Part III

Marketing Approval Procedures

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Duration of Rights

I. Fundamentals of Patent Term

The term of a U.S. patent was traditionally measured from the date the PTO issued it. The Act of 1790 allowed the issuance of patents "for any term not exceeding fourteen years."[1] The Act of 1870 increased this term to "seventeen years from the date of issue."[2] This durational standard was a fixture of U.S. law until June 8, 1995, when the U.S. patent system shifted to a term based upon the filing date.[3] As the law currently stands, for patents resulting from applications filed after

[1]Act of April 10, 1790, 1 Stat. 109(1790).

[2]Act of July 8, 1870, Ch. 230, 16 Stat. 198(1870).

[3]Uruguay Round Agreements Act, 103 Pub. L. No. 465, 108 Stat. 4809 (1994).

June 8, 1995, the patent term is ordinarily 20 years from the date the patent application was filed.[4] For patents issued prior to June 8, 1995, as well as for patents resulting from applications pending at the PTO as of that date, the patent endures for the greater of 20 years from filing or 17 years from grant.[5]

Although the life of the patent is now measured from the filing date, the patentee gains no enforceable rights merely by filing a patent application. These rights accrue only if and when a patent issues, and they include the power to enjoin infringers and obtain an award of damages. If the application was published in accordance with the Domestic Publication of Patent Applications Abroad Act of 1999,[6] then the patentee also obtains provisional rights equivalent to a reasonable royalty, as of the date the application is published.[7] In such a case, however, the patentee may not assert these provisional rights until the patent issues.

While the distinction between a patent term based on the date of issue and one based on the date of the application may not appear to loom particularly large, significant consequences flow from U.S. adoption of a 20-year patent term measured from the filing date. Prior to June 8, 1995, the filing of continuing applications did not affect the length of the effective patent term. Once the patent issued, it obtained a 17-year term from the date of issue, even if it had been pending at the PTO for many years, due to a lengthy string of continuing applications.[8] Moreover, during that era, patent applications were not published, but rather were held in secrecy by the PTO throughout the entire period of prosecution. These rules permitted applicants to manipulate the patent prosecution system to the detriment of their competitors. Patents that issued after long delays of this sort came to be called "submarine" patents,[9] because they emerged from a series of concealed continuation applications and could "torpedo" industries that had developed in ignorance of the pending applications.

The current durational scheme will eventually eliminate the possibility of submarine patents. For patent applications filed after June 8, 1995, the term is now measured from the date of the first application in the series, no matter how many continuing applications are filed. As a result, an applicant who files multiple continuing applications that unduly delay the prosecution process at the PTO is merely shortening his own term of eventual patent protection. Further, in

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[4] 35 U.S.C. §154(a)(2) (2004).

[5] *Id.* §154(c)(1).

[6] Subtitle E of the American Inventors Protection Act, Title IV, 113 Stat. at 1501A-552. The American Inventors Protection Act formed a component of the Intellectual Property and Communications Omnibus Reform Act, Pub. L. No. 106-113, app. I, 113 Stat. 1501, 1501A-521 (1999), which in turn was incorporated by reference into the District of Columbia Appropriations Act. 113 Stat. at 1501, 1535–36.

[7] 35 U.S.C. §154(d) (2004).

[8] *See id.* §120.

[9] *See* Steve Blount & Louis S. Zarfas, *The Use of Delaying Tactics to Obtain Submarine Patents and Amend Around a Patent That a Competitor Has Designed Around*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 11 (1999).

cases where an applicant also plans to seek patent protection abroad, the application will be published 18 months after filing, thus putting competitors on notice of his pending rights.[10]

II. Maintenance Fees

Enjoyment of the full patent term is subject to the payment of maintenance fees. United States patents expire after 4, 8, or 12 years if maintenance fees are not timely paid on each occasion.[11] As of January 31, 2005, the amounts due are $900 due 3½ years after the patent's issuance date, $2,300 after 7½ years, and $3,800 after 11½ years.[12] As only about one-third of U.S. patents are maintained beyond their eleventh year,[13] maintenance fees effectively dedicate a great deal of patented technology to the public domain.

III. The Patent Term Guarantee Act

The Patent Term Guarantee Act of 1999 provides certain deadlines that, if not met by the PTO, result in an automatic "adjustment" of the term of an individual patent.[14] As might be expected, each day of PTO delay beyond these statutory limits results in one additional day of patent term. Among the more significant of these deadlines are 14 months for the issuance of a first Office Action and four months for the issuance of a subsequent Office Action.[15] In addition, the prosecution of an original patent application must be complete within three years of the actual U.S. filing date, with exceptions granted for continuing applications and appeals.[16]

The PTO Director is charged with calculating any patent term extensions that might result from missed PTO deadlines. An applicant who is dissatisfied with the Director's calculation of the patent term adjustment may bring a civil action against the Director in the District Court for the District of Columbia within 180 days of the grant of the patent.[17]

IV. Specialized Legislation

On occasion, Congress has enacted laws extending the term of particular patents. Unusually, two of these statutes were codified in Title 35 of the United States Code. Sections 155 and 155A of the Patent Act do not identify particular patents by number. However, each of

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[10] 35 U.S.C. §122(b) (2004).

[11] *Id.* §41(b).

[12] 37 C.F.R. §1.20. Individuals and small entities obtain a 50% discount. *Id.*

[13] *See* Charles E. Van Horn, *Practicalities and Potential Pitfalls When Using Provisional Patent Applications*, 22 AIPLA Q.J. 259, 296 (1994).

[14] Subtitle D of the American Inventor Protection Act of 1999, which in turn was Title IV of the District of Columbia Appropriations Act of 1999, Pub. L. No. 106-113, §1000(a)(9), 113 Stat. 1501A-557.

[15] 35 U.S.C. §154(b)(1)(A) (2004).

[16] *Id.* §154(b)(1)(B).

