

PUBLIC COPY

Nos. 03-1227, -1258

United States Court of Appeals
For the Federal Circuit

PFIZER INC.,

Plaintiff-Appellant,

v.

DR. REDDY'S LABORATORIES, INC. and
DR. REDDY'S LABORATORIES, LTD.,

Defendants-Appellees.

**Appeals From The United States District Court
For The District Of New Jersey In No. 02-CV-2329
Katharine S. Hayden, United States District Judge**

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2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None.

3. All present corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

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TABLE OF CONTENTS

CERTIFICATE OF INTEREST	i
TABLE OF AUTHORITIES.....	iv
STATEMENT OF RELATED CASES	ix
STATEMENT OF JURISDICTION.....	1
STATEMENT OF THE ISSUE	1
STATEMENT OF THE CASE.....	1
A. The Statutory Framework.....	2
B. Statement of Facts.....	14
C. The District Court’s Decision.....	19
SUMMARY OF ARGUMENT.....	21
ARGUMENT.....	27
I. STANDARD OF REVIEW	27
II. DR. REDDY’S PROPOSED AMLODIPINE MALEATE DRUG PRODUCT INFRINGES THE “RIGHTS DERIVED” FROM PFIZER’S ‘909 PATENT, AS EXTENDED BY SECTION 156.....	27
A. Section 156 Extends “The Term Of The Patent” And Thus Allows Pfizer To Exclude The Marketing Of Amlodipine Maleate.....	28
B. The Limitation In Section 156(b) Is Inapplicable To Dr. Reddy’s Proposed Marketing Of Amlodipine Maleate.....	29
C. Barring Infringement By Dr. Reddy’s Amlodipine Maleate Product Promotes The Purposes Of The Hatch-Waxman Act	31
D. The Statutory Scheme Confirms That Section 156 Is Best Read As Extending Patent Coverage To All Salt Forms Claimed By The Patent And Marketed For The Same Use.....	34
E. The District Court’s Stated Reasons For Limiting Pfizer’s PTR Only To The “Approved Product” Are Unsound.....	38
III. THE APPROVED PRODUCT INCLUDES AMLODIPINE MALEATE.....	48
A. The “Approved Product” Includes “Any Salt” Of Amlodipine	48
B. The District Court’s Contrary Reasoning Is Unsound	52

CONCLUSION 59
ADDENDUM.....
CERTIFICATE OF SERVICE.....
CERTIFICATE OF COMPLIANCE

TABLE OF AUTHORITIES

CASES

<i>ACS Hosp. Sys., Inc. v. Montefiore Hosp.</i> , 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984).....	36
<i>AbTox, Inc. v. Exitron Corp.</i> , 122 F.3d 1019, 43 USPQ2d 1545 (Fed. Cir. 1997).....	7, 13, 33, 34
<i>Abbott Labs. v. Novopharm Ltd.</i> , 104 F.3d 1305, 41 USPQ2d 1535 (Fed. Cir. 1997).....	27
<i>Abbott Labs. v. Young</i> , 920 F.2d 984, 17 USPQ2d 1027 (D.C. Cir. 1990)	26, 50, 56
<i>Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.</i> , 988 F.2d 1157, 26 USPQ2d 1038 (Fed. Cir. 1993).....	53
<i>Blue Chip Stamps v. Manor Drug Stores</i> , 421 U.S. 723 (1975).....	28
<i>Bonito Boats, Inc. v. Thunder Craft Boats, Inc.</i> , 489 U.S. 141 (1989).....	3
<i>Chickasaw Nation v. United States</i> , 534 U.S. 84 (2001)	44
<i>Communications Workers of Am. v. Beck</i> , 487 U.S. 735 (1988).....	57
<i>Eli Lilly & Co. v. Am. Cyanamid Co.</i> , 82 F.3d 1568, 36 USPQ2d 1011 (Fed. Cir. 1996).....	58
<i>Eli Lilly & Co. v. Medtronic, Inc.</i> , 496 U.S. 661 (1990).....	4, 5, 7, 35
<i>Fed. Land Bank of St. Paul v. Bismarck Lumber Co.</i> , 314 U.S. 95 (1941)	42
<i>Fisons plc v. Quigg</i> , 876 F.2d 99, 10 USPQ2d 1869 (Fed. Cir. 1989).....	43, 49
<i>Gibraltar Fin. Corp. v. United States</i> , 825 F.2d 1568 (Fed. Cir. 1987)	37
<i>Glaxo, Inc. v. Novopharm, Ltd.</i> , 110 F.3d 1562, 42 USPQ2d 1257 (Fed. Cir. 1997).....	13, 33

