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# The Effect of Lilly v. Medtronic on the Scope of 35 USC 271(e)(1): The Patent Infringement Exemption - Broad or Narrow

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# THE EFFECT OF *LILLY v. MEDTRONICS* ON THE SCOPE OF 35 USC § 271(e)(1): THE PATENT INFRINGEMENT EXEMPTION—BROAD OR NARROW?

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## I. INTRODUCTION

Until June 1990,<sup>1</sup> some medical device manufacturers risked being sued for patent infringement by the patent holder when they collected pre-marketing data as required by the Food and Drug Administration (FDA) prior to the expiration of the patent. In 1984, drug manufacturers were expressly exempted from similar patent infringement lawsuits by the Patent Term Restoration Act (PTR Act of 1984 or DPC-PTR Act of 1984) which was signed into law by President Reagan.<sup>2</sup> Among the provisions of that Act, Congress amended 35 USC § 271 by adding a new section 35 USC § 271(e). This new section contains language which provides that “[i]t shall not be an act of infringement to make, use, or sell a patented

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<sup>1</sup> *Eli Lilly and Co. v. Medtronic, Inc.*, 110 S. Ct. 2683 (1990).

<sup>2</sup> The Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98th Cong., 2d Sess., 98 Stat. 1585 (1986).

### OVERVIEW OF THE PATENT TERM RESTORATION ACT OF 1984:

Title I of the PTR Act of 1984 contains *section 101* of the Act. *Section 101* of the PTR Act of 1984 amends section 505 of the Federal Food, Drug, and Cosmetic Act (21 USC § 355) which provides for submission of ANDAs (*see infra* note 47) and paper NDAs.

Title II of the PTR Act of 1984 contains *sections 201* and *202*. *Section 201* of the Act contains section 156 which provides for the extension of a patent term. *Section 202* of the Act amends 35 USC § 271 by adding section 271(e)(1) which provides for the *infringement exemption* to section 271(a).

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." The purpose of § 271(e)(1) is to permit competitors to engage in data gathering activities solely for the development and submission of information to a Federal agency prior to the expiration of a patent. Without the existence of 35 USC § 271(e)(1), such data gathering activities conducted prior to the expiration of a relevant patent would constitute patent infringement under 35 USC § 271(a).

Section 271(a) states that "[e]xcept as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." Activity undertaken without authority or license from the patentee which involves the use of a patented drug, for commercial purposes, prior to the expiration of the patent term was considered patent infringement under 35 USC § 271(a) before the enactment of 35 USC § 271(e)(1). This was the precise conclusion reached by the courts in *Pfizer v. International Rectifier*<sup>3</sup> and *Roche Products v. Bolar Pharmaceuticals*,<sup>4</sup> both of which were decided before the PTR Act of 1984 was signed into law. It was widely believed that the *infringement exemption* provided for in 35 USC § 271(e)(1) applied specifically to drugs (SECTION 101 OF THE PTR ACT OF 1984, *infra*) especially since the language in 35 USC § 271(e)(1) refers expressly to "the manufacture, use, or sale of drugs." However, the scope of this new provision assumes a new dimension in view of the recent Supreme Court decision in *Lilly v. Medtronics*<sup>5</sup> which held that the *infringement exemption* of 35 USC § 271(e)(1) applies not only to drugs but to medical devices as well.

This article undertakes to examine, critically, the case history, legislative history, and the construction of sections 101, 201, and 202<sup>6</sup> of the Patent Term Restoration Act of 1984 in an effort to analyze the Supreme Court's recent decision in *Lilly v. Medtronics* and to discern how the scope of § 271(e)(1) is likely to be treated in future cases in light of that recent Supreme Court decision.

## II. CASES PRECEDING PASSAGE OF THE PTR ACT OF 1984

Analysis of the interpretation by the federal courts of 35 USC § 271(e)(1) begins with the decisions that immediately preceded passage of the PTR Act of 1984 containing the provisions of 35 USC § 271(e)(1), starting with *Pfizer v. International Rectifier*. Prior to the passage of the PTR Act of

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<sup>3</sup> *Pfizer v. International Rectifier*, 217 USPQ 157 (C.D. Cal. 1982).

<sup>4</sup> *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (Fed. Cir. 1984).

<sup>5</sup> See *supra* note 1.

<sup>6</sup> See *supra* note 2.

1984, a party alleged to have violated 35 USC § 271(a) could defend itself by showing that its alleged activity constituted a common law experimental use<sup>7</sup> infringement exemption to 35 USC § 271(a). In *Pfizer*, the court held that for activity to be classified as an experimental use common law exemption applicable to alleged infringing activity under 35 USC § 271(a), the activity must not be related to any commercial use.<sup>8</sup> In *Pfizer*, the respondent, International Rectifier, contended that in making and using doxycycline, a patented Pfizer product, it was engaging in collecting premarketing data for the Food and Drug Administration (FDA) and, therefore, making a common law experimental use of the drug *exempted* from infringement liability under 35 USC § 271(a). The district court did not accept this defense and ruled in favor of the patentee.

Following *Pfizer*, *Bolar* was decided on similar grounds. There, prior to the patent expiration, the defendant generic drug company engaged in obtaining FDA premarketing approval of the generic form of Roche's patented product, Dalmane. The Court of Appeals for the Federal Circuit (CAFC) held that the use of the patented drug, prior to the expiration of the Dalmane patent, solely for development and submission of data to the FDA for obtaining premarketing approval was an act of infringement. In so holding, the CAFC overruled the decision of the district court and stated that Bolar's activities in seeking FDA approval of its generic version of Dalmane, prior to expiration of the relevant patent, constituted patent infringement pursuant to 35 USC § 271(a). It should be noted that Bolar did not engage in selling the generic equivalent of Dalmane to the consumer during the patent term of that product. Within the framework of the PTR Act of 1984, Congress, thereafter, passed § 271(e)(1) specifically overruling the *Bolar* decision.<sup>9</sup>

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<sup>7</sup> "[T]he underlying rule of permissible experimental use demands there must be intended commercial use of the patented article, none whatsoever, . . . . To constitute an infringement, the making must be with an intent to use for profit, and not for the mere purpose of a philosophical experiment." *Pfizer, Inc. v. International Rectifier*, 217 USPQ 157,161 (C.D. Cal. 1982).

<sup>8</sup> *Id.*

<sup>9</sup> The Court of Appeals for the Federal Circuit stated that "[t]he district court correctly recognized that the issue in this case is narrow: does the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute a use which, unless, licensed, the patent statute [35 USC § 271(a)] makes actionable? The district court held that it does not. This was an error of law." *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 861, 221 USPQ 937, 939 (Fed. Cir. 1984). The language of 35 USC § 271(e)(1) permits the conduct which was specifically prohibited by the decision of the Court of Appeals for the Federal Circuit in *Bolar*. The language of 35 USC § 271(e)(1) states: "It 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."

## III. LEGISLATIVE HISTORY OF § 271(E)(1)

## A. Senate – Introduction of the Bill

On January 27, 1981 Senators Mathias, Byrd, Thurmond, Percy, and Deconcini introduced Senate Bill 255 (S. 255)<sup>10</sup> on the floor of the Senate. The *stated objective of the bill* was “to amend the patent law to restore the term of the patent grant for the period of time that non-patent regulatory requirements prevent the marketing of the patented product

<sup>10</sup> Legislative History (in Chronological Order) of the Passage of the Patent Term Restoration Act of 1984:

DATE	ACTION	BILL	SENATOR/REPRESENTATIVE	CONG/RPT	COMMENT
1979	introduced	HR3589	Symes		
1980	introduced	S2892	Bayh, Thurmond, Mathias, Morgan, Percy	96th	
1980	introduced	HR7952	Kastenmeier, Sawyer		
1-27-81	introduced	S255	Mathias, others		S255 is similar to 96th Congress' S2892
6-16-81	REPORTED OUT	S255	Senate Judiciary Comm.	S. Rpt. 97-138	Recommended passage
7-9-81	PASSED	S255	Only in Senate		
1981	introduced	HR1937	Kastenmeier, Sawyer	97th	Essentially the same as S255; the House version
5-20-82	introduced	HR6444	Kastenmeier Subcomm.	97th	HR6444 is a clean version of HR1937 and is related to S255
7-20-82	<u>Pfizer v. Int'l. Rectifier</u>				Held commercial use of drug to amount to patent infringement under 35 USC § 271(a)
8-4-82	REPORTED OUT	HR6444	House Judiciary Comm.	H. Rpt. 97-696	
9-15-82	FAILED	HR6444	In House of Represent.		Said defeated due to Waxman's efforts
5-17-83	introduced	S1306	Mathias		Essentially the same as the 1981 version of S255 that passed in the Senate
6-23-83	introduced	S1538		98th	
6-30-83	introduced	HR3502	Synar, others		Essentially the same as the 1981 version of S255 that passed in the Senate
7-19-83	introduced	HR3605	Waxman	98th	
10-11-83	<u>Roche v. Bolar</u>				District court held the use of the drug as non-infringing under 35 USC § 271(a)

...<sup>11</sup> This bill was referred to as the Patent Term Restoration Act of 1981.