[17] *Id.* §154(b)(4).

them allows term extension only under a highly particularized set of circumstances, and as a result only a small number of patents qualify under either provision. The net effect of Section 155 of the Patent Act is therefore to add 5 years, 10 months, and 17 days to a number of patents relating to the artificial sweetener ASPARTAME®,[18] while Section 155A of the Patent Act granted a term extension of 1,923 days to two patents claiming the anesthetic drug FORANE®.[19] As all the eligible patents under either of these provisions have expired, Section 155 and Section 155A are effectively deadwood in the U.S. Patent Act.

In addition, Congress has, over the years, enacted a number of private laws that have increased the term of individual patents. Thankfully, these statutes were not incorporated into the general patent code, but a list of these patents can be found on the PTO Web site.[20]

V. The Hatch-Waxman Act

As has been noted many times, the Hatch-Waxman Act established a tradeoff between generic and brand-name pharmaceutical firms.[21] Generic firms benefited from an accelerated marketing approval process, including the privilege to employ a product patented by another for uses reasonably related to obtaining FDA marketing approval. In favor of brand-name firms, however, Congress provided patent proprietors with a means for restoring a patent's term that had been lost while awaiting FDA approval at the beginning of the patent term.

Codified at 35 U.S.C. §156, the patent term extension provision of the Hatch-Waxman Act stands among the most unwieldy statutes in the federal code. In a nutshell, a patent proprietor who wishes to obtain the term extension offered by the Hatch-Waxman Act must submit an application to the PTO.[22] That application must be filed prior to the expiration of that patent,[23] and within 60 days of receiving FDA marketing approval.[24] Only one patent can be extended based upon an approval for commercial marketing use. In the event

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[18]U.S. Patent & Trademark Office, *Patent Terms Extended Under 35 U.S.C. §355* (available at http://www.uspto.gov/web/offices/pac/dapp/opla/term/155.html).

[19]U.S. Patent & Trademark Office, *Patent Terms Extended Under 35 U.S.C. §355A* (available at http://www.uspto.gov/web/offices/pac/dapp/opla/term/155.html).

[20]U.S. Patent & Trademark Office, *Patent Terms Extended Under Private Laws (Not Codified Into Title 35)* (available at http://www.uspto.gov/web/offices/pac/dapp/opla/term/index.html).

[21]*See* Andrx Pharms, Inc. v. Biovail Corp., 276 F.3d 1368, 1371, 61 USPQ2d 1414, 1415 (Fed. Cir. 2002) (In enacting the Hatch-Waxman Act, "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market."); Bristol-Myers Squibb Co. v. Royce Labs., Inc., 69 F.3d 1130, 1132, 36 USPQ2d 1641, 1643 (Fed. Cir. 1995) ("the Hatch-Waxman Act strikes a balance between the interests of a party seeking approval of an ANDA and the owner of a drug patent"); Abbott Labs. v. Young, 920 F.2d 984, 986, 17 USPQ2d 1027, 1028 (D.C. Cir. 1990) ("Facing the classic question of the appropriate trade-off between greater incentives for the invention of new products and greater affordability of those products, Congress struck a balance between expediting generic drug applications and protecting the interests of the original drug manufacturers.").

[22]35 U.S.C. §156(d)(1) (2004).

[23]*Id.* §156(a)(1).

[24]*Id.* §156(d)(1).

multiple patents cover that product, the proprietor must choose one.[25] The period of extension is set to one-half of the testing phase (IND to NDA filing), less any period during which the applicant did not act with due diligence, plus the entirety of the FDA review period. However, the maximum extension period is capped at a five-year extension period, or a total effective patent term after the extension of not more than 14 years.[26] The scope of rights during the period of extension is generally limited to the use approved for the product that subjected it to regulatory delay.[27] The remainder of this chapter explores the details of 35 U.S.C. §156 in greater detail.

A. Eligible Patents

1. Drug Products

For a patent to be eligible for term extension under Section 156 of the Patent Act, the "product" must have been "subject to a regulatory review period" and "the permission for the commercial marketing or use of the product after such regulatory review period [must have been] the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred." Section 156(f) defines the term "product" as follows:

> (1) The term "product" means:
> (A) A 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 "drug product" means the active ingredient of—
> (A) 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), 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 processes involving site specific genetic manipulation techniques,
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> including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.[28]

As this statutory language indicates, to be eligible for term extension under 35 U.S.C. §156, a "drug product" patent must concern the "active ingredient," or "any salt or ester of the active ingredient" of the regulated product. In its 1989 decision in *Fisons PLC v. Quigg*,[29] the Federal Circuit confirmed that eligibility for term extension of a drug product patent depends upon the approved product's active ingredient. It therefore concluded that patent term extension was

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[25] *Id.* §156(c)(4).

[26] *Id.* §156(b), (c).

[27] *Id.* §156(b)(1).

[28] *Id.* §156(f).

[29] 876 F.2d 99, 10 USPQ2d 1869 (Fed. Cir. 1989).

inappropriate for regulatory delays associated with FDA approval of a different dosage or use of previously approved product.

At issue in *Fisons v. Quigg* were three Fisons patents involving cromolyn sodium. The three patents each claimed an innovative use or dosage form of this compound. The FDA had first allowed commercial marketing of cromolyn sodium in inhalation capsule form in 1973. Subsequently, the FDA also issued marketing approvals for the new uses and dosage forms of cromolyn sodium that Fisons had patented. Fisons then sought term extension under 35 U.S.C. §156 for its three patents relating to the new uses and dosage forms, asserting that the term "product" in 35 U.S.C. §156(a)(5)(A) meant a particular drug product that the FDA had approved. The PTO and district court disagreed, reasoning that 35 U.S.C. §156(f) expressly defined the term "product" to mean "the *active ingredient* of a new drug."[30]

Following an appeal to the Federal Circuit, Judge Nies agreed that the three Fisons patents were not eligible for term extension. Under the plain language of the statute, she reasoned, extensions to the term of a drug product patent are limited to the first marketing or commercial use of a particular active ingredient.[31] Given this express statutory language, Judge Nies was not persuaded by the "policy argument" that the development of new uses and doses for existing drugs was potentially just as medically significant as the development of new chemical entities, and therefore just as worthy of patent term extension. "Matters of policy are for Congress, not courts, to decide," she concluded.[32] The *Fisons v. Quigg* ruling establishes that a drug product patent is not eligible for term extension based upon any subsequent FDA approval for commercial marketing or use of a drug product containing the identical active ingredient, or salt or ester of that active ingredient.