<i>Glaxo Operations UK Ltd. v. Quigg</i> , 706 F. Supp. 1224, 10 USPQ 1100 (E.D. Va. 1989).....	55
<i>Glaxo Operations UK Ltd. v. Quigg</i> , 894 F.2d 392, 13 USPQ2d 1628 (Fed. Cir. 1990).....	26, 52, 55, 56, 57
<i>Helvering v. Morgan's, Inc.</i> , 293 U.S. 121 (1934)	42
<i>Hoechst-Roussel Pharm., Inc. v. Lehman</i> , 109 F.3d 756, 42 USPQ2d 1220 (Fed. Cir. 1997).....	13, 49
<i>INS v. Cardoza-Fonseca</i> , 480 U.S. 421 (1987).....	44
<i>Int'l Visual Corp. v. Crown Metal Mfg. Co.</i> , 991 F.2d 768, 26 USPQ2d 1588 (Fed. Cir. 1993).....	36
<i>Kastigar v. United States</i> , 406 U.S. 441 (1972).....	40
<i>Kewanee Oil Co. v. Bicron Corp.</i> , 416 U.S. 470 (1974).....	3
<i>Kokoszka v. Belford</i> , 417 U.S. 642 (1974)	33
<i>Koyo Seiko Co. v. United States</i> , 36 F.3d 1565 (Fed. Cir. 1994).....	37
<i>Kremer v. Chem. Constr. Corp.</i> , 456 U.S. 461 (1982).....	37
<i>Litton Sys., Inc. v. Whirlpool Corp.</i> , 728 F.2d 1423, 221 USPQ 97 (Fed. Cir. 1984).....	47
<i>Mead Johnson Pharm. Group v. Bowen</i> , 838 F.2d 1332, 6 USPQ2d 1565 (D.C. Cir. 1988)	51
<i>Merck & Co., Inc. v. Kessler</i> , 80 F.3d 1543, 38 USPQ2d 1347 (Fed. Cir. 1996).....	<i>passim</i>
<i>In re Recreative Techs. Corp.</i> , 83 F.3d 1394, 38 USPQ2d 1776 (Fed. Cir. 1996)	47

<i>Roche Prod., Inc. v. Bolar Pharm. Co.</i> , 733 F.2d 858, 221 USPQ 937 (Fed. Cir.), <i>cert. denied</i> , 469 U.S. 856 (1984).....	4, 34
<i>Smith v. Orr</i> , 855 F.2d 1544 (Fed. Cir. 1988).....	40
<i>Teleflex, Inc. v. Ficosa N.A. Corp.</i> , 299 F.3d 1313, 63 USPQ2d 1374 (Fed. Cir. 2002).....	36
<i>Unimed, Inc. v. Quigg</i> , 888 F.2d 826, 12 USPQ2d 1644 (Fed. Cir. 1989).....	13
<i>United States v. New York Tel. Co.</i> , 434 U.S. 159 (1977)	41
<i>United States v. U.S. Gypsum Co.</i> , 438 U.S. 422 (1978)	36
<i>Univ. of W. Va. Bd. of Tr. v. Vanvoorhies</i> , 278 F.3d 1288, 61 USPQ2d 1449 (Fed. Cir. 2002).....	26
<i>Warner-Lambert Co. v. Apotex Corp.</i> , 316 F.3d 1348, 65 USPQ2d 1481 (Fed. Cir. 2003).....	34, 39

STATUTES, RULES AND REGULATIONS

21 U.S.C. § 321(p).....	3, 12
21 U.S.C. § 355(a).....	3
21 U.S.C. § 355(b).....	18
21 U.S.C. § 355(j).....	25, 50, 57
21 U.S.C. § 355a.....	15
28 U.S.C. § 1295(a)(1).....	1
28 U.S.C. §§ 1331 & 1338	1
28 U.S.C. § 2107	1
35 U.S.C. § 154(a).....	2, 3

35 U.S.C. § 154(c)(1) (2000)	4
35 U.S.C. § 156	<i>passim</i>
35 U.S.C. § 156(a).....	<i>passim</i>
35 U.S.C. § 156(b).....	<i>passim</i>
35 U.S.C. § 156(c).....	51
35 U.S.C. § 156(f)	<i>passim</i>
35 U.S.C. § 271	6
35 U.S.C. § 271(e).....	6, 19, 23, 34
35 U.S.C. § 271(g).....	58
21 C.F.R. § 314.108(a).....	51, 57
21 C.F.R. § 314.50(i)(1)(4)	18
21 C.F.R. § 60.3(b).....	50
37 C.F.R. § 1.740.....	53
Pub. L. No. 98-417, 98 Stat. 1585.....	3
Pub. L. No. 103-465, 108 Stat. 4809, § 532(a)(1) (1994).....	4
<i>Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338 (Oct. 3, 1994)</i>	<i>50</i>
Fed. R. App. P. 4	1
Fed. R. Civ. P. 12(b)(6).	19, 26, 52, 54

LEGISLATIVE HISTORY

H.R. Rep. No. 97-696 (1982).....	12, 32, 44
----------------------------------	------------

H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. 2647 *passim*
 S. 255, 97th Cong., § 155(a)(1) (1981) 24, 44

MISCELLANEOUS

Donald O. Beers, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements* § 3.05 18
 2A Norman J. Singer, *Sutherland Statutory Construction* § 47.07 (6th ed. 2000) 41

STATEMENT OF RELATED CASES

The '909 patent that is the subject of this case is also the subject of *Pfizer Inc. v. Mylan Pharmaceuticals, Inc.*, No. 2002 CV 01628, pending in the United States District Court for the Western District of Pennsylvania.

