(e)(1) (1994) and the artificial act of infringement was codified as *35 U.S.C 271*(e)(2) (1994).

n46 *21 U.S.C. 355*(b)(1), 355(j)(2)(A)(vi) (1994).

n47 *21 U.S.C. 355*(b)(2)(A), 355(j)(2)(A)(vii) (1994).

n48 *21 U.S.C. 355*(b)(3)(B), 355(j)(2)(B)(ii) (1994).

n49 *21 U.S.C. 355*(c)(3)(C), 355(j)(5)(B)(iii) (1994).

n50 H.R. Rep. No. 98-857, pt. 1, at 27 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2660. This time period was increased to thirty months in the final version of the Act. *21 U.S.C. 355*(c)(3)(C), 355(j)(5)(B)(iii) (1994).

n51 *21 U.S.C. 355*(c)(3)(C)(ii), 355(j)(5)(B)(iii)(II) (1994).

n52 *35 U.S.C. 271*(e)(4)(C) (1994).

n53 *21 U.S.C. 355*(j)(5)(B)(iv) (1994).

n54 H.R. 3605 had been originally introduced in 1983 to deal solely with the proposed new abbreviated drug approval process for generic drugs. New Drug Applications: Hearings on H.R. 3605 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong. 4 (1983).

n55 H.R. Rep. No. 98-857, pt. 1, reprinted in 1984 U.S.C.C.A.N. 2647.

n56 How Much Haven for Drug Pioneers?, New York Times, June 25, 1984.

n57 H.R. Rep. No. 98-857, pt. 2, at 27-30, reprinted in 1984 U.S.C.C.A.N. 2686, 2711-14.

n58 The hearings are also of historical interest because the compromise was fully supported by Lew Engman, president of the PMA, and vigorously opposed by Gerald Mossinghoff, the Commissioner of Patents. Within a year after enactment of the '84 Act, Mossinhoff replaced Engman as the president of the PMA. Many years later, Engman became the president of the GPIA.

n59 *35 U.S.C. 156*(a)(5) (1994).

n60 H.R. Rep. 98-857, pt. 1, at 38 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2671.

n61 *21 U.S.C. 355*(c)(3)(C), 355(j)(5)(B)(iii) (1994).

n62 *21 U.S.C. 355*(c)(3)(D)(ii), 355(j)(5)(D)(ii) (1994).

n63 *21 U.S.C. 355*(c)(3)(D)(iii) & (iv), 355(j)(5)(D)(iii) & (iv) (1994).

n64 *21 U.S.C. 355*(c)(3)(D)(v), 355(j)(5)(D)(v) (1994).

n65 It is of more than passing interest that a seven- year period of market exclusivity was a key provision of the 1983 Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049

(1983), that sought to encourage companies to invest in the development of drugs for diseases with relatively small patient populations. *21 U.S.C. 360cc*(a) (1994).

n66 See, e.g., Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), *7 U.S.C. 136* et. seq. (1994); *Ruckelshaus v. Monsanto Co., 463 U.S. 1315 (1983).*

n67 H.R. Rep No. 98-857, pt. 1 at 41 (1984). Thus, the recent claims by pipeline patent owners that they were inadvertently shortchanged by the 1984 Act and deserve additional extensions as a matter of equity is contradicted by the legislative history of the Act.

n68 *872 F.2d 402, 406, 10 U.S.P.Q.2d (BNA) 1304, 1307 (Fed. Cir. 1989).*

n69 *Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 679, 15 U.S.P.Q.2d (BNA) 1121, 1130 (1990).*

n70 *Id. at 669, 15 U.S.P.Q.2d at 1126.*

n71 *Id. at 669-70, 71, 15 U.S.P.Q.2d 1126-27* (citations and footnotes omitted).

n72 *Id. at 676-78, 15 U.S.P.Q.2d 1129-30* (citations and internal quotations omitted).

n73 *35 U.S.C. 271*(e)(1) (1994).

n74 5 Chisum, supra note 16, 16.03[1][d][iii], at 16-126 (rel. no. 61, Mar. 1997).

n75 See, e.g., *Scripps Clinic & Research Found. v. Genentech Inc., 666 F. Supp. 1379, 1396-97, 3 U.S.P.Q.2d (BNA) 1481, 1494 (N.D. Cal. 1987),* aff'd in part, rev'd in part, *927 F.2d 1565, 18 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 1991); American Std., Inc. v. Pfizer Inc., 722 F. Supp. 86, 103, 14 U.S.P.Q.2d (BNA) 1673, 1686 (D. Del. 1989); Scripps Clinic & Research Found. v. Baxter Travenol Labs., Inc., 7 U.S.P.Q.2d (BNA) 1562, 1565 (D. Del. 1988); Telectronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.2d 1520, 1523-24, 25 U.S.P.Q.2d (BNA) 1196, 1198-99 (Fed. Cir. 1992); Ortho Pharm. Corp. v. Smith, 18 U.S.P.Q.2d (BNA) 1977, 1992 (E.D. Pa. 1990),* aff'd, *959 F.2d 936, 22 U.S.P.Q.2d (BNA) 1119 (Fed. Cir. 1992); Intermedics, Inc. v. Ventritex, Inc. 775 F. Supp. 1269, 1277-78, 20 U.S.P.Q.2d (BNA) 1422, 1427-28 (N.D. Cal. 1991),* aff'd, *991 F.2d 808, 26 U.S.P.Q.2d (BNA) 1524 (Fed. Cir. 1993)* (unpublished table decision); *NeoRx Corp. v. Immunomedics Inc., 877 F. Supp. 202, 206, 31 U.S.P.Q.2d (BNA) 1423, 1426 (D.N.J. 1994); Elan Transdermal Ltd. v. Cygnus Therapeutic Sys., 24 U.S.P.Q.2d (BNA) 1926, 1932-33 (N.D. Cal. 1992)* (unpublished table decision); *Abtox Inc. v. Exitron Corp., 888 F. Supp. 6, 9, 35 U.S.P.Q.2d (BNA) 1508, 1510 (D. Mass. 1995).*