The subsequent Federal Circuit opinion in *Glaxo Operations UK Ltd. v. Quigg*[33] followed the approach of *Fisons v. Quigg*, this time with more favorable results for the patent proprietor. In this case, Glaxo was the owner of two patents relating to the antibiotic cefuroxime.[34] One of these patents claimed cefuroxime and its salts, which were FDA approved and sold under the trademarks ZINACEF® and KERUROX®. The other patent claimed cefuroxime axetil, an ester of cefuroxime, which was also an FDA-approved product sold under the trademark CEFTIN®.[35] The former compounds were therapeutically active antibiotics only when administered intramuscularly or intravenously, while cefuroxime axetil could be administered orally.[36]

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[30] *Id.* at 100, 10 USPQ2d at 1870 (emphasis in original).

[31] *Id.* at 101, 10 USPQ2d at 1870.

[32] *Id.* at 101, 10 USPQ2d at 1871.

[33] 894 F.2d 392, 13 USPQ2d 1628 (Fed. Cir. 1990).

[34] *Id.* at 393, 13 USPQ2d at 1628–29.

[35] *Id.* at 393–94, 13 USPQ2d at 1628–29.

[36] *Id.* at 393–94, 13 USPQ2d at 1629.

Litigation arose when the PTO denied Glaxo's request for term extension for its cefuroxime axetil patent. In reaching its decision, the PTO observed that the FDA had previously approved ZINACEF® and KERUROX®, two products employing salts of cefuroxime. The PTO reasoned that the FDA approval of cefuroxime axetil was not the "first permitted commercial marketing or use of the product" by the FDA, as 35 U.S.C. §156(a)(5)(A) required. Put differently, the PTO took the position that the statutory use of the term "drug product" incorporated any "'new chemical entity,' i.e., 'new active moiety,' which would encompass *all* acid, salt, or ester forms of a single therapeutically active substance even if the drug before being administered contained only other substances."[37]

Glaxo instead took the position that the patent for which extension was sought claimed cefuroxime axetil. Glaxo conceded that the previously approved products, ZINACEF® and KERUROX®, consisted of salts of cefuroxime. Glaxo further observed, however, that neither of these products contained salts or esters of cefuroxime axetil, as required by 35 U.S.C. §156(f). As a result, Glaxo contended that CEFTIN® was properly considered the "first commercial marketing or use" of the patented drug product.[38]

On appeal, the Federal Circuit rejected the PTO's interpretation of the statutory term "drug product" and instead sided with Glaxo. According to the court of appeals, Congress had used words with well-established, ordinary, and common meanings—"active ingredient," "salt," and "ester"—in defining which drug products were eligible for patent term extension under 35 U.S.C. §156.[39] Judge Michel further reasoned that Congress specifically selected these well-established scientific terms over other options, such as "new molecular entity" or "active moiety," that had a broader meaning.[40] Judge Michel further declined to accord *Chevron* deference to the PTO interpretation, as the statute's "operative terms, individually and as combined in the full definition, have a common and unambiguous meaning, which leaves no gap to be filled in by the administering agency."[41] The result of the decision was that Glaxo received a term extension for its cefuroxime axetil patent, even though the FDA had previously approved products incorporating salts of cefuroxime as their active ingredient.

In the controversial 2003 decision in *Merck & Co. v. Teva Pharmaceuticals USA Inc.*,[42] the Federal Circuit majority also upheld a patent term extension under 35 U.S.C. §156. *Merck v. Teva* concerned Merck's patent on a method of treating osteoporosis through the administration of 4-amnio-1-hydroxybutane-1, 1-biphosphonic acid.

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[37] *Id.* at 394, 13 USPQ2d at 1629.

[38] *Id.*

[39] *Id.* at 395, 13 USPQ2d at 1629.

[40] *Id.* at 399 n.10, 13 USPQ2d at 1633 n.10.

[41] *Id.* at 398, 13 USPQ2d at 1633.

[42] 347 F.3d 1367 , 68 USPQ2d 1857 (Fed. Cir. 2003).

Merck's product, FOSAMAX®, had been approved by the FDA for use in treating osteoporosis and Paget's disease. FOSAMAX® consisted of 4-amnio-1-hydroxybutane-1, 1-biphosphonic acid monosodium salt trihydrate, which is more concisely known as alendronate salt.[43] Due to significant delays that Merck had experienced in obtaining FDA marketing approval for FOSAMAX®, Merck's patent had been subject to term extension under 35 U.S.C. §156.[44]

Teva subsequently filed an ANDA with the FDA, proposing to market a generic version of FOSAMAX®. Teva's proposed product employed the salt form of the acid as its active ingredient.[45] Merck responded by filing a suit for patent infringement under the procedures established by the Hatch-Waxman Act. Although Teva argued that it did not infringe the claims of the Merck patent, the district court concluded that Merck's claims encompassed the salt as well as the acid version of the active acid agent. The district court observed that the patent's specification referred to the acid active agent as encompassing both the acid and "salt forms," and experts in the field testified that bone disorder treatments commonly include the acid salt form of whatever active agent is administered.[46]

Teva appealed to the Federal Circuit, in part asserting that (1) its proposed product did not infringe the Merck patent; and (2) the term extension granted by the PTO was invalid because Merck's patent claimed an acid, while the FDA approval concerned the salt. The Federal Circuit disagreed with Teva on both counts. With respect to the argument of noninfringement, Judge Newman concluded that skilled pharmacologists would understand that when 4-amino-1-hydroxybutane-1, 1-bisphosponic acid is administered to treat urolithiasis and to inhibit bone reabsorption, that administration encompasses the acid salt.[47] Turning to the term extension issue, the Federal Circuit majority observed that 35 U.S.C. §156 expressly contemplated the extensions for "any salt or ester of the active ingredient" in the drug product. As a result, the PTO had appropriately granted term extension to Merck's patent.[48]

Chief Justice Mayer issued a brief dissenting opinion. In his view, Teva's proposed product did not infringe Merck's patent because the term "acid" should not be read to encompass both acids and salts. He also concluded that term extension was inappropriate because the patent claimed only the acid form of the compound, rather than the FDA-approved salt form of the compound.[49]

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[43] *Id.* at 1369, 68 USPQ2d at 1858.