STATEMENT OF JURISDICTION

The district court's jurisdiction was based upon 28 U.S.C. §§ 1331 and 1338.

Pfizer timely filed these appeals pursuant to 28 U.S.C. § 2107 and Fed. R. App. P. 4. This Court's jurisdiction is based upon 28 U.S.C. § 1295(a)(1).

STATEMENT OF THE ISSUE

Whether, during its extended term, Pfizer's U.S. Patent No. 4,572,909 (the '909 patent), as restored pursuant to 35 U.S.C. § 156, covers amlodipine and all of its salts, or, as the district court held, only the one specific salt of amlodipine marketed by Pfizer as Norvasc®?

STATEMENT OF THE CASE

This case raises a significant question concerning the scope of patent rights under the patent term restoration (PTR) provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), codified at 35 U.S.C. § 156. Appellee Dr. Reddy's seeks to market a drug product containing amlodipine in its maleate salt form, notwithstanding that both amlodipine and its maleate salt are claimed by Appellant Pfizer's '909 patent. Although Dr. Reddy's proposes to market its product for exactly the same uses as, and in direct competition with, Pfizer's Norvasc®, which contains the besylate salt of amlodipine, the district court ruled that Dr. Reddy's proposed product does not infringe the '909 patent during its restored term.

As interpreted by the district court, the Hatch-Waxman Act limited Pfizer's patent rights during the restored portion of the '909 patent's term to the particular salt form of amlodipine for which Pfizer received marketing approval from the U.S. Food and Drug Administration (FDA). This holding contradicts the text of Section 156 and severely undermines the purposes of that law. The express statutory goal of patent term restoration is to encourage pharmaceutical discovery and innovation by restoring *patent life* that is effectively lost due to the regulatory review required of new chemical entities. If an innovator company's patent rights are narrowly limited to the specific salt form in which a new drug is marketed, this incentive to innovation will be severely undermined, because, as in this case, a generic company will be able to market the patented invention (here, amlodipine) in direct competition with the innovator's patented product. In other words, under the district court's approach, the incentives that Congress created for pharmaceutical companies to make new drugs will be wrongly converted into an incentive for generic copyists to just reformulate these same drugs as different salt forms.

A. The Statutory Framework

Under the Patent Laws of the United States, a patent grants the patent holder "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States, or importing the invention into the United

States.” 35 U.S.C. § 154(a)(1). The right to exclude encourages inventors to make their discoveries known, and to “risk the often enormous costs in terms of time, research, and development” necessary to create an invention. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974). A concomitant of the right to exclude others is that the patentee itself obtains “the exclusive right to practice the invention for a period of years.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989).

Under the present version of the Patent Laws, the grant of the “right to exclude” begins on the date that the patent issues, but expires on a date 20 years from the day of the patent’s application. 35 U.S.C. § 154(a)(2). As a consequence, under the statute, a patent’s life is equal to 20 years *less* the amount of time that the patent application spends in the U.S. Patent and Trademark Office (PTO) prior to issuance. *See id.* In the case of pharmaceuticals, however, the effective life of a patent may be much less, because a new drug cannot be marketed in the United States until the FDA approves it, *see* 21 U.S.C. § 355(a), and, “[t]o obtain such approval, drugs must undergo extensive testing to prove [that] they are both safe and effective.” “Drug Price Competition and Patent Term Restoration Act,” H.R. Rep. No. 98-857, Pub. L. No. 98-417, 1984 U.S.C.C.A.N. 2647, 2650.

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, more commonly known as the Hatch-Waxman Act,

was enacted by Congress “to respond to two unintended distortions of the 17-year [now 20-year] patent term produced by the requirement that certain products must receive premarket regulatory approval.” *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990). *See also* Pub. L. No. 103-465, 108 Stat. 4809, § 532(a)(1) (1994), *codified at* 35 U.S.C. § 154(c)(1) (2000) (changing the term of exclusivity from 17 years to 20 years). One of the “unintended distortions” from the FDA regulatory process, occurring at the outset of the patent term, was that the patent holder could not, “as a practical matter,” exercise his right to exclude, or his concomitant right to practice the invention, because of the FDA approval process. Even though the patentee had been issued a patent, it was largely valueless at inception, because the patentee itself could not practice its invention without FDA approval: “[T]he ‘clock’ on his patent term will be running even though he is not yet able to derive any profit from the invention.” *Eli Lilly*, 496 U.S. at 669-70.