n76 General Agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Apr. 15, 1994, *33 I.L.M. 1125, 1209.*

n77 Letter from Gerald R. Mossinghoff, President, Pharmaceutical Manufacturer's Association, to Michael Kantor, United States Trade Representative 4 (Apr. 6, 1993) (emphasis added) (on file with author).

n78 Message from the President of the United States Transmitting the Uruguay Round Trade Agreements, Texts of Agreements Implementing the Bill, Statement of Administrative Action and Required Supporting Statements, H.R. Doc. No. 103-316, at 986 (1994).

n79 Id.

n80 Application for FDA Approval to Market a New Drug, 21 C.F.R. pt. 314 (1998).

n81 The FDA is prohibited from approving an ANDA for thirty months after litigation begins except in the unlikely event that there is a final judgment disposing of the patent in less than thirty months.

n82 Indeed, in some instances, the non-infringement was so apparent that the patent holder simply succumbed to the challenge and never filed a suit for patent infringement. This was true, for example, with respect to the patents covering a particular formulation of MAXIDE, a polymorph of MINIPRESS, and a sustained release version of INDERAL.

n83 Multiple challenges are not the result of one company "free-riding" on the patent challenge commenced by a competitor. It normally takes a period of six to twelve months to develop the data required before an ANDA containing a patent challenge can be filed.

n84 This is precisely what has occurred in the case of Tamoxifen. In that case, the settlement provided Barr with the right to distribute a generically labeled version of Tamoxifen manufactured by the patent owner. Similarly, in the series of cases involving ZANTAC, the first challenger settled with Glaxo but nevertheless claimed entitlement to the 180-day exclusivity following the entry of judgment adverse to the patent in a case involving a subsequent challenger.

n85 In a pending controversy involving Hoffman LaRoche's TICLID (ticlopidine), the first ANDA filed by Torpharm has been unable to garner FDA approval and Roche elected not to sue any of the subsequent challengers. As a result, there is no possibility of any judgment and no possibility of an approved generic product unless and until the Torpharm product is approved.

n86 See, e.g., Mova Pharm. Corp. v. Shalala, No. 97- 5082, *1998 U.S. App. LEXIS 7391* (D.C. Cir. Apr. 14, 1998); *Granutec, Inc. v. Shalala, Nos. 97-1873, 97-1874, 1998 U.S. App. LEXIS 6685* (4th Cir. Apr. 3, 1998); *Inwood Labs., Inc. v. Young, 723 F. Supp. 1523, 12 U.S.P.Q.2d (BNA) 1065 (D.D.C. 1989),* vacated as moot, *43 F.3d 712 (D.C. Cir. 1989)* (unpublished table decision).

n87 See Guidance for Industry on 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, *63 Fed. Reg. 37890 (1998).*

n88 The FDA clearly has the authority to require applicants to amend an ANDA to insure that all statements made are truthful. A paragraph IV certification stating that a patent is believed to be invalid or non-infringed would no longer be truthful after a patent challenge is withdrawn by settlement.

n89 F-D-C Reports, "The Pink Sheet," Mar. 15, 1999, at 4.

n90 The non-patent exclusivity which prohibits the filing of an ANDA application for five years after the first approval of an NDA for a new chemical entity should be preserved. This would insure a period of about seven years of market exclusivity for a new drug, irrespective of the existence of any patents and would insure that investments would continue to be made to develop unpatentable new drugs.

n91 How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry (visited Mar. 23, 1999) <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0&from=1> .

n92 Id.

n93 Id.

n94 Patent Terms Extended *35 USC 156* (visited Mar. 23, 1999) <http://www.uspto.gov/web/offices/pac/dapp/opla/term/156.htm l>. The last patent to receive a full five-year extension is U.S. patent No. 4,639,436 issued in 1987. The seventy patents issued since that date which have received extensions have been extended for less than five years, normally due to the fourteen- year cap.

n95 How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry (visited Mar. 23, 1999) <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0&from=1> .

n96 Id.

n97 Will 1999 Be As Kind to Pfizer As 1998?, F-D-C Reports, "The Pink Sheet," Jan. 11 1999, at 7.

n98 The current annual report of Eli Lilly & Co. states "The PROZAC patent expiration is serving as a catalyst to bring greater intensity to everything we do." The report goes on to describe the accelerated development of new products to replace the expected loss of profits from PROZAC when its patent expires in 2004. See F-D-C Reports, "The Pink Sheet," Apr. 5, 1999, at 10.

n99 See *Illinois Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 681, 15 U.S.P.Q.2d (BNA) 1307, 1308 (Fed. Cir. 1990).*