[44] *Id.* at 1373, 68 USPQ2d at 1861–62.

[45] *Id.* at 1369, 68 USPQ2d at 1858.

[46] 228 F. Supp. 2d 480 (D. Del. 2002).

[47] 347 F.3d at 1371–72, 68 USPQ2d at 1860.

[48] *Id.* at 1373–74, 68 USPQ2d at 1862.

[49] *Id.* at 1374–75, 68 USPQ2d at 1863.

2. *Combination Therapies*

As has been noted previously,[50] innovative drug companies have increasingly combined two or more existing medicines into a single pill. Patents may be obtained on such combinations in appropriate circumstances, but in many cases the patent term extension of 35 U.S.C. §156 will be unavailable. This state of affairs results from the Federal Circuit's 2004 decision in *Arnold Partnership v. Dudas*.[51] In that case, the Arnold Partnership (Arnold) held a patent claiming compositions containing hydrocodone (or a salt thereof) and ibuprofen (or a salt thereof), as well as methods of treating pain using these compositions. This product was available commercially as VICOPROFEN®, which specifically combined hydrocodone bitartrate and ibuprofen. Although these two components had previously been available separately, the FDA required Arnold to file an NDA in order to market the combined product.[52]

Arnold subsequently sought term extension from the PTO under 35 U.S.C. §156 in order to compensate for regulatory review delays. The PTO rejected Arnold's application, however, on the basis that VICOPROFEN® did not comply with the "first commercial marketing" requirement of 35 U.S.C. §156(a)(5)(A). Arnold therefore commenced litigation in the U.S. District Court for the Eastern District of Virginia, which sided with the PTO.[53]

Arnold then appealed to the Federal Circuit, which affirmed. The appeals court observed that 35 U.S.C. §156(a)(5)(A) stipulated that term extension is only appropriate where "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 which such regulatory review occurred...." This statute further defined the term "product" to mean "drug product,"[54] with "drug product" in turn defined as "the active ingredient of ... a new drug ... including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient."[55] According to Judge Dyk, this statutory language expressly indicated that a drug product's eligibility for extension depended upon an analysis of its individual ingredients, rather than the compound as a whole. As the district court had previously explained:

> Even though a drug may contain two or more active ingredients in combination with each other, for the purpose of the patent extension that drug is defined through reference to only one of those active ingredients;

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[50]For more on combination therapies in this text, see *supra* §III.H in Chapter 2.

[51]362 F.3d 1338, 70 USPQ2d 1311 (Fed. Cir. 2004).

[52]*Id.* at 1339, 70 USPQ2d at 1312.

[53]246 F. Supp. 2d 460 (E.D. Va. 2003).

[54]35 U.S.C. §156(f)(1) (2004).

[55]*Id.* §156(f)(2).

> the other active ingredient or ingredients are merely "in combination" with this first active ingredient.[56]

Under this interpretation, if a patent claimed a composition comprising two ingredients, A and B, the patent was eligible for term extension if either A or B had not been previously marketed. In a case such as this, however, where both ingredients had been subject to prior commercial marketing, the combination patent could not benefit from the term extension provisions of the Hatch-Waxman Act.[57]

The Federal Circuit read 35 U.S.C. §156 fairly in *Arnold Partnership v. Dudas*, but its opinion creates an unfortunate result. The FDA does not approve of combination therapies on an ingredient-by-ingredient basis, but rather requires testing of the combination as a whole. Combination therapies are therefore subject to regulatory delays that can result in lost patent term. Unfortunately, the inartfully drafted 35 U.S.C. §156 does not protect the patent term of innovative drug companies for combinations of previously marketed drugs—even in cases where the combination produces synergistic effects.[58] This regrettable outcome suggests a need for legislative reform of the Hatch-Waxman Act's patent term restoration statute.

3. Metabolites

The Federal Circuit has reasoned that metabolite patents are not eligible for term extension under 35 U.S.C. §156 based upon regulatory approval delays associated with review of the chemical precursor to the metabolite. As discussed previously in this text,[59] a metabolite is "the compound formed in the patient's body upon ingestion of a pharmaceutical. The ingested pharmaceutical undergoes a chemical conversion in the digestion process to form a new metabolite compound."[60] The 2003 Federal Circuit decision in *Schering Corp v. Geneva Pharmaceuticals, Inc.*,[61] which held that ingestion of a prior art pharmaceutical would inherently anticipate claims to naturally occurring metabolites, cast the validity of many previously issued metabolite patents in doubt. Already certain at that time, thanks to the earlier Federal Circuit decision in *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*,[62] was that metabolite patents were not eligible for term extension under 35 U.S.C. §156.

The *Hoechst-Roussel v. Lehman* case concerned COGNEX®, a medication for treating Alzheimer's disease. The active ingredient in

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[56] 246 F. Supp. 2d at 464–65.

[57] 362 F.3d at 1341, 70 USPQ2d at 1314.

[58] *Id.* at 1342–43, 70 USPQ2d at 1315.

[59] *See supra* §III.D of Chapter 2.

[60] Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1375, 67 USPQ2d 1664, 1665 (Fed. Cir. 2003).

[61] 339 F.3d 1373, 67 USPQ2d 1664 (Fed. Cir. 2003).

[62] 109 F.3d 756, 42 USPQ2d 1220 (Fed. Cir. 1997).