The second “unintended distortion” from the FDA regulatory approval process occurred at the *end* of the patent term. In 1984, a panel of this Court held that a generic drug manufacturer could not, prior to the expiration of the pioneer drug company’s patent, “use” a drug covered by a patent in order to conduct the federally mandated premarketing tests required before bringing the generic product to market. *See Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861-65, 221 USPQ 937, 938-42 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). Because the

Roche decision prevented competitors from even beginning the premarket testing process “until expiration of the entire patent term, the patentee’s *de facto* monopoly would continue for an often substantial period until regulatory approval was obtained. In other words, the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term.” *Eli Lilly*, 496 U.S. at 670.

The Hatch-Waxman Act “sought to eliminate this distortion from both ends of the patent period” (*id.* at 670) – at the “front end,” the loss of effective patent rights to innovator companies due to marketing delays because of regulatory review; and at the “back end,” the inability of generic companies to prepare applications for FDA approval without infringing the pioneer’s patents. *Id.* at 669-70. To address the “front-end” distortion, Section 201 of the Hatch-Waxman Act added the PTR provision at issue in this case, 35 U.S.C. § 156, to the statutory scheme.

As the House Report accompanying the Hatch-Waxman Act explained, because of delays in regulatory approval, companies that innovate in the particularly important area of new pharmaceutical drugs were losing substantial portions of their exclusivity, which, it was feared, “would result in decreased expenditures for research and development and, eventually, in a decline in the introduction of new drugs.” H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. at 2650.

To prevent this impediment to innovation, Title II of the Hatch-Waxman Act, entitled “Patent Term Restoration Act,” added “a new section 156 to Title 35 of the United States Code, the Patent Law. It is entitled ‘Extension of Patent Term.’ The new section provides for the extension of the normal 17 year term of a product, use, or process patent if a product which is the subject of the patent is required by Federal law to be approved before it is commercially marketed.” H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. at 2670. As the House Report further explained, Section 156 was designed to “create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval. The incentive is the restoration of some of the time lost on patent life while the product is awaiting pre-market approval.” *Id.* at 2648.

To address the “back-end” distortion, Section 202 of the Hatch-Waxman Act added a subsection (e) to the section of the Patent Laws that prohibits patent infringement, 35 U.S.C. § 271. New Section 271(e)(1) was designed to legislatively overrule this Court’s decision in *Roche*, and provides that: “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.” 35 U.S.C. § 271(e)(1) (1984). “This [provision] allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to

obtain regulatory approval.” *Eli Lilly*, 496 U.S. at 671. The Hatch-Waxman Act also established abbreviated procedures for FDA approval of generic drugs under which the generic copier can avoid the expense of conducting its own testing of a drug and instead rely on data developed by the originator. *Id.* at 676.

As the Supreme Court explained in *Eli Lilly*, these “front-end” and “back-end” adjustments to the effective patent terms for pharmaceutical innovations “are meant generally to be complementary.” *Id.* at 673. For example, the Court in *Eli Lilly* held that, because medical device inventions are eligible for patent term restoration (*i.e.*, adjustment of the “front-end” distortion), the statute should be construed as also providing a complementary research exemption at the “back end.” *Id.* at 672-73. The same principle applies to pharmaceuticals: “From the perspective of R & D pharmaceutical corporations, for instance, the law giveth, section 156, and the law taketh away, section 271(e)(1).” *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029, 43 USPQ2d 1545, 1553 (Fed. Cir. 1997).

In particular, subsection (a) of Section 156 provides that:

(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, which shall include any patent term adjustment granted under section 154(b), if –

(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(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 paragraphs (1) through (4) of subsection (d);

(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) 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; or

(C) for purposes of subparagraph (A), in the case of a patent which –

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

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

35 U.S.C. § 156(a).

As the House Report indicates, Section 156(a) uses the phrase “[t]he term of a patent which *claims a product* . . . shall be extended” because the word “claims” is “the term used in the patent law to describe the invention which the patent owner or its assignee may prevent others from making, using or selling during the seventeen year term of the patent. For instance, in the case of a product patent which ‘claims’ a broad genus of compounds, the patent owner could prevent others from making, using or selling any compound which is a species of that genus.” H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. at 2670. Also of significance, Section 156(a) uses the term “product” in two different ways: In the opening clause, which sets forth the requirement that the patent to be extended be “a patent which claims a product,” the generally applicable definition of “product” set forth in 35 U.S.C. § 156(f) is used. But, in paragraphs (4) and (5) of Section 156(a), the term

“product” refers only to the product approved by the FDA; thus, the last sentence of subsection (a) states that “[t]he product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the ‘approved product.’”

Subsection (b) of Section 156 then goes on to set forth a limitation on the “rights derived from” a patent during the term of an extension granted under Section 156(a). Specifically, that subsection provides that:

(b) Except as provided in subsection (d)(5)(F), the rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended –

(1) in the case of a patent which claims a product, be limited to any use approved for the product –

(A) before the expiration of the term of the patent
–

(i) under the provision of law under which the applicable regulatory review occurred, or

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based;

(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the product –

(A) before the expiration of the term of the patent
–

- (i) under any provision of law under which an applicable regulatory review occurred, and
 - (ii) under the provision of law under which any regulatory review described in paragraphs (1), (4), or (5) of subsection (g) occurred, and
- (B) on or after the expiration of the regulatory review period upon which the extension of the patent was based; and
- (3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make –
- (A) the approved product, or
 - (B) the product if it has been subject to a regulatory review period described in paragraphs (1), (4), or (5) of subsection (g).