Senator Mathias introduced this bill to address the concerns of several Congressmen which were subsequently printed in the accompanying Sen-

DATE	ACTION	BILL	SENATOR/REPRESENTATIVE	CONG/RPT	COMMENT
4-23-84	<u>Roche v. Bolar</u>				CAFC held use of the drug as infringing under 35 USC § 271(a); Reversed the district court's holding; agreed with the holding in <u>Pfizer</u>
4-26-84	introduced	HR5529	Kastenmeier, Dewine, Glickman		Agricultural Patent Term Reform Act; addressed agrochemical patent extensions
5-24-85	amended	HR3605	Waxman		Deleted agrochemicals from this bill; amended HR3605
6-12-84	introduced	S2748	Hatch, Mathias, DeConcini, Kennedy		Essentially the same as the House version of HR3605
6-21-84	REPORTED OUT	HR3605	House Energy & Commerce Comm	H. Rpt. 98-857 Part I	
6-29-84	PASSED	S1538	Only in Senate		An amended version of S1538 passed in the senate
8-1-84	REPORTED OUT	HR3605	House Judiciary Comm.	H. Rpt. 98-857 Part II	
8-9-84	introduced	S2926			Senate version of HR3605 as amended and reported out
8-10-84	PASSED	S2926	Only in Senate		
9-6-84	PASSED	HR3605	Only in House		Amended version of HR3605 passes in the House; House then amends S1538 to conform to the passed versions of HR3605 & S2926 and sends bill S1538 to Senate for vote
9-12-84	PASSED	S1538	In Senate as well		Senate accepts House's amendments to S1538 to conform to passed version of HR3605 and passes S1538; Bill goes to President to sign
9-24-84	BECOMES LAW	PTR Act	President Ronald Reagan		Legislation passed and signed into law and known as the PTR Act of 1984

<sup>11</sup> 127 CONG. REC. S674 (daily ed. January 27, 1981) (statement of Sen. Mathias).

ate Report of the Judiciary Committee.<sup>12</sup> The 17-year duration<sup>13</sup> of a patent is designed to give the patent holder market exclusivity on that patent for the full 17 years. However, some patented products require regulatory review and marketing approval by a federal agency before such products may be sold to the public. Obtaining marketing approval delays the introduction of these products into the marketplace. Generally, manufacturers obtain patents for their products before seeking marketing approval. Thus, to determine the period of actual market exclusivity afforded a federally regulated product one must deduct from the 17-year term of a patent the time spent in obtaining premarketing approval. In effect, compliance with premarketing federal regulations results in substantially reducing the effective patent life<sup>14</sup> of a patented product. According to the Judiciary Committee's report on the Patent Term Restoration Act of 1981, the effective patent term of premarketing regulated products has gone below 10 years.<sup>15</sup>

### *B. Judiciary Committee Report – Public Policy Considerations*

In 1861, Congress selected a 17-year life for a patent.<sup>16</sup> The purpose of the patent was to "[provide] an incentive for the costly and lengthy work of developing an invention by giving the inventor a sufficient opportunity to market a new product exclusively."<sup>17</sup> The incentive to invest is greater for a patent whose life of market exclusivity is closer to 17 years than to 10 years or less.

Industries that have high research and development (R&D) costs are hardest hit by a reduction in the incentive to invent. Among these are the manufacturers of drugs and medical devices. It is estimated that

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<sup>12</sup> S. REP. NO. 138, 97th Cong., 1st Sess. 6 (1981); *See supra* note 10.

<sup>13</sup> *See infra* note 16.

<sup>14</sup> "The 'effective patent life' of a drug is measured from the date of FDA approval of the NDA (*See infra* note 47) to the date of expiration of the patent." Flannery & Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L. J. 269, 301 (1985).

<sup>15</sup> S. REP. NO., *supra* note 12, at 6. "Today, the process of getting a new medication approved by the Food and Drug Administration (FDA) has become so complex that, on the average, almost half of the patent life of a drug now expires before the product can be put on the market." 127 CONG. REC. S7355 (daily ed. July 9, 1981) (statement of Sen. Percy); "Academic studies (Eisman and Wardell, *Research Management* 21(1), 18-21 (1981) and others) had shown that the effective patent life for pharmaceutical products had declined sharply in recent years. They concluded that, from 1966 to 1979, effective patent life had fallen from 13.6 years to 9.5 years." Alan D. Lourie, *Patent Term Restoration*, 66 J. PAT. OFF. SOC'Y. 526, 527 (1984); "A recent study indicated that it now can take on average from 7 to 10 years for a pharmaceutical company to satisfy the current regulatory requirements. . . . Because most FDA-required testing is done after a patent issues, the remaining effective life of patent protection asserted may be as low as 7 years." *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 221 USPQ 937, 941 (1984).

<sup>16</sup> S. REP. NO. 138, *supra* note 12, at 6. Act of March 2, 1861, Ch. 88 § 16, 12 Stat. 246.

<sup>17</sup> S. REP. NO. 138, *supra* note 12, at 6.

"[between] 1954 and 1975, R&D expenditures in the U.S. drug industry went from 90 million to 420 million."<sup>18</sup> It is noted that "[t]he erosion of the patent term has been most severe on some industries whose innovations provide important benefits to society. For example, society has the strongest interest in encouraging the development of new and improved drug therapies, [and] more effective medical devices . . ."<sup>19</sup> The result of this erosion of the effective patent life and the high cost of R&D has been to decrease "the average number of new chemical entities discovered and introduced in the country each year, . . . from 20 [in 1954] to 10 [in 1975]."<sup>20</sup> It is pertinent to note that while total R&D expenditures has increased, the resultant development of marketed products has sharply decreased.

The problem of a decreased patent life is compounded by the realities of R&D. For example,

Nearly 90 percent of the drug candidates studied in humans [became research 'deadends' and] were dropped prior to the submission of a marketing application to [the Food and Drug Administration.] An analysis of 1029 new chemical entities submitted [for] testing between 1963-75 showed that only 59, or six percent of the total, were eventually marketed.<sup>21</sup> The annual growth rate for pharmaceutical R&D activities in America from 1973-1979 was 11 percent, as compared to 25 percent in the United Kingdom, 20 percent in Germany, and 22 percent in Japan.<sup>22</sup>

The Judiciary Committee's report on S. 255<sup>23</sup> stated that the Committee was "particularly disturbed by the declining position of the U.S. industry in the international field of pharmaceutical research" and that it was "urgent to remove the handicap of reduced patent protection. . ."<sup>24</sup> The Judiciary Committee concluded that "S. 255 will provide added cash flow

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<sup>18</sup> *Id.*; "With less chance to earn back their initial investment,—it cost an average of \$80 million to develop a new drug in 1979 compared to \$6 million in 1962—pharmaceutical companies are less motivated to invest in research and drug development and increasingly inclined to shift to non-drug products." 127 CONG. REC. S7355 (daily ed. July 9, 1981) (statement of Sen. Percy); "In 1962, for example, it took approximately 2 years and \$6 million (or \$15 million in 1979) to bring a new medicine from the laboratory to the marketplace. It now takes, on average, 7 to 10 years and about \$70 million to complete this testing period" 127 CONG. REC. S674 (daily ed. January 27, 1981) (statement of Sen. Mathias).