COGNEX® is tacrine hydrochloride. Hoechst-Roussel sought term extension under 35 U.S.C. §156 for U.S. Patent No. 4,631,286, which did not itself claim tacrine hydrochloride. The '286 patent instead claimed 1-hydroxy-tacrine—a compound into which tacrine hydrochloride metabolized after digestion—as well as a method of treating memory loss using 1-hydroxy-tacrine.[63] The PTO denied Hoechst-Roussel's request, reasoning in part that the '286 patent did not itself claim tacrine hydrochloride.[64]

The Federal Circuit affirmed the PTO's decision on appeal. Judge Clevenger observed that 35 U.S.C. §156(a) stated that the "term of a patent *which claims* a product ... shall be extended in accordance with this section from the original expiration date if ... the product has been subject to a regulatory review period before its commercial marketing or use."[65] He further reasoned that the claims of the '286 patent were directed neither to the active ingredient that received FDA approval, tacrine hydrochloride, nor to a method of using that ingredient.[66] As a result, the '286 patent failed to qualify for term extension under 35 U.S.C. §156.

Under the reasoning of *Hoechst-Roussel v. Lehman*, no metabolite patent qualifies for term extension under 35 U.S.C. §156 due to FDA marketing approval delays based upon the chemical precursor to the metabolite. A patent claiming a metabolite could obtain term extension only if the FDA-approved product was itself the metabolite, provided that the other conditions for term extension are met.

4. Medical Devices

The 2004 opinion of the Federal Circuit in *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*,[67] considered the availability of term extensions for patents on medical devices. In *Cardiac Pacemakers, Inc. v. St. Jude Medical*, Cardiac Pacemakers, Inc. (CPI) held U.S. Patent No. 4,407,288, relating to an implantable heart stimulator and stimulation method.[68] When CPI accused St. Jude of infringing the '288 patent, St. Jude in part asserted that the PTO had improvidently extended the '288 patent's term under 35 U.S.C. §156. St. Jude based its position upon the fact that the CPI device was not the first device covered by the '288 patent to receive FDA approval. CPI had granted licenses under the '288 patent to two other companies for their defibrillators, but had not requested term extension based upon the licensee's devices. Instead, the term extension of the '288 patent had been based upon regulatory delays encountered during FDA approval of CPI's

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[63] *Id.* at 757, 42 USPQ2d at 1221.

[64] *Id.* at 757–78, 42 USPQ2d at 1222.

[65] 35 U.S.C. §156(a)(4) (2004) (emphasis added).

[66] 109 F.3d at 759, 42 USPQ2d at 1223.

[67] 381 F.3d 1371, 72 USPQ2d 1333 (Fed. Cir. 2004).

[68] *Id.* at 1373–74, 72 USPQ2d at 1334.

own product. According to St. Jude, the term extension of the '288 patent therefore did not comply with 35 U.S.C. §156(a)(5)(A), which limits term extensions to cases where "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...."

At first blush, St. Jude's argument would appear to have considerable merit, particularly in view of the 1989 Federal Circuit opinion in *Fisons PLC v. Quigg*.[69] As discussed previously, *Fisons v. Quigg* held that a drug product patent is not eligible for term extension based upon any subsequent FDA approval for commercial marketing or use of a drug product containing the identical active ingredient, or a salt or ester of that active ingredient. Nonetheless the PTO, district court, and Federal Circuit each agreed that the '288 patent qualified for term extension. As the court of appeals explained, "§156(a)(5)(A) does not require that the device on which the extension is based is the first approved product within the claims of the patent."[70]

In reaching this conclusion, the Federal Circuit found the statutory distinction between 35 U.S.C. §156(a)(5)(A) and §156(a)(5)(A) to be telling. With emphasis added, those statutes provide:

> (5) (A) except as provided in subparagraph (B) or (C), 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;
>
> (B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, 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 a product manufactured under the process claimed in the patent....*

As can be seen, subparagraph (A) refers to "marketing or use of *the* product" that the patentee has selected, while subparagraph (B) requires that term extension be based upon "the first permitted commercial marketing or use of *a* product" manufactured via the patented method. This distinction between "a" and "the" carried great weight in the court's analysis. Quoting from the district court opinion, Judge Newman stated: "The court should not read into subparagraph (a)(5)(A) the limiting requirement that Congress imposed so clearly in writing subparagraph (a)(5)(B), but only for method patents primarily using recombinant DNA technology."[71] In other words, given subparagraph (B)'s strong implication that term extension must be

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[69] 876 F.2d 99, 10 USPQ2d 1869 (Fed. Cir. 1989).

[70] 381 F.3d at 1384, 72 USPQ2d at 1343.

[71] *Id.*

based upon the first commercial marketing or use of the product manufactured using recombinant DNA technology, the differently worded subparagraph (A) instead did not require that the term extension focus upon the first patented product that received FDA approval.

According to Judge Newman, *Fisons v. Quigg* was not to the contrary. That opinion had

> held that a drug-patent extension must be based on the first FDA approval of the active ingredient of the patented product because, under the definition provided in §156(f)(2), the active ingredient is the approved 'product.' Thus, in *Fisons,* the court held that subsequent extensions were not available for subsequent products using the same active ingredient that was the basis of the first extension, implementing the principle that only one extension is available per approved product.[72]

Affirming the lower court's judgment on this point, Judge Newman concluded that the "district court agreed that only one extension was available, but held that the patentee was not required to rely on a licensee's version of the device as the basis for the extension."[73]

The *Cardiac Pacemakers v. St. Jude Medical* court's characterization of *Fisons v. Quigg* as holding no more than that only a single patent term extension is available under 35 U.S.C. §156 is debatable. The court of appeals was on somewhat firmer ground when it observed that 35 U.S.C. §156(f)(1) defines the term "product" to mean either a "drug product" or "[a]ny medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act." Although the statute further defines the term "drug product" to mean the "active ingredient" or "salt or ester of the active ingredient,"[74] no analogous provision exists for medical devices, food additives, or color additives. The result, of course, is significantly greater flexibility in pursuing patent term extensions with respect to medical devices than with drug products, a fact that allows for more effective strategies in pursuing patent term extensions in this arena.

B. Application for Term Extension

1. Time Limit for Filing

Under 35 U.S.C. §156(d)(1), an application for term extension "may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." The Federal Circuit interpreted this language strictly in its 1989 decision in *Unimed, Inc. v. Quigg*.[75] The patent at issue in that case, U.S. Patent No. 3,668,224, described and claimed a process for making dibenzo-pyran. That compound, known under the

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[72] *Id.* at 1385, 72 USPQ2d at 1385.