As used in this subsection, the term “product” includes an approved product.

35 U.S.C. § 156(b).

Subsection (b) thus contains only a single restriction on the “rights derived” from an extension of a patent’s term – to wit, the rights derived from the claims of the extended patent are limited to “any use approved for the product.” The House Report to the 1982 bill that initially proposed this “use” limitation explains that the “use” limitation keeps patent term restorations from protecting uses of the patented invention beyond the approved uses: “[I]f a chemical is subjected to regulatory review for new drug uses, but is also marketed for other commercial uses, the patent term extension would apply only to the new drug uses for which regulatory

review was required.” H.R. Rep. No. 97-696, at 10 (1982). *See also* H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. at 2672. This “use” limitation was known informally as the “Kodak amendment,” because a representative from Kodak had proposed it during the drafting process in order to ensure that only exclusivity of pharmaceutical use was extended, and that other non-pharmaceutical uses of patented compositions (such as for dye, paint thinners, fertilizers, etc.) would not be extended.

Finally, subsection (f) of section 156 contains definitions which apply “[f]or purposes of this section,” including a generally applicable definition of “product”:

(f) For purposes of this section:

(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,

including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

35 U.S.C. § 156(f). The definition of “drug product” in subsection (f) includes “the active ingredient of . . . a new drug,” as that term is “used in the Federal Food, Drug and Cosmetic Act,” which in turn “includ[es] any salt or ester of the active ingredient.” *Id.*

Through these provisions, “Section 156 supplie[s] patentees, mostly large research and development operations, the benefits of term extensions to erase the de facto reduction of their patent term.” *AbTox*, 122 F.3d at 1029. *See also Hoechst-Roussel Pharm., Inc. v. Lehman*, 109 F.3d 756, 764, 42 USPQ2d 1220, 1227 (Fed. Cir. 1997) (Newman, J., concurring) (“The purpose of § 156 is to extend the time during which the patent can be enforced against infringers . . .”). By providing for an extension of the claims of the patent, Section 156 “ameliorate[s] the loss incurred when *patent terms* tick away while the *patented product* is awaiting [FDA] regulatory approval for marketing.” *Unimed, Inc. v. Quigg*, 888 F.2d 826, 829, 12 USPQ2d 1644, 1647 (Fed. Cir. 1989) (emphasis added). In other words, Section 156 “provid[es] patent holders with limited extensions of patent term in order to recover a portion of the market exclusivity

lost during the lengthy process of development and FDA review.” *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568, 42 USPQ2d 1257, 1262 (Fed. Cir. 1997).

B. Statement of Facts

Pfizer and the ‘909 Patent. Pfizer is a United States corporation, incorporated in Delaware and having its principal place of business in New York City. (A146) It is engaged in the research, development, manufacture and marketing of pharmaceuticals. (A146)

Pfizer is the assignee of U.S. Patent No. 4,572,909 (the ‘909 patent), issued on February 25, 1986 and entitled “2-(Secondary Aminoalkoxymethyl) Dihydropyridine Derivatives as Anti-Ischaemic and Antihypertensive Agents.” (A148; *see* A153-69) The ‘909 patent, which Pfizer applied for on February 3, 1984, claims, among other things, certain 1,4-dihydropyridine compounds or their pharmaceutically acceptable acid addition salts, including amlodipine, amlodipine besylate, and amlodipine maleate. (A148; *see* A168, col. 30, lines 2-58) The ‘909 patent also claims pharmaceutical compositions containing these compounds, and methods of treating ischaemic heart disease and hypertension by administering these compounds. (A148; *see* A168, col. 30, lines 59-66) The ‘909 patent describes maleates as the preferred salts of the disclosed compounds, although it also describes and covers other salts of amlodipine. (A154, col. 2, lines 4-11)

Claim 1 is the only independent claim in the '909 patent. It claims a generic structure for "a dihydropyridine compound," as well as "a pharmaceutically acceptable acid addition salt thereof." (A168, col. 30, lines 2-24) Claim 8 of the '909 patent claims amlodipine and its salts. (A168, col. 30, lines 38-39) None of the claims of the '909 patent is drawn specifically to cover only amlodipine maleate, or only amlodipine besylate. (See A168, col. 30, lines 2-58) However, the claims of the patent do cover the besylate and maleate salts of amlodipine, as Dr. Reddy's has acknowledged. (A173)

Pfizer's Norvasc® Drug Product. Pfizer holds an approved New Drug Application (NDA) for amlodipine tablets, 2.5 mg, 5 mg, and 10 mg dosage strengths, which it sells under the registered name Norvasc®. (A148) Norvasc® is approved by the FDA for use in the treatment of hypertension, chronic stable angina, and vasospastic angina. (A722) The '909 patent is listed in the FDA's Orange Book (actually titled "Approved Drug Products with Therapeutic Equivalence Evaluations") with respect to Pfizer's Norvasc® drug product. (A148)