<sup>19</sup> S. REP. NO. 138, 13.7b.4.2a, *supra* note 12, at 6.

<sup>20</sup> *See id.* at 7; "For example, from 1955 through 1962, an average of 46 new drugs were introduced annually in the United States; today that average is only 17 new drugs a year, a decline of 63 percent." 127 CONG. REC. S674 (daily ed. January 27, 1981) (statement of Sen. Mathias).

<sup>21</sup> S. REP. NO. 138, *supra* note 12, at 6-7. "On the average, scientists now screen more than 10,000 possibilities for every one new medication that is eventually approved by the FDA and put on the market." 127 CONG. REC. S7355-56 (daily ed. July 9, 1981) (statement of Sen. Percy).

<sup>22</sup> S. REP. NO. 138, *supra* note 12, at 7.

<sup>23</sup> *Id.* at 6; *see supra* note 10.

<sup>24</sup> *See supra* note 22.



to finance the costly future research efforts . . . [and] . . . it will increase the expected return from new drug innovations, thereby, providing both the incentive and the economic capability to conduct expensive long-term research and development."<sup>25</sup> Notably, a firm cannot be expected to invest in expensive long-term R&D unless the firm expects to recover the investment in the future years on the expectation of a patent and the ensuing market exclusivity granted by that patent. If the duration of market exclusivity is eroded by the premarketing regulatory process, then the incentive to invest in R&D is, at least, proportionately diminished.

As proposed by S. 255, increasing the effective patent life would generate additional funds crucially needed by the small research oriented firms. With these funds the smaller companies have the opportunity to invest in R&D which is otherwise prohibitively expensive. The result is that greater competition from the smaller firms is promoted.<sup>26</sup> The proposed legislation would also benefit teaching institutions such as universities, where most of the country's fundamental research is conducted, which "find it difficult to license their inventions because of their shortened patent lives."<sup>27</sup> The Committee stated that it had a "strong interest in the responsibilities of the pharmaceutical industry for pursuing and manufacturing drugs to treat relatively rare diseases, which can anticipate only a limited market."<sup>28</sup> With regard to generic drugs, the Committee concluded that even though the proposed patent term restoration (S.255) will primarily cause a delay in the copying of drugs which can be produced and sold at lower prices, the innovation of a greater number of pioneering drugs will eventually become a source of greater income for the generic drug industry. Presumably, the incentive to invest in R&D due to patent term restoration would have lead to the marketing of a larger number of pioneer drugs which otherwise would not have been developed and marketed. In turn, these undeveloped pioneer drugs would not have been available for copying by the generic drug manufacturers.

The problem that was to be corrected by the proposed legislation in S. 255 was to counteract the effect of the

[I]ncreasing number of laws passed by the Congress to insure that new products are safe for the public to use. Unfortunately, the time required for this testing runs against the 17-year life of a patent. [Though] [t]hese tests are unrelated to the [granting of a] patent, [they] severely limit the time available to market the product.<sup>29</sup>

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<sup>25</sup> *Id.*

<sup>26</sup> *See id.* at 8; "This inequity hits small innovative businesses especially hard. They need the protection that a patent offers in order to protect their new ideas and innovations. These companies cannot afford to lose valuable years of patent coverage while awaiting premarket clearances from Federal regulatory agencies. It has been well documented that small businesses are the most innovative segment of our economy and the most dependable source of new jobs for our workers." 127 CONG. REC. S674 (daily ed. January 27, 1981) (statement of Sen. Mathias).

<sup>27</sup> S. REP. NO. 138, *supra* note 12, at 8.

<sup>28</sup> *See id.* at 9.

<sup>29</sup> 127 CONG. REC. S675 (daily ed. January 27, 1981) (statement of Sen. Thurmond).

On July 9, 1981 the Senate passed S. 255.<sup>30</sup>

*C. House of Representatives – Amendments to the Bill*

The House of Representatives introduced a bill substantially the same as S. 255 referred to as H.R. 1937.<sup>31</sup> However, there was much opposition to H.R. 1937 in the House.<sup>32</sup> After making changes to H.R. 1937, the bill was introduced as a “clean” version in H.R. 6444 on May 20, 1982.<sup>33</sup> This legislative effort, known as the Patent Term Restoration Act of 1982, was defeated in the 97th Congress in the House.<sup>34</sup> The Patent Term Restoration Act of 1981 (S. 255) failed to pass in the House when it was voted on under the designation of H.R. 6444.<sup>35</sup> The failure to pass this legislation has been attributed to Representative Henry Waxman<sup>36</sup> who was concerned that any patent term restoration would have to accommodate the interests of the generic drug manufacturers.<sup>37</sup>

A compromise was reached between the research based drug industry, represented by the Pharmaceutical Manufacturer’s Association (PMA), and the members of the generic drug industry, represented by the Generic Pharmaceutical Industry Association (GPIA). The details of the negotiations between the PMA and the GPIA are published elsewhere.<sup>38</sup> From the compromise between the PMA and the GPIA, new legislation, known as H.R. 3605, was introduced in the House on July 19, 1983<sup>39</sup> and referred to the Judiciary Committee.<sup>40</sup> This bill eventually became the Patent Term Restoration Act of 1984. The main purpose of the referral was to obtain authorization from the Judiciary Committee for amendments made to section 505 of the Federal Food, Drug and Cosmetic Act (FDCA) authorizing use of abbreviated new drug applications (ANDAs<sup>41</sup>) for generic drugs of previously approved pioneer drugs. The committee report,<sup>42</sup> re-

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<sup>30</sup> Alan D. Lourie, *Patent Term Restoration: History, Summary, and Appraisal*, 40 FOOD DRUG COSM. L.J. 351, 353 (1985).

<sup>31</sup> *Id.*; see also *supra* note 10.

<sup>32</sup> Lourie, *supra* note 30, at 353. “In the House, Congressmen Kastenmeier and Sawyer introduced H.R. 1937, essentially the same as S. 255. By this time, however, substantial opposition to the bill had emerged from groups historically antagonistic to the research-based drug industry, which had become the principal focus of the bill. At hearings held by Kastenmeier subcommittee, generic drug manufacturers, retired persons groups, and what are referred to as ‘public interest’ groups testified against it.” Lourie, *supra* note 15, at 530.

<sup>33</sup> CIS/Annual 1884, *Legislative Histories, January - December 1984* (CONG. INFO. SERVICE, INC.) Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585 (98th Cong., 2nd Session), 279, 280.

<sup>34</sup> *Id.*; see also *supra* note 10.

<sup>35</sup> See *supra* note 10 which lists in table form the chronological legislative history of the Patent Term Restoration Act of 1984 beginning in 1979.

<sup>36</sup> Lourie, *supra* note 30, at 354; Lourie, *supra* note 15, at 533.

<sup>37</sup> Lourie, *supra* note 30, at 354; Lourie, *supra* note 15, at 533.

<sup>38</sup> Lourie, *supra* note 30, at 355.

<sup>39</sup> Flannery & Hutt, *supra* note 14, at 271; Lourie, *supra* note 15, at 533.

<sup>40</sup> See *supra* note 10.

<sup>41</sup> See *infra* note 47.