[73] *Id.*

[74] 35 U.S.C. §156(f)(2) (2004).

[75] 888 F.2d 826, 12 USPQ2d 1644 (Fed. Cir. 1999).

trademark MARINOL®, is the synthetic equivalent of an isomer of delta-9-tetrahydrocannabinol (THC), the principal psychoactive substance in *Cannabis sativa L.* marijuana.

The exclusive licensee of the '224 patent, Unimed, submitted an NDA to the FDA on June 24, 1981, pursuant to the Federal Food, Drug, and Cosmetic Act.[76] The FDA approved the NDA on May 31, 1985, but reminded Unimed that "MARINOL may not be legally marketed until the Drug Enforcement Administration has completed rescheduling activities as required by the Controlled Substances Act."[77] This latter step took place on May 13, 1986, when the Drug Enforcement Administration (DEA) finalized the removal of MARINOL® from Schedule I to Schedule II of the Controlled Substances Act.[78] Unimed filed its application for extension of the '224 patent term under 35 U.S.C. §156 at the PTO 14 days later. By that point, more than one year had elapsed since the FDA had issued marketing approval for MARINOL®.[79]

The PTO denied Unimed's application, concluding that it had not been filed within 60 days of receipt of FDA marketing approval. Although the District Court for the District of Columbia reversed the PTO's decision,[80] on appeal the Federal Circuit again reversed. Judge Mayer stated the issue crisply: "The timeliness issue boils down to whether the sixty-day period specified in section 156(d)(1) began, as the [PTO] Commissioner argues, when the FDA sent its approval letter, on May 31, 1985, or, as Unimed argues, when the DEA rescheduled Marinol nearly a year later."[81] Siding with the PTO, the court of appeals reasoned that the 60-day period identified in 35 U.S.C. §156(d)(1) commenced "on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." Section 156(g)(1)(B) in turn defined the "applicable regulatory review period" as Section 505 of the Federal Food, Drug, and Cosmetic Act, which governs the approval of new drugs by the FDA, and nowhere mentioned the role of the DEA. The Federal Circuit therefore agreed with the PTO that the 60-day period began upon the FDA approval date. As a result, the '224 patent term extension application was considered to have been untimely filed and was therefore rejected.[82]

2. Identity of the Applicant

An application for patent term extension under the Hatch-Waxman Act must be submitted by "the owner of record of the patent or its

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[76] *See* 21 U.S.C. §355 (2004).

[77] 888 F.2d at 827, 12 USPQ2d at 1645.

[78] 21 U.S.C. §812 (2004).

[79] 888 F.2d at 827, 12 USPQ2d at 1645.

[80] 707 F. Supp. 17, 10 USPQ2d 1698 (D.D.C. 1989).

[81] 888 F.2d at 828, 12 USPQ2d at 1646.

[82] *Id.* at 828–29, 12 USPQ2d at 1646–47.

agent."[83] The PTO may require proof that any agent of the patentee—including a licensee—is authorized to act on behalf of the patent owner.[84] Licensees would therefore be well advised, when structuring their commercial arrangements with the patent owner, to require the patentee to submit applications for term extension under 35 U.S.C. §156 to the PTO.

3. Contents

Applications for term extension under 35 U.S.C. §156 must be filed at the PTO. The PTO requires that each application for term extension include 15 elements.[85] In addition to such expected components as the identity of the approved product and relevant patent, a statement of the relevant dates of FDA activity, and fee,[86] a complete application must incorporate the following notable items:

- an identification of the applicable federal statute under which regulatory review occurred;
- in the case of a drug product, an identification of each active ingredient in the product and, as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use;
- a statement that the application has been filed within the 60-day statutory period, including an identification of the last day on which the application could be submitted;
- a brief description of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities;
- a calculation of the length of the extension claimed; and
- a statement that the applicant acknowledges a duty to disclose any material that is pertinent to the determination of entitlement to the extension sought.[87]

The PTO will assign a filing date to an application for term extension that falls somewhat short of its regulatory standards, however. If the application (1) identifies the approved product; (2) identifies each federal statute under which regulatory review occurred; (3) identifies the patent for which an extension is being sought; (4) identifies each claim of the patent which claims the approved product or a method of using or manufacturing the approved product; (5) provides sufficient information to enable the PTO to determine whether the patent is eligible for extension, and the rights that will be derived from the extension, and information to enable the Director and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the length of the regulatory review period; and (6) includes a

[83] 35 U.S.C. §156(d)(1) (2004).

[84] 37 C.F.R. §1.730 (2004).

[85] *Id.* §1.740(a).

[86] As of December 8, 2004, the fee was $1,120.00. *Id.* §1.20(j).

[87] *Id.* §1.740.

brief description of the activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities, then the PTO will accord the application a filing date.[88] This PTO policy is based on the obligatory nature of these six elements in a term extension application under 35 U.S.C. §156(d)(1)(A)–(D), while the remainder of the PTO requirements were established via regulation in keeping with 35 U.S.C. §156(d)(1)(E).

If the PTO determines that the term extension application should be accorded a filing date, but that it does not fully comply with PTO regulations, the applicant ordinarily has two months to complete the application.[89] The applicant may extend this period through the payment of additional surcharges in accordance with usual PTO practice.[90]

4. Review of the Application

The submission of a complete application for term extension under 35 U.S.C. §156 commences a fairly elaborate proceeding involving the PTO, FDA, and patent proprietor and possibly third parties as well. In short, within 60 days of receiving the application, the PTO will request either the Secretary of Agriculture (if the product is subject to the Virus-Serum-Toxin Act) or the Secretary of Health and Human Services (in all other cases) to calculate the applicable "regulatory review period," which is then published in the *Federal Register*.[91]

The date of publication is followed by a 180-day period during which any interested party may file a petition contending that the applicant has not acted with due diligence.[92] For purposes of this determination, the Hatch-Waxman Act stipulates that the term "due diligence" is defined as "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period."[93] The appropriate secretary must determine within 90 days of filing whether the applicant has acted with due diligence or not, and then publish this determination in the *Federal Register*.[94] An interested person may then request an informal hearing on this determination within 60 days of publication, which is held within 60 days of the request.[95] Following the hearing, the appropriate secretary is allotted

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[88] *Id.* §1.741.