Norvasc® contains the besylate salt of amlodipine. (A710-11; A722) Even though the '909 patent claims amlodipine itself as well as its various salts, Pfizer determined to market the besylate salt of amlodipine as Norvasc® because of certain physical properties relating to stability and tablet manufacturing that the

besylate formulation possessed. (A 709) But the besylate part of the molecule has no therapeutic effect; the addition salt part of the molecule (*i.e.*, the besylate or the maleate) is a means of delivering the amlodipine part of the molecule, which provides the therapeutic value. (A621; A624; A626; A628; A1115-16)

Pfizer initially conducted its clinical trials using the maleate salt, and conducted further tests with amlodipine besylate. (A709-10) Pfizer's NDA for Norvasc® included test data on amlodipine, amlodipine besylate, and amlodipine maleate. (A711) The FDA approved Norvasc® for use in the treatment of hypertension, chronic stable angina, and vasospastic angina on July 31, 1992 – albeit, eight and one-half years after Pfizer's application for the '909 patent.

(A711)

The '909 Patent Term Extension. When initially issued in 1986, the '909 patent was scheduled to expire on February 25, 2003. (*See* A153) However, as the result of a PTR extension granted by the PTO pursuant to 35 U.S.C. § 156, the '909 patent was extended by 1,252 days and thus will not expire until July 31, 2006. (*See* A169)

In order to obtain this extension, Pfizer certified to the PTO that Norvasc® was covered by the claims of the '909 patent. (A1288-92; A1295) The "Certificate Extending Patent Term Under 35 U.S.C. § 156," which is part of the file history of the '909 patent, informs the public that "this certificate extends the

term of the patent for the period of 1,252 days with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).” (A169)

Dr. Reddy’s and its NDA for Amlodipine Maleate. Dr. Reddy’s

Laboratories, Ltd., one of the two defendants, is a corporation organized under the laws of India and having its principal place of business in Hyderabad, India.

(A147) The other defendant, Dr. Reddy’s Laboratories, Inc., is a wholly owned subsidiary of the Indian corporation, is incorporated in New Jersey, and has its principal place of business in Upper Saddle River, New Jersey. (A147) (For ease of reference, we will refer to both defendants, collectively, as “Dr. Reddy’s.”)

Dr. Reddy’s is in the business of making and selling generic drug products.

(A147)

On May 1, 2002, Dr. Reddy’s sent a notice letter and accompanying memorandum to Pfizer indicating that Dr. Reddy’s had submitted to the FDA a NDA for “Amlodipine Maleate Tablets (2.5, 5, and 10 mg base).” (A149; *see* A272-74) According to Dr. Reddy’s NDA, these amlodipine maleate tablets are indicated for use in the treatment of hypertension, chronic stable angina, and vasospastic angina – precisely the same uses for which Pfizer’s Norvasc® is approved. (*Compare* A276 with A722) This NDA, which was assigned application number 21-435, included a patent certification pursuant to section

505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)) and 21 C.F.R. § 314.50(i)(1)(i)(A). (A270)

Dr. Reddy's NDA is what is known as a "paper NDA." *See generally* Donald O. Beers, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements* § 3.05, at 3-63 to 3-75 (5th ed. 1999). "Paper NDA's are defined as any application submitted under section 505(b) of the FDCA in which the investigations relied upon by the applicant to show safety and effectiveness were not conducted by or for the applicant, and the applicant has not obtained a right of reference or use from the person who conducted the studies or for whom the studies were conducted." H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. at 2665. Dr. Reddy's paper NDA relied on the studies and data that Pfizer conducted on amlodipine as part of its development of Norvasc®. (A583; *see generally* 21 U.S.C. § 355(b)(2))

Even though Dr. Reddy's pursued a paper NDA, it nevertheless was required to make a patent certification. *See* 21 U.S.C. § 355(b)(2)(A)(iii), (iv). In that regard, Dr. Reddy's attested to the FDA that the manufacture, use, or sale of Dr. Reddy's Amlodipine Tablets, *after February 25, 2003*, would not infringe the '909 patent. (A276) Dr. Reddy's acknowledged, however, that the drug product that it seeks to make and market – amlodipine maleate – is covered by the claims of the

'909 patent, at least until the patent's pre-term-extension expiration date of February 25, 2003. (A173; A278; A283-84)

C. The District Court's Decision

Pfizer filed suit against Dr. Reddy's on June 12, 2002 (A146), alleging that Dr. Reddy's filing of NDA No. 21-435 was an act of infringement of the '909 patent. *See* 35 U.S.C. § 271(e)(2)(A). Dr. Reddy's answered on June 21, 2002 with a motion to dismiss, pursuant to Fed. R. Civ. P. 12(b)(6). (A170)