<sup>42</sup> H.R. REP. NO. 857, 98th Cong., 2d Sess., Pt.II (1984).

garding H.R. 3605, approved the proposed bill. This bill was revised to a large extent and introduced as S. 2748 in the Senate on June 12, 1984.<sup>43</sup> The House Committee on Energy and Commerce made its report on June 21, 1984.<sup>44</sup>

#### *D. Major Differences Between the Several Amended Versions*

There were several major differences among the provisions proposed in S. 255, H.R. 1937, H.R. 6444 and S. 2748. The legislation known as the Patent Term Restoration Act of 1981 (S. 255 and H.R. 1937) and the Patent Term Restoration Act of 1982 (H.R. 6444), in effect, provided the members of the PMA with a patent extension provision for a maximum duration of seven additional years<sup>45</sup> without any regard for the interests of the members of the GPIA. In contrast, the Patent Term Restoration Act of 1984 (S. 2748, S. 2926, S. 1538 and H.R. 3605) provided members of the PMA with a maximum possible patent extension of seven and a half years (5 years patent extension plus 30 months<sup>46</sup>) while providing for an expedited method of approving generic drugs through the use of abbreviated new drug applications (ANDAs)<sup>47</sup> and paper new drug ap-

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<sup>43</sup> Flannery & Hutt, *supra* note 14, at 271.

<sup>44</sup> Flannery & Hutt, *supra* note 14, at 271.

<sup>45</sup> "The purpose of the present bill is to restore to products subject to premarket review requirements a period equal to the time required for this clearance—up to a maximum of 7 years." 127 CONG. REC. S674 (daily ed. January 27, 1981) (statement of Sen. Mathias).

<sup>46</sup> Lourie, *supra* note 15, at 548; "[E]ven though an ANDA containing a certification of patent invalidity or noninfringement [§ 505(j)(2)(A)(vii)(IV) of the FDCA] may be submitted to FDA . . . permitting the patent litigation to begin at that time, the legislation provides a further period during which the generic version may not be marketed if the patent owner initiates litigation. Thus, the ANDA may not be made effective by FDA for a total of seven and a half years after the approval of the pioneer NDA if litigation is brought, unless the court holds the patent invalid or not infringed at an earlier date." Flannery & Hutt, *supra* note 14, at 289.

<sup>47</sup> "The FD&C Act, [Federal Food, Drug and Cosmetic], requires every person who wishes to market a new drug to submit a *new drug application (NDA)* demonstrating the safety and effectiveness of the drug. FDA [Food and Drug Administration] must approve the NDA before the drug may be marketed. A 'full NDA' contains all of the required animal and human proof of safety and effectiveness, through studies conducted by or for the applicant or for which the applicant has obtained a right of reference or use from the person by or for whom the studies were conducted. A new drug for which a full NDA is submitted to FDA is called a 'pioneer new drug' or 'pioneer drug' (or, under the DFC-PTR Act, a 'listed' drug). An NDA for such a drug is called a 'pioneer NDA' or a 'full NDA,' and the person who submits that application is called the 'pioneer applicant.' In contrast, a new drug for which approval is sought on the basis that it is equivalent to a previously approved pioneer new drug, and for which no animal and human studies on safety and effectiveness are independently conducted, is called a 'generic drug.' An NDA for a generic drug is called an '*abbreviated NDA (ANDA)*,' a 'paper NDA,' or a 'generic application,' and the person who submits it is called a 'generic applicant.'" (Emphasis added.) Flannery & Hutt, *supra* note 14, at 272. "[I]n 1980, FDA adopted a 'paper NDA' policy for generic copies of all pioneer new drugs, whether

plications (paper NDAs).<sup>48</sup>

In addition, the Drug Price Competition and Patent Term Restoration Act of 1984 (PTR Act of 1984 or DPC-PTR Act of 1984) provided for testing of generic drugs using the patented drug solely for the purpose of providing data to the Food and Drug Administration (FDA) prior to the expiration of the patent on the pioneer drug.<sup>49</sup> The provision of the PTR Act of 1984 allowing for comparison testing between a generic and a patented drug prior to the expiration of the patent is embodied in Title II, *section 202* of the Act. "Section 202 of the Act amends section 271 of the patent law (35 U.S.C.) to add a new subsection, [35 USC § 271(e)], establishing the circumstances under which use of a patented human drug is and is not an infringement of a valid unexpired patent."<sup>50</sup> Furthermore, S. 2748 was changed in other respects limiting conditions under which an ANDA could be approved by the FDA<sup>51</sup> and a clean bill, S. 2926, was introduced in the Senate on August 9, 1984 and passed by the Senate on August 10, 1984.<sup>52</sup>

#### *E. Final Passage of the PTR Act of 1984*

"When S. 2926 was received by the House, Representative Henry Waxman, the House sponsor, took up the House version, H.R. 3605, brought it into conformity with the Senate bill, with a few minor additional amendments, and substituted H.R. 3605 for the text of S. 1538."<sup>53</sup> S. 1538 was the successor of S. 2926 and the same as H.R. 3605. H.R. 3605 was passed by the House on September 6, 1984.<sup>54</sup> On September 12, 1984 the Senate agreed to the House amendments and passed S. 1538 and President

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pre-1962 or post-1962. Under this policy, any information on safety or effectiveness published in the scientific literature could be relied upon by a generic manufacturer in submitting any form of an NDA for a generic copy of a pioneer new drug." *Id.* at 275. "A paper NDA is a full NDA and must satisfy all of the same requirements as a pioneer NDA, but may satisfy those requirements in the form of summaries from published literature of studies done by others rather than through the reports of studies sponsored by the applicant. The difference between a paper NDA and an ANDA is that a paper NDA relies on published literature for all of the same animal and human data that are contained in a pioneer NDA, whereas an ANDA includes no literature or other reports of safety and effectiveness and instead relies only upon bioavailability and bioequivalence data." *Id.* at 277. "Accordingly, the statute recognizes two different but closely related types of approval mechanisms for generic drugs—ANDAs and paper NDAs. An ANDA is an NDA which substitutes bioavailability and bioequivalence data for full animal and human studies of safety and effectiveness (which studies are required in a full NDA). A paper NDA encloses published literature to satisfy the requirement for animal and human studies demonstrating safety and effectiveness." *Id.* at 296.

<sup>48</sup> *Id.* at 272, 275, 277.

<sup>49</sup> *Id.* at 272.

<sup>50</sup> *Id.* at 307; *see also supra* note 2.

<sup>51</sup> Lourie, *supra* note 15, at 544.

<sup>52</sup> Flannery & Hutt, *supra* note 14, at 287.

<sup>53</sup> 130 CONG. REC. 24977 (September 12, 1984).

<sup>54</sup> CONG. REC. DAILY DIGEST D808 (December 12, 1984).

Reagan signed the bill into law (PTR Act of 1984) on September 24, 1984.<sup>55</sup>

F. Section 202 of the PTR Act of 1984

It is useful to consider in some detail the legislative history with specific reference to section 202 of the PTR Act of 1984 which clarifies Congress' intent underlying the passage of § 271(e)(1). Section 202 of the PTR Act of 1984 introduced new legislation 35 USC § 271(e)(1), which reversed the effect of the Court of Appeals for the Federal Circuit's (CAFC) decision in *Roche Products v. Bolar Pharmaceuticals*.<sup>56</sup> The new subsection, (e)(1),<sup>57</sup> was added to 35 USC § 271 which rendered it no longer an act of patent infringement to engage in the use of pioneer drugs solely for the purpose of submitting premarketing data to the FDA prior to the expiration of the pioneer drug's patent life. Several Congressmen were concerned that § 271(e)(1) drastically altered the patent law with regard to infringement in the drug industry. Congressman Moorehead of the House stated that

A particularly disturbing provision, [§ 271(e)(1)], . . . was maintained and I am concerned by its implications and consequences, if enacted. Specifically, I refer to section 202 [of the PTR Act of 1984] which would overrule the recent Federal Court of Appeals decision in *Roche v. Bolar*. Enactment of this section, [§ 271(e)(1)], would create an unprecedented exception<sup>58</sup> to the exclusionary rights to which a patent holder is entitled during the patent term. Overturning the *Bolar* decision would allow *experimental use of a drug product* prior to expiration of the patent. There is no legitimate basis for distinguishing between the exclusionary rights accorded a pharmaceutical manufacturer during the patent term and those enjoyed by any other holder . . . For this reason, section 202 should be amended to permit experimental use of a drug by a non-patentee only during the period for which the patent has been extended. (Emphasis added.)<sup>59</sup>

<sup>55</sup> *Id.*

<sup>56</sup> See *supra* note 4.