[89] *Id.* §1.741(b).

[90] *Id.* §1.136.

[91] 35 U.S.C. §156(d)(2)(A) (2004). *See* Aktiebolaget Astra v. Lehman, 71 F.3d 1578, 1580–81, 37 USPQ2d 1212, 1214–15 (Fed. Cir. 1995).

[92] 35 U.S.C. §156(d)(2)(B)(i) (2004).

[93] *Id.* §156(d)(3).

[94] *Id.*

[95] *Id.* §156(d)(2)(B)(ii).

30 days to affirm or modify its original decision and then notify the PTO Director.[96]

The PTO then forwards a Notice of Final Determination to the applicant. The applicant may make a single request for reconsideration of the determination within one month, or such other time period set forth in the determination.[97] If no such request for reconsideration is filed, or upon the completion of its review of such a request, the PTO will then issue a Certificate of Extension of Patent Term to the applicant.[98]

5. Interim Extensions

The Hatch-Waxman Act stipulates that an extension of patent term is proper only if the patent has not expired before the application is submitted to the PTO.[99] This rule potentially creates difficulties for patent proprietors who face lengthy periods of FDA approval. The possibility exists that a patent could expire prior to the issuance of a certificate of extension, thus denying the patent proprietor a term extension to which it would otherwise be entitled.

Fortunately, Congress provided for the issuance of a "certificate of interim extension" to address this hazard. According to 35 U.S.C. §156(d)(5), if a patent owner or its agent reasonably expects that the federal regulatory review period for the product in that patent may extend beyond the expiration of the patent term, that individual may request an interim extension during the period beginning six months, and ending 15 days, before the patent's expiration date.[100] If the patent would otherwise be eligible for extension, then the PTO Director must issue a certificate of interim extension for a period of not more than one year.[101] A patent owner who has procured one interim extension may apply for up to four subsequent extensions,[102] although the interim extensions may not be longer than the maximum period for extension to which the applicant would be eligible.[103] Any interim extension granted will end 60 days after the FDA grants regulatory approval, unless the patentee or its agent files further information.[104] In any case, the extension may not extend past a total of five years from the expiration of the original patent term.[105] During the period of

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[96] *Id.*

[97] U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE §2755 (May 2004) (MPEP).

[98] 37 C.F.R. §1.780.

[99] 35 U.S.C. §156(a)(1) (2004).

[100] *Id.* §156(d)(5)(A).

[101] *Id.* §156(d)(5)(B).

[102] *Id.* §156(d)(5)(C).

[103] 37 C.F.R. §1.760.

[104] 35 U.S.C. §156(d)(5)(E) (2004).

[105] *Id.* §156(d)(5)(E)(i).

interim term extension, the rights provided by the patent are limited to the specific use then under regulatory review.[106]

6. Strategic Considerations

Not uncommonly, multiple patents cover a single FDA-approved product. Yet, under the Hatch-Waxman Act, only one patent may enjoy the benefit of term extension.[107] As a result, the patent proprietor should weigh carefully which patent is most appropriate for term extension. This decision can be deferred to some degree, as PTO regulations allow the patent proprietor to file multiple applications. The PTO's final determination will provide a period of time—ordinarily set to one month—during which the applicant must select the patent to be extended.[108] If the applicant does not voluntarily withdraw all but one of the conflicting applications, then the PTO will issue a certificate of extension with respect to the patent having the earliest date of issuance.[109]

C. Period of Extension

Under the Hatch-Waxman Act, the period of patent term extension is set to the "regulatory review period."[110] Generally speaking, 35 U.S.C. §156(c) defines the term "regulatory review period" as one-half of what may be termed the "testing phase" of the product, plus the entirety of what may be termed the "approval phase" at the FDA.[111] To illustrate this basic formula of 35 U.S.C. §156(c) through a simple example, suppose that clinical trials consumed three years, while FDA approval took an additional two years. If none of the statute's numerous qualifications applied, then the patent term would be extended by $(1/2 \times 3) + 2 = 3.5$ years.

The nature of the regulated product sets the precise dates that commence the testing and approval phases that together comprise the regulatory review period. For a human drug, antibiotic, or human biological product, the testing period begins on the date the Investigational New Drug (IND) application is filed, while the approval phase period starts on the date of filing of either the New Drug Application (NDA) or Product License Application (PLA).[112] With respect to a patent claiming a new animal drug, the testing period begins on the date a major health or environmental effects test on the drug was initiated, or the date of an exemption under subsection (j) of Section 512 of the Federal Food, Drug, and Cosmetic Act, with the approval

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[106] *Id.* §156(d)(5)(F).

[107] *Id.* §156(c)(4).

[108] MPEP §2761.

[109] 37 C.F.R. §1.785.

[110] 35 U.S.C. §156(c) (2004).

[111] *Id.* §156(c)(2).

[112] 37 CFR §1.740(a)(10)(i).

phase set to the date a New Animal Drug Application (NADA) was submitted.[113] For a patent claiming a veterinary biological product, the testing period commences on the date on which the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective, while the approval date is the date on which an application for a license was submitted under the Virus-Serum-Toxin Act.[114]

The relevant dates for a patent claiming a food or color additive are, for the testing period, the date that a major health or environmental effects test on the additive was initiated and, for the approval phase, the date on which a petition for product approval under the Federal Food, Drug, and Cosmetic Act was initially submitted.[115] Finally, for a patent claiming a medical device, the testing date commences on the effective date of the Investigational Device Exemption (IDE) or, if no IDE was submitted, on the date on which the applicant began the first clinical investigation involving the device. The approval phase commences on the date on which the application for product approval or notice of completion of a product development protocol under Section 515 of the Federal Food, Drug, and Cosmetic Act was initially submitted.[116]

The Hatch-Waxman Act provides a number of exceptions to its basic term extension formula. First, if the applicant did not act with due diligence at any time during the regulatory review period, then the length of the regulatory review period is reduced by that number of days.[117] Second, for patents issued after the date of enactment of the Hatch-Waxman Act, September 24, 1984,[118] the maximum period of term extension is capped at five years.[119] In addition, the remaining patent term, combined with the period of term extension, may not exceed 14 years.[120] Finally, any part of the regulatory review period that took place prior to the issuance of the patent is not included in this calculation.[121]

D. Limitation Upon Scope of Rights

The Hatch-Waxman Act does not go so far as to provide a patent term extension in the usual sense—that is to say, a temporal extension of the original right to exclude others from practicing the patented

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[113] *Id.* §1.740(a)(10)(ii).