Dr. Reddy's motion to dismiss argued that, under its preferred interpretation of the statute, a PTR only extends the patent rights to the approved drug product on which the PTR is based. (A181-93) Thus, according to Dr. Reddy's, Pfizer's PTR only extended the '909 patent past February 25, 2003 insofar as it covers amlodipine besylate – Norvasc® – and did not continue the patent's coverage of anything else, even though the patent expressly claims other patented salts of amlodipine, including amlodipine maleate. (A175)

The district court agreed with Dr. Reddy's and, on December 20, 2002, issued an order granting the defendants' motion to dismiss. (A34) The district court reasoned that it was "implicit" in this Court's decision in *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 38 USPQ2d 1347 (Fed. Cir. 1996), that "only one drug product per patent is allowed an extension under the Hatch-Waxman Act." (A8-9) The district court further reasoned that, because Section 156(a) imposes "stringent

requirements for PTE applicants,” it would be anomalous to read the statute as “what section 156(a) takes away, by virtue of these stringent requirements, section 156(b) gives back.” (A10) The district court added that it is “inherent in the wording of the subsection . . . that ‘product’ means ‘approved product,’” and that, as a consequence, Section 156(b) imposes a limitation of patent term extensions both to the “use approved” and to the “approved product” itself. (A11) The district court viewed its holding as effectuating the goal of the statute “to compensate innovators only for what was actually lost in the regulatory review period, that is the right to sell their product for use approved by the government.” (A11-12) The district court drew support for its holding from a section of the *Manual of Patent Examining Procedure* (MPEP) dealing with patent term extensions; and the district court rejected Pfizer’s argument that it is inappropriate to read both a “use approved” limitation and an “approved product” limitation into Section 156(b), when Congress considered a version of the statute that expressly contained both limitations but did not pass it. (A13-14) Finally, the district court held that the “approved product” encompassed only amlodipine besylate and did not encompass amlodipine maleate. (A22-23)

Judgment was entered on the docket on December 27, 2002. (A145) Pfizer timely filed its notice of appeal from this decision on January 24, 2003. (A1528) On February 11, 2003, Pfizer timely filed a second notice of appeal from the

district court's decision denying its motion to enter Pfizer's proposed post-trial order. (A1529; *see* A35-36) This Court has consolidated the two appeals.

SUMMARY OF ARGUMENT

Dr. Reddy's proposed amlodipine maleate drug product infringes Pfizer's '909 patent, as extended by 35 U.S.C. § 156. The proposed amlodipine maleate drug product is covered by the claims of the '909 patent, and Dr. Reddy's is seeking FDA approval for the same uses as Pfizer's FDA-approved Norvasc® drug product. Indeed, Dr. Reddy's is relying upon Pfizer's own invention, and testing, of amlodipine maleate. Dr. Reddy's proposed marketing of amlodipine maleate constitutes unlawful infringement.

Contrary to the district court, the patent term extension obtained under Section 156 applies to the full scope of the claims of the '909 patent, not just to the Norvasc® drug product approved by the FDA. The plain language of Section 156 extends "the term of the patent," 35 U.S.C. § 156(a), not simply the patent's protection for a specific, limited product.

The *only* limitation on that extension, set forth in Section 156(b), is that, "in the case of a patent which claims a product," "the rights derived" from that patent extension are "limited to any use approved for the product" (35 U.S.C. § 156(b)). The "rights derived" from Pfizer's '909 patent include not only the exclusive right to market drugs including amlodipine besylate (*e.g.*, Norvasc®), but also the right

to exclude other salts claimed by the patent such as amlodipine maleate. While the “rights derived” from the patent are “limited to any use approved for the product,” amlodipine maleate is, according to Dr. Reddy’s paper NDA, indicated for the same use as that approved by the FDA for amlodipine besylate. In other words, this “use” limitation is no impediment to Pfizer’s infringement claim against Dr. Reddy’s proposed amlodipine maleate product, because that product is indicated for exactly the same uses (treatment of hypertension, chronic stable angina, and vasospastic angina) as the uses for which Norvasc® is approved.

This construction of Section 156 best promotes the purposes of the Hatch-Waxman Act. The statute was intended to create more economic incentives for pioneering pharmaceutical manufacturers to invest in research and development. It did so by extending the period of exclusivity beyond the end of the statutory patent term, in order to restore the period of patent protection effectively lost during the regulatory process. Like the statutory text, the legislative history indicates a specific intent both that the patent term extension would apply to all salts of a compound claimed by a patent, not just the compound approved by the FDA, and that the “use” limitation in Section 156(b) would only prevent a patent holder from excluding uses different from those approved by the FDA. *See, e.g.*, H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. at 2672. Indeed, the benefits of patent term extension would be rendered largely worthless if extensions were limited only to the specific

embodiment of the patent that the FDA approved, as it would allow generic drug manufacturers such as Dr. Reddy's simply to change a drug product's salt and then, during the extended term, market – in direct competition with the approved drug product – pharmacological variants embodying the same therapeutic entity that pioneering manufacturers such as Pfizer have themselves studied, invented, and patented.