<sup>57</sup> "It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal, Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques solely for the uses related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products." (Emphasis added.) 35 USC § 271(e)(1) (as of November 16, 1988). "It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) 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." 35 USC § 271(e)(1) (as of September 24, 1984).

<sup>58</sup> What Congressman Moorehead refers to as the "exception" is consistent with the meaning of the word "exemption" as used by the Supreme Court. (See *infra* note 82).

<sup>59</sup> 130 CONG. REC. 24456-57 (September 6, 1984).

Representative Coleman stated that

The bill, [PTR Act of 1984; H R. 3605], represents another step toward free-market economics in the pharmaceutical industry, and it provides easier entry into the marketplace for generic substitutes of brand name drugs, which often enjoy long periods of market exclusivity . . . . By providing rapid approval of generic drugs . . . H.R. 3605 promised to save consumers . . . \$1 billion over the next decade. However, it quickly became apparent that passage of H.R. 3605 was unlikely unless a compromise could be reached with major drug manufacturers. Therefore, Chairman Waxman engaged in extensive negotiations with representatives of the brand name [and] generic drug companies in order to craft a workable compromise that would satisfy all interested parties.<sup>60</sup>

"The compromise that was fashioned provided for both faster approval of generic drugs along with extended patent terms for companies that developed pioneer drugs."<sup>61</sup> Senator Hatch stated that the PTR Act of 1984 "reconciles the opposing, competitive interests of two segments of the pharmaceutical industry which have often stymied each other's attempts to improve the law"<sup>62</sup> Finally, Senator Metzenbaum stated that

[T]here are many people asking what this bill is all about . . . . Nobody can change the language of the legislation. It speaks for itself . . . . I want the courts to understand that the legislation speaks for itself and the interpretation which anyone may make on the floor does not really add anything to that interpretation.<sup>63</sup>

From the foregoing comments of Mr. Moorehead, Mr. Coleman, Mr. Hatch and Mr. Metzenbaum, it appears that § 271(e)(1) was meant to reverse the decision in *Bolar* and the language in § 271(e)(1) was meant to apply specifically to drugs only. Senator Metzenbaum cautioned the court in his statements that the language of the bill, which included the language of § 271(e)(1), should be strictly adhered to and that any other interpretation of the language would be contrary to the intent of Congress. Not only do the comments of the quoted Congressmen support a narrow reading of § 271(e)(1) but so do the public policy considerations articulated by the Judiciary Committee when S. 255 was proposed. It should also be noted that the compromise that led to the passage of PTR Act of 1984 was due to the compromises made between the PMA and the GPIA, members of the pharmaceutical drug industry. However, as we will see, the CAFC and the Supreme Court have not limited the application of § 271(e)(1) to drugs, but have also applied it to medical devices.<sup>64</sup>

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<sup>60</sup> *Id.* at 24457.

<sup>61</sup> *Id.*

<sup>62</sup> 130 CONG. REC. 23764 (August 10, 1984).

<sup>63</sup> *Id.*

<sup>64</sup> *Eli Lilly and Co. v. Medtronic Inc.*, 110 S. Ct. 2683 (1990).

## IV. CONSTRUCTION OF SECTION 101 OF THE PTR ACT OF 1984

*Section 101* of the PTR Act of 1984 amends § 505 of the Federal Food, Drug and Cosmetic Act (21 USC § 355; FDCA). By this amendment, *section 101* establishes expeditious procedures for obtaining premarketing approval of generic drugs. Notably, the premarketing approval procedure, by the provisions of *section 101*, may be initiated before the patent on the pioneer drug expires. Provisions of the legislation allow the submission of an ANDA<sup>65</sup> by a generic drug manufacturer prior to the expiration of the patent term of the pioneer drug. Specifically, section 505 of the Federal Food, Drug and Cosmetic Act (21 USC § 355; FDCA) was amended by *section 101* of the PTR Act of 1984 by adding a new subsection (j) to section 505 of the FDCA and designating the old section (j) as (k). In pertinent part, section 505(j)(2)(A) provides that

an abbreviated application for a new drug shall contain— . . .

(iv) information to show that the new drug is bioequivalent to the listed [pioneer] drug . . .

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed [pioneer] drug . . . for which the [generic drug] applicant is seeking approval under this subsection and for which information is required to be filed . . . —

(I) that such patent information is not filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new [generic] drug for which the application is submitted; . . . (Emphasis added.)

Clearly, the language of section 505 of the FDCA, namely, section 505(j)(2)(A)(vii)(III) which states "(III) of the date on which such patent will expire" undoubtedly recognizes the submission of an ANDA application to the FDA prior to the expiration of the patent term of a pioneer drug. Insertion of section 505(j)(2)(A)(vii)(III) was the result of a compromise between the PMA and GPIA in that the FDA was precluded from granting marketing approval for an ANDA which would become effective before the patent on the pioneer drug had expired even though the ANDA was submitted to the FDA prior to the expiration of the patent on the pioneer drug.<sup>66</sup> The conclusion is clear that one cannot submit an ANDA prior to the expiration of the patent term as provided by 505(j)(2)(A)(vii)(III) of 21 USC § 355 (FDCA) and at the same time avoid violating 35 USC § 271(a), in keeping with the decisions in *Pfizer v. International Rectifier* and *Roche Products v. Bolar Pharmaceuticals*, both of which held that "use of a patented drug for federally mandated pre-

<sup>65</sup> See *supra* note 47.

<sup>66</sup> Flannery & Hutt, *supra* note 14, at 285.

marketing tests"<sup>67</sup> prior to the expiration of the patent term constitutes patent infringement (35 USC § 271(a)).<sup>68</sup>

In order to accommodate an ANDA filing pursuant to 505(j)(2)(A)(vii)(III), the decision in *Bolar* had to be reversed, making the FDA required premarketing data gathering activities of generic companies, during the patent term of a pioneer drugs, non-infringing. To allow a non-infringing ANDA filing prior to the expiration of the relevant pioneer drug patent, section 202 of the PTR Act of 1984 contained the language of 35 USC § 271(e)(1). The compromise between the PMA and the GPIA, which was intended to reverse *Bolar* in the narrowest fashion possible, but at the same time leave the patentee's market exclusivity intact for the remaining term of the patent, resulted in 35 USC § 271(e)(1). In effect, the language of 35 USC § 271(e)(1) "was to reverse *Roche v. Bolar*, only to the extent that a company had no intent to commercialize the invention before the patent expiration date."<sup>69</sup>

In the final version of the Patent Term Restoration Act of 1984, a patent's validity could be otherwise challenged when an ANDA was submitted to the FDA, under the FDCA § 505(j)(2)(A)(vii)(IV), prior to expiration of the patent term. Under this provision of § 505 (FDCA) the ANDA was required to contain the statement "... that such patent is invalid . . ."<sup>70</sup> Clearly, when a generic manufacturer intended to challenge the validity of a patent via an ANDA submitted under FDCA § 505(j)(2)(A)(vii)(IV), the manufacturer could do so prior to the expiration of the patent term. With the passage of section 101 of the PTR Act of 1984 adding the new language in § 505(j), the decision in *Bolar* could not be preserved. Congress specifically accomplished the reversal of *Bolar*, by passing 35 USC § 217(e)(1) contained in section 202 of the PTR Act of 1984.<sup>71</sup>

In a 1985 article published in the Food Drug Cosmetic Law Journal, the writers Flannery and Hutt stated:

New section 271(e)(1) is limited to human drug products, and does not include medical devices, animal drugs, food additives, color additives, or other related products. This provision, [35 USC § 271(e)(1)], overrules the decision in *Roche Products v. Bolar Pharmaceutical Co.* which held that the testing of a patented drug to meet FDA requirements before the expiration of a valid patent constitutes infringement. Because section 271(e)(1) was intended solely to overrule this judicial decision, it is narrow in application. This statutory provision applies only to a patented human drug product, not to any other invention.<sup>72</sup>

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<sup>67</sup> *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 860 (Fed. Cir. 1984).