[114] *Id.* §1.740(a)(10)(iii).

[115] *Id.* §1.740(a)(10)(iv).

[116] *Id.* §1.740(a)(10)(v).

[117] 35 U.S.C. §156(c)(1) (2004).

[118] The relevant date for animal drug products and veterinary biological products is November 16, 1988, the date of enactment of the Generic Animal Drug and Patent Term Restoration Act.

[119] 35 U.S.C. §156(g)(6) (2004). For a discussion of the statutory scheme for patents that issued prior to September 24, 1984, see *Hoechst AG v. Quigg*, 917 F.2d 522, 16 USPQ2d 1549 (Fed. Cir. 1990).

[120] 35 U.S.C. §156(c)(3) (2004).

[121] *Id.* §156(c).

invention. During the period of term extension, the rights provided by the patent are instead limited, generally speaking, to the specific use that the FDA has approved. More specifically, 35 U.S.C. §156 stipulates that in the case of an extended product patent, the patent's rights during the extension period are generally "limited to any use approved for the product" that subjected it to regulatory approval delays at the FDA.[122] In the case of a patent that claims a method of using a product, the patent's rights during the extension period are "limited to any use claimed by the patent and approved for the product" that subjected it to regulatory delays at the FDA.[123] Finally, in the case of a patent that claims a method of manufacturing a product, the patentee's rights during the extension period are "limited to the method of manufacturing as used to make . . . the approved product" that was subject to regulatory delays at the FDA.[124]

In an important 2004 decision, *Pfizer Inc. v. Dr. Reddy's Laboratories, Ltd.*,[125] the Federal Circuit interpreted this language broadly. In that case, Pfizer owned U.S. Patent No. 4,572,909, which related to certain dihydropyridine compounds and their acid addition salts. The compound recited in claim 8 was commonly known as amlodipine.[126] Pfizer obtained FDA approval to sell an anti-hypertensive, anti-ischemic drug product whose active ingredient is amlodipine, as the besylate salt. Although Pfizer had submitted clinical data to the FDA with respect to both amlodipine besylate and amlodipine maleate, it chose the besylate salt due to ease of tableting.[127]

Although the '909 patent was set to expire on February 25, 2003, Pfizer obtained a term extension of 1,252 days under 35 U.S.C. §156. Dr. Reddy's subsequently filed a paper NDA proposing to market amlodipine maleate. Although certain claims of the '909 patent unquestionably read upon Dr. Reddy's proposed product, Dr. Reddy's argued that the term extension applied only to the registered product, the besylate salt.[128] In contrast, Pfizer cited 35 U.S.C. §156(f), which reads in relevant part:

> (1) The term "product" means:
> (A) A drug product.
>
> * * *
>
> (2) The term "drug product" means the active ingredient of—
> (A) 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)

[122] *Id.* §156(b)(1).

[123] *Id.* §156(b)(2).

[124] *Id.* §156(b)(3).

[125] 359 F.3d 1361, 69 USPQ2d 2016 (Fed. Cir. 2004).

[126] *Id.* at 1363, 69 USPQ2d at 2017.

[127] *Id.* at 1363–64, 69 USPQ2d at 2017.

[128] *Id.* at 1364, 69 USPQ2d at 2017.

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> *including any salt or ester of the active ingredient*, as a single entity or in combination with another active ingredient.[129]

Pfizer observed that 35 U.S.C. §156(f) contemplated that a therapeutic product could be administered as a "salt or ester of the active ingredient," and the Hatch-Waxman Act's term extension is not defeated merely by changing the salt or ester. Although the district court sided with Dr. Reddy's,[130] the Federal Circuit reversed this holding on appeal.

In its opinion, the Federal Circuit reasoned that the stipulation in 35 U.S.C. §156(b) that any patent term extension be "limited to any use approved for the product" meant that "other, e.g., non-pharmaceutical uses, are not subject to the extension." This provision did not limit the form of the product subject to the extension.[131] Judge Newman further explained:

> We conclude that the active ingredient is amlodipine, and that it is the same whether administered as the besylate salt or the maleate salt. The statutory definition of "drug product" is met by amlodipine and its salts. Dr. Reddy's is proposing to market the "drug product," as defined in 35 U.S.C. §156(f), for the same approved uses. The statute foresaw variation in the salt or ester of an active ingredient, and guarded against the very loophole now urged.[132]

The ruling in *Pfizer v. Dr. Reddy's* is sound. Manufacturers commonly combine an "off-the-shelf" anion, such as the maleate and besylate involved in this case, with an active ion to form a salt. Affirmance of the district court's holding would have made it child's play to circumvent the 35 U.S.C. §156 term extension simply by formulating a drug compound as a different salt. Such a result would have been particularly troubling under the facts of that case, as Pfizer had both published and submitted to the FDA data regarding both the amlodipine maleate and amlodipine besylate forms of the compound, and as Dr. Reddy's had relied upon that information while submitting its paper NDA. By giving weight to the Hatch-Waxman Act's term extension provisions, the Federal Circuit retained the balance between competition and incentives to innovate that Congress had established in that statute.

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[129] 35 U.S.C. §156(f) (2004) (emphasis added).

[130] 2002 WL 31833744 (D.N.J. 2002).

[131] 359 F.3d at 1366, 69 USPQ2d at 2019.

[132] *Id.* at 1366, 69 USPQ2d at 2018–19.