<sup>68</sup> This is a critical point reiterated in the Conclusion, *infra*.

<sup>69</sup> *Lourie*, *supra* note 15, at 541.

<sup>70</sup> Federal Food Drug & Cosmetic Act § 505(j)(2)(A)(vii) (IV).

<sup>71</sup> *Laurie*, *supra* note 15, at 543.

<sup>72</sup> *Flannery & Hutt*, *supra* note 14, at 308; "Ms. Flannery is an associate and Mr. Hutt is a partner with the law firm of Covington & Burlington, Washington, D. C. Mr. Hutt represented the Pharmaceutical Manufacturers Association in the



Another writer, Alan D. Lourie, states that

While loss of the *Roche-Bolar* doctrine . . . greatly troubled lawyers and industry executives, the fact is that until [the] *Pfizer International Rectifier* case, there really was no clear judicial precedent on the issue and generic companies often formulated, tested, and submitted applications to the FDA during the patent period with impunity. Thus, on the issue, the law under the DPC-PTR Act<sup>73</sup> will be little different from what it was three years before its passage.<sup>74</sup>

Finally, according to Steven J. Goldstein, "[t]he DPC-PTR Act presents the anomalous situation that while the holding of *Roche v. Bolar* is reversed as to drugs, the implications of that case, as they relate to all regulated compounds other than human drugs, still remain in effect."<sup>75</sup>

#### V. CONSTRUCTION OF SECTION 201 OF THE PTR ACT OF 1984

Section 201 of the PTR Act of 1984 provides for extension of a patent term by adding new section 156 to Title 35 of the United States Code. In pertinent part, 35 USC 156 states:

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if—

- (1) the term of the patent has not expired before an application is submitted under subsection (d) for its extension;
- (2) the term of the patent has never been extended;
- (3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of subsection (d);

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consideration of this legislation. He also served as a moderator at the Food and Drug Law Institute's Briefing on the Drug Price Competition-Patent Term Restoration Act, Washington, D. C. (Nov. 1984)." *Id.* at 269.

<sup>73</sup> The abbreviation DPC-PTR Act of 1984 also refers to the Patent Term Restoration Act of 1984.

<sup>74</sup> Lourie, *supra* note 30, at 361; "Dr. Lourie is Vice President, Corporate Patents and Trademarks, and Associate General Counsel, Smith Kline Beckman Corporation. He presented this paper to the Food and Drug Law Institute's Briefing on the Drug Price Competition and Patent Term Restoration Act of 1984, Washington D. C. (Nov. 1984). The views expressed [therein were] strictly those of the author and are not to be attributed to any organization with which he is associated." *Id.* at 351.

<sup>75</sup> Steven J. Goldstein, *The Drug Price Competition and Patent Term Restoration Act of 1984 Title II Patent Extension Provisions*, 40 FOOD, DRUG AND COSM. L. J. 363, 367 (1985); "Mr. Goldstein is Patent Counsel with The Procter & Gamble Company, Cincinnati, Ohio. He delivered this paper to the Food and Drug Law Institute's Briefing on the Drug Price Competition and Patent Term Restoration Act of 1984, Washington D. C. (Nov. 1984). The views expressed in [the submitted] paper are those of the author and do not necessarily reflect those of The Procter & Gamble Company." *Id.* at 363.

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; . . .

The product referred to in paragraphs (4) and (5) is hereinafter in the section referred to as the 'approved' product.

(b) The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

(1) in the case of a patent which claims a product, be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

\* \* \*

(f) For purposes of this section:

(1) The term 'product' means:

(A) A human drug product.

(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(2) The term 'human drug product' means the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. 35 USC § 156.

Pursuant to § 156(f), products eligible for patent term extension are human drug products, medical devices, food additives, or color additives subject to regulation under the Federal Food, Drug, and Cosmetic Act (FDCA). In addition, the patent term extension provision is limited to patents for their first permitted commercial marketing and only for uses initially approved and associated with that marketing. 35 USC § 156(5)(A) and (b)(1). Subsequent new approved uses are not eligible for patent term extension. 35 USC §§ 156 (a)(2) and (b)(1).

## VI. LILLY V. MEDTRONIC

After passage of the PTR Act of 1984, Eli Lilly brought a patent infringement action against Medtronic Inc. pursuant to 35 USC § 271(a) in which Lilly alleged that Medtronic infringed two of Lilly's medical device patents. Medtronic countered that since medical devices are regulated by the FDA, it was merely acting solely for presenting premarketing approval data to the FDA pursuant to 21 USC § 360 and 35 USC

§ 271(e)(1).<sup>76</sup> The district court rejected Medtronic's defense and ruled that 35 USC § 271(e)(1) applied only to drugs and not to medical devices. The district court stated that "the statutory language of § 271(e)(1) and the legislative history of the section support Lilly's contention that § 271(e)(1) is inapplicable to medical devices."<sup>77</sup> Subsequently, the district court granted Lilly's request for injunctive relief<sup>78</sup> against Medtronic. Medtronic thereafter unsuccessfully attempted to invalidate the Lilly patents.<sup>79</sup>

Medtronic then sought an interlocutory appeal from the permanent injunction<sup>80</sup> ordered by the district court. In its appeal to the CAFC, Medtronic asserted that it did not violate 35 USC § 271(a) because its conduct relating to medical devices was permitted under 35 USC § 271(e)(1). The CAFC held that "35 USC § 271(e)(1) applie[d] to any manufacture, use or sale of any type of patented invention if used solely for restricted purposes specified, and [was] not limited simply to drugs."<sup>81</sup> However, the court remanded the case to the district court "because it was unclear [which] of Medtronic's activities [fell] within the § 271(e)(1) exception<sup>82</sup> [and left] it for the [district court] on remand to decide to what extent the injunction should be vacated, modified, or stayed during further proceedings."<sup>83</sup> Lilly requested a rehearing en banc which the CAFC declined to grant, already having remanded the case.<sup>84</sup> On remand the injunction against Medtronic was modified.<sup>85</sup>

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<sup>76</sup> *Eli Lilly and Co. v. Medtronic Inc.*, 5 USPQ 2d 1760 (E.D.Pa. 1987).

<sup>77</sup> *Id.* at 1761.

<sup>78</sup> *Eli Lilly and Co. v. Medtronic Inc.*, 5 USPQ 2d 1439 (E.D.Pa. 1988).

<sup>79</sup> Medtronic alleged that the inventors of the Lilly patents, in question, had engaged in inequitable conduct while the patents were being examined by the Patent and Trademark Office (PTO) and, therefore, the patents were unenforceable. The district court ruled in favor of Lilly stating that Medtronic had not shown inequitable conduct on the part of the patent inventors and, therefore, the patents in question were enforceable; *Eli Lilly and Co v. Medtronic Inc.*, 696 F. Supp. 1033 (E.D. Pa. 1988).

<sup>80</sup> See *supra* note 78.

<sup>81</sup> *Eli Lilly and Co. v. Medtronic Inc.*, 10 USPQ 2d 1304, (Fed. Cir. 1989).

<sup>82</sup> The Supreme Court refers to 35 USC § 271(e)(1) as the *infringement exemption to 35 USC § 271(a)* and it refers to the language "other than a new animal drug or veterinary biological product . . ." found in 35 USC § 271(e)(1) as the *exception to the coverage of 35 USC § 271(e)(1)*. What the CAFC calls a "*§ 271(e)(1) exception*" is in its meaning consistent with the term *exemption* as used by the Supreme Court.

<sup>83</sup> *Eli Lilly and Co. v. Medtronic Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989).

<sup>84</sup> *Eli Lilly and Co. v. Medtronic Inc.*, 879 F.2d 849, (Fed. Cir. 1989).

<sup>85</sup> On June 28, 1989, the district court modified the injunction against Medtronic pursuant to the decision of the CAFC. The modified injunction was geared against only those activities of Medtronic which were not solely intended for purposes permitted under 35 USC § 271(e)(1). *Eli Lilly and Co. v. Medtronic Inc.*, 735 F. Supp. 652, 663 (E. D. Pa 1990). Medtronic then brought an unfair competition suit against Lilly which was unrelated to the interpretation of 35 USC § 271(e)(1). *Eli Lilly and Co. v. Medtronic Inc.*, 15 USPQ 2d 1465 (D. Minn. 1990). On February 22, 1990, the district court found Medtronic in contempt of court of its modified injunction of June 28, 1989 *Eli Lilly and Co. v. Medtronic Inc.*, 735 F. Supp. 652 (E. D. Pa. 1990).

Lilly sought and was granted certiorari.<sup>86</sup> On June 18, 1990, the Supreme Court affirmed the decision of the CAFC ruling that 35 USC § 271(e)(1) applied to medical devices as well as to drugs. The court further stated that whichever products were provided patent term extension under *section 201* (35 USC § 156(f)) of the PTR Act of 1984 were also covered by the *infringement exemption* under *section 202* (35 USC § 271(e)(1)) of the PTR Act of 1984.<sup>87</sup>

The Supreme Court, in *Lilly v. Medtronic*, held that

[35 USC §] 271(e)(1) exempts from infringement the use of patented inventions reasonably related to the development and submission of information needed to obtain marketing approval of medical devices under the FDCA, [the Federal Food Drug and Cosmetic Act], [and that] [t]he statutory phrase of § 271(e)(1), 'a Federal law which regulates the manufacture, use, or sale of drugs' is ambiguous.<sup>88</sup>

The Court concluded that

The 1984 Act, [the PTR Act of 1984], was designed to remedy two unintended distortions of the standard 17-year patent term produced by the requirement that certain products receive pre-market regulatory approval: (1) the patentee would as a practical matter not be able to reap any financial rewards during the early years of the [patent] term while he was engaged in seeking [FDA marketing] approval; and (2) the end of the term would be effectively extended until [FDA marketing] approval was obtained for competing inventions, since competitors could not initiate the regulatory process until the term's expiration.<sup>89</sup>

The Court explained that

[S]ection 201 of the Act, [the PTR Act of 1984], sought to eliminate the former distortion, [in (1) above], by creating 35 USC § 156, which sets forth a patent-term extension for inventions subject to a lengthy regulatory approval process<sup>90</sup> [and that] [s]ection 202 of the Act addressed the latter distortion, [in (2) above], by creating § 271(e)(1).<sup>91</sup>

The Court reached the conclusion that

[I]t is implausible that Congress . . . should choose to address both distortions, [(1) and (2) above], only for drug products, and for other products named in § 201 should enact provisions, [§ 271(e)(1)], which not only leave in place an anticompetitive

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<sup>86</sup> *Eli Lilly and Co. v. Medtronic Inc.*, 110 S. Ct. 232 (1989).

<sup>87</sup> *Eli Lilly and Co. v. Medtronic Inc.*, 110 S. Ct. 2683 (1990).

<sup>88</sup> *Id.* at 2684.

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> *Id.* at 2684-85.

restriction at the end of the monopoly term, [by not applying § 271(e)(1) to medical devices], but simultaneously expanding the term itself . . . [under *section 201* of the PTR Act of 1984 and 35 USC § 156].<sup>92</sup>

The Court apparently reads the language,

It shall not be an act of infringement to make, use, or sell a patented invention (*other than a new animal drug or veterinary biological product* (as those terms are described in the Federal Food, Drug and Cosmetic Act and the Act of March 4, 1913)) 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,

of 35 USC § 271(e)(1) to mean that *it is an act of infringement* for a non-patent holder or an unlicensed user to make, use, or sell *a new animal drug or veterinary biological product* during the patent term solely for uses reasonably related to the submission and development of information under a Federal law which regulates the manufacture, use, or sale of drugs. (Emphasis added.) The Court then states that

[T]he fact that § 202, [which contains 35 USC § 271(e)(1)], expressly excepts from its infringement exemption *a new animal drug or veterinary biological product*—each of which is subject to premarketing licensing and approval . . . and neither of which was included in § 201's patent term extension provision—indicates that §§ 201 and 202 are meant generally to be complementary. (Emphasis added).<sup>93</sup>

In other words, the Court seems to have ruled that all products subject to the patent term extension provisions under *section 201* (35 USC § 156) are exempted from patent infringement because those products are therefore also considered to be covered under *section 202* (35 USC § 271(e)(1)) of the PTR Act of 1984. In essence, the Court is expanding the application under *section 202* of 35 USC § 271(e)(1) from drugs to all products, including medical devices, which are eligible for patent term extension under § 201 (35 USC § 156) of the PTR Act of 1984.

What the Court fails to address in its reasoning is that new animal drugs or veterinary biological products were not included in *sections 201* (35 USC § 156) and *202* (35 USC § 271(e)(1)) of the PTR Act of 1984 because prior to passage of that Act,

Congressmen Glickman (Kansas) and DeWine (Ohio) drafted and introduced on April 26, 1984, H.R. 5529, the Agricultural Patent Reform Act, in order to free the agrochemical industry from the tangle in which the [P]atent [T]erm [R]estoration [Act of 1984] had become enmeshed . . . . This bill was limited to animal drugs and biologicals . . . . It was essentially [the same as] the earlier Patent Term Restoration Act.<sup>94</sup>

<sup>93</sup> *Id.* at 2685.

<sup>94</sup> Lourie, *supra* note 15, at 540.

“Agrochemicals were dropped [from the PTR Act of 1984] because of the introduction of H.R. 5529.”<sup>95</sup> Senator Waxman confirmed that “[u]nfortunately, due to the complexities of the human drug bill, [the PTR Act of 1984], we did not include animal drugs.”<sup>96</sup> It appears that the reason § 201 (35 USC § 156(f)) of the PTR Act of 1984 did not cover a new animal drug or veterinary biological product was not, as the Court suggests, to maintain any product-correlation between sections 201 and 202 of the PTR Act of 1984, but simply because of the fears of the agrochemical industry that the PTR Act of 1984 would never pass.

The Court’s assertion of an intentional Congressional purpose to maintain a product-correlation between § 201 and § 202 of the PTR Act of 1984 is not substantiated. However, the Court acknowledges the weakness in its product-correlation argument by stating in footnote 6

[T]hat the seemingly complete product correlation between § 201 and § 202 was destroyed in 1986, when, without adding ‘new infant formula’ to the defined products eligible for patent-term extension under § 156 [§ 201 of the PTR Act of 1984], Congress established a premarket approval requirement for that product, and thus automatically rendered it eligible for the § 271(e)(1) [§ 202 of the PTR Act of 1984] exemption from patent infringement.<sup>97</sup>

Lastly, the Court suggests further in footnote 6 that the

[I]solated indication of lack of correlation between § 156 [§ 201 of the PTR Act of 1984] and § 271(e)(1) [§ 202 of the PTR Act of 1984] is in any event contradicted by the 1988 amendment, [the Generic Animal Drug and Patent Term Restoration Act of 1988], that added most new animal drugs and veterinary biological products to § 156 and simultaneously deleted from § 271(e)(1) the infringement exception [see *infra* note 82] for those products.<sup>98</sup>

The Court is indicating that Congress acknowledges its product-correlation argument by enacting the 1988 Generic Animal Drug and Patent Term Restoration Act (GAD-PTR Act of 1988), which permits patent-extension for new animal drugs and veterinary biological products and simultaneously includes these products in the infringement exemption of § 271(e)(1). See *infra* note 57. What the Court fails to note is that the manner in which federally regulated premarketing approval is accomplished for these animal products is by amending § 101 of the Patent Term Restoration Act of 1984 to include these animal products in § 505. Moreover, § 505 of the FDCA dictates that the mechanism of regulatory approval for animal products is through the use of an abbreviated new

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<sup>95</sup> *Id.*

<sup>96</sup> 134 CONG. REC. H9785 (daily ed. October 6, 1988).

<sup>97</sup> *Eli Lilly and Co. v. Medtronic Inc.*, 110 S. Ct. 2683, 2691, n.6 (1990).

<sup>98</sup> *Id.* at 2691, n.6.

drug application (ANDA) essentially the same as for human drug products. From the construction of section 101 of the PTR Act of 1984, an infringement exemption provision of § 271(e)(1) must cover all products which are submitted prior to the expiration of the relevant patent for premarketing regulatory approval, via an ANDA, as provided in § 101 of the PTR Act of 1984 under § 505(j)(2)(A)(vii)(III) of 21 USC § 355 (FDCA). Further, no product-correlation between § 156 (§ 201 of the PTR Act of 1984) and § 271(e)(1) (§ 202 of the PTR Act of 1984) would have been present had the method of federal premarketing approval for these animal products been accomplished by means other than ANDAs essentially the same as used for human drug products.<sup>99</sup>

## VII. CONCLUSION

The Supreme Court in *Lilly v. Medtronic*<sup>100</sup> suggests a product-correlation argument between sections 201 and 202 of the PTR Act of 1984. In essence, the argument is that products eligible for patent term extension under § 201 (35 USC § 156) are also exempted from patent infringement insofar as activities are permitted under § 202 (35 USC § 271(e)(1)).<sup>101</sup> At the same time the Court has stated that an "isolated lack of correlation between § 156 and § 271(e)(1)"<sup>102</sup> "does not change [its]

### <sup>99</sup> COMPARISON OF THE PTR ACT OF 1984 AND THE GAD-PTR ACT OF 1988:

The language of section 101 of the PTR Act of 1984 is literally identical to the language employed in section 101 of the Generic Animal Drug and Patent Term Restoration Act of 1988 (GAD-PTR Act of 1988). The language of § 505(2)(A)(vii)(I)-(IV) (21 USC § 355; referenced in PTR Act of 1984) is identical to the language of § 512(b)(n)(1)(H)(i)-(iv) (21 USC § 360(b); referenced in GAD-PTR Act of 1988).

The GAD-PTR Act of 1988 amends 35 USC § 156 (f):

(1) by striking "human" in paragraph (A) and by amending paragraph (2) to read as follows:

The term 'drug product' means the active ingredient of—

- (A) a new drug, antibiotic drug, or human biological product (as those term are used in the Federal Food, Drug, and Cosmetic Act), or
- (B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other process involving site specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient." 35 USC § 156(f).

For amendments to 35 USC § 271(e)(1) see *supra* note 57.

<sup>100</sup> Subsequent to the decision of the Supreme Court, Medtronic Inc. sought to have the injunction issued by the district court vacated. On August 17, 1990 the CAFC vacated the injunction against Medtronics holding that "no permanent injunction may be granted unless and until a judgment of infringement is entered following consideration of the asserted [exemption] to infringement under 271(e)(1)." *Eli Lilly and Co. v. Medtronic Inc.*, 915 F.2d 670, 675 (Fed. Cir. 1990).

<sup>101</sup> *Eli Lilly and Co. v. Medtronic Inc.*, 110 S. Ct. 2683, 2691, n. 6 (1990).

<sup>102</sup> *Id.*

view of what the statute means." In other words, it is not essential for a product to be eligible for patent term extension under § 201 (35 USC § 156) to be eligible for the infringement exemption under § 202 (35 USC § 271(e)(1)).

The Court thus appears to state a product-correlation argument and simultaneously holds that such correlation is not essential. For example, the Court states that "when, without adding 'new infant formula' to the defined products eligible for patent-term extension under § 156 [section 201], Congress established a premarket approval requirement for that product, and thus [Congress] automatically rendered it eligible for the § 271(e)(1) [section 202] exemption from patent infringement."<sup>103</sup> The Court apparently is suggesting that any product which requires premarketing approval is eligible for the § 271(e)(1) infringement exemption regardless of whether that product is eligible for patent term extension under § 201 (35 USC § 156).

One can attempt to justify the Court's reasoning and decision on public policy grounds (See III. B. *Judiciary Committee Report – Public Policy Considerations, supra*) to expand the coverage of under section 202 of 35 USC § 271(e)(1) to products not specifically eligible for patent term extension under section 201 (35 USC § 156) but which may, in the future, require extensive premarketing approval as was done with 'infant formula.' Some possible candidate products that may become eligible for patent term exemption under 35 USC § 271(e)(1) in the near future are cosmetics, pesticides, food and vitamins under the Court's current decision.<sup>104</sup> Currently these products need only meet "generally applicable standards"<sup>105</sup> as set forth by the FDCA. "See, e.g., 21 USC § 341 (food); § 361 (cosmetics); § 346a (pesticides); cf. § 350 (vitamins)."<sup>106</sup>

Regardless of its reasoning, the Supreme Court has expanded the coverage of 35 USC § 271(e)(1) with an open door for coverage of products which require extensive premarketing approval. The Court appears to be signaling a wider coverage of 35 USC § 271(e)(1) than was originally intended by Congress. One may conclude that any time a patented product must undergo extensive premarketing approval procedures mandated by a Federal law then that product is covered by the patent infringement exemption of 35 USC § 271(e)(1).

In summary, when one submits an ANDA prior to the expiration of the relevant patent as allowed under § 101 of the PTR Act of 1984 (§ 505(j)(2)(A)(vii)(III); 21 USC § 355) it would be improper to hold such a submission violative of another law, namely, 35 USC § 271(a). In essence

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<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*



we would have one law that permits submission of an ANDA prior to the expiration of the pioneer drug patent and another law which holds activities necessary for the submission of the ANDA to be simultaneously violative of 35 USC § 271(a). If the provision of the PTR Act of 1984 permitting the submission of an ANDA prior to the expiration of the relevant patent is to have any effect such submission must not be held violative of 35 USC § 271(a). In order that the language of 35 USC § 271(a) does not conflict with the ANDA provisions of the PTR Act of 1984, it was absolutely necessary to pass 35 USC § 271(e)(1) which provided a necessary exemption to 35 USC § 271(a) especially in light of the *Bolar* and *Pfizer* decisions which held activities similar to those of filing an ANDA during the term of the patent to be violative of 35 USC § 271(a).

Congress reasonably passed 35 USC § 271(e)(1) to provide the narrow exemption to 35 USC § 271(a) needed in order to give effect to the ANDA provisions of the PTR Act of 1984 which apply to drugs and not to medical devices. Nowhere in the legislative history does it provide that 35 USC § 271(e)(1) was meant to apply to medical devices and indeed the intent of Congress supports the contrary view that 35 USC § 271(e)(1) was meant to apply only to drugs. However, the Court's decision in *Lilly v. Medtronics*<sup>107</sup> greatly broadens the scope of the patent term exemption of 35 USC § 271(e)(1) to products beyond drugs to medical devices and a host of candidate products ranging from cosmetics to pesticides.

Justices Kennedy and White<sup>108</sup> in their dissenting opinion state that "we do not tell Congress how to express its intent. Instead we discern its intent by assuming that Congress employs words and phrases in accordance with their ordinary usage."<sup>109</sup> The dissenters further state that the ANDA provisions of the PTR Act of 1984 apply only to drugs, whether human or veterinary, and not to medical devices, and therefore, hold the view that 35 USC § 271(e)(1) does not apply to medical devices. The dissenting justices state that "[a]s petitioner [Lilly] has asserted, manufacturers may test generic versions of patented drugs, but not devices, under abbreviated procedures. See 21 USC § 355 (j)."<sup>110</sup>

AJAY S. PATHAK

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<sup>107</sup> *Id.*

<sup>108</sup> The only dissenters were Justices Kennedy and White. Justice O'Connor did not participate in the Court's decision. *Eli Lilly and Co. v. Medtronic Inc.*, 110 S. Ct. 2683 (1990).

<sup>109</sup> *Id.* at 2694. The dissenting opinion is limited to three pages. The opinion gives several examples of what the dissenters consider "words and phrases in accordance with their ordinary usage." *Id.*

<sup>110</sup> *Id.* at 2695. The dissent states that [ANDA] procedures, under 21 USC § 355(j)(7)(B), which state "the requirements of showing the 'bioavailability' (see *supra* note 47) of drugs" do not apply to medical devices. *Id.*