The statutory scheme further confirms that no such self-defeating construction was intended. As this Court has held, the infringement section of the Hatch-Waxman Act, 35 U.S.C. § 271(e), itself focuses on FDA-approved “uses,” not on “approved products.” Moreover, as this Court has long recognized, the statutory scheme contemplates that the claims of the patent, and not a patentee's commercial embodiment of its invention, define the scope of the right to exclude. The Patent Laws do not contemplate a comparison of the accused composition with an “approved product.” There is no indication at all, much less the necessary “plainly stated” indication, that Congress meant to work such a radical change to patents and to infringement law.

The district court's reasons for holding that Section 156 limits the patentee to patent coverage only to the approved product's approved use are unconvincing. The cited language in *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 38 USPQ2d 1347 (Fed. Cir. 1996), does not resolve whether the “rights derived” from the

patent's extension apply to any "use approved" for the product (as the statute says) or only to the specific approved product itself (as the district court held); indeed, since *Merck* did not purport to define the scope of the rights extended by Section 156, the language quoted by the district court is pure and simple *dicta*. Moreover, the district court also erroneously assumed that, because Section 156(a) imposes "stringent requirements for PTE applicants," this subsection also restricts the scope of rights conferred when a patent term extension is granted by the PTO; nothing in the text supports that assumption. The district court likewise erred in concluding that the term "product," as used in Section 156(b), is "inherent[ly]" limited to "approved products," since Section 156(b) expressly provides that "the term 'product' *includes* an approved product." Additionally, the district court's reliance on policy considerations was itself premised on a misunderstanding of the purposes of the Hatch-Waxman Act, and cannot be squared with the text or history of that Act. Finally, the district court erred both in relying on a section of the MPEP that, like the language of the *Merck* decision, does not resolve the legal question presented here, and in declining to give any interpretive significance to the fact that Congress considered, but declined to pass, a version of the PTR provision that would have limited patent term extensions "to *the product* . . . subject to the regulatory review period *and to the statutory use* for which regulatory review was required." S. 255, 97th Cong., § 155(a)(1) (1981) (emphasis added).

In any event, contrary to the district court, amlodipine maleate is encompassed by the “approved product” whose exclusive rights were extended by Pfizer’s PTR. The “approved product” is a “product” that the FDA has approved; and, under Section 156(f), the term “product” means “the active ingredient of . . . a new drug . . . including any salt or ester of the active ingredient. . . .” 35 U.S.C. § 156(f). The active ingredient of Norvasc® is amlodipine, and it is undisputed that maleate and besylate are both salts of amlodipine. Thus, the “product” that the FDA approved when it approved Norvasc® is amlodipine and “any salt or ester” of amlodipine, which includes both amlodipine maleate and amlodipine besylate.

The FDA has interpreted the statutory term “active ingredient (including any ester or salt of the active ingredient)” in Sections 505(c) and 505(j) of the Federal Food, Drug, and Cosmetic Act, *see* 21 U.S.C. §§ 355(c)(3)(D), 355(j)(5)(D), in exactly this way. For purposes of the data-exclusivity provisions of the Hatch-Waxman Act, the FDA construes “active ingredient” to mean the chemical entity that has therapeutic effect – the “active moiety” – regardless of which salt is associated with the moiety. There is no sound reason to give a different construction to the very same language in Section 156, when both Section 156 and the data-exclusivity provisions were part of the same Act, and when both serve the same purpose of encouraging pharmaceutical innovation.

The district court's holding that the "approved product" in this case is, narrowly, amlodipine besylate, is flawed. That court erroneously read Pfizer's FDA applications as defining the active ingredient in Norvasc® as limited to amlodipine besylate. Not only does that approach improperly apply all available inferences against Pfizer (rather than for Pfizer) on a Rule 12(b)(6) motion, it also improperly allows factual assertions to resolve a legal question.

The district court read this Court's decision in *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 13 USPQ2d 1628 (Fed. Cir. 1990), far too broadly. That decision merely held that a composition not present in a drug before it is administered is not an "active ingredient"; the Court did not hold that each separate salt form is a separate "active ingredient" under Section 156(f). Indeed, if the district court's reading of *Glaxo* was correct, then *Glaxo* would conflict with the D.C. Circuit's decision in *Abbott Labs. v. Young*, 920 F.2d 984, 17 USPQ2d 1027 (D.C. Cir. 1990), with the FDA's interpretation and application of the virtually identical "active ingredient" language in the data-exclusivity provisions of the Hatch-Waxman Act, and with the stated purposes of the Act's PTR provision. The Court should reject any such overbroad reading of *Glaxo*.

ARGUMENT

I. STANDARD OF REVIEW

This Court reviews the grant of a motion to dismiss pursuant to Rule 12(b)(6) under a *de novo* standard, according no deference to the district court's decision and taking all of the facts pleaded in the complaint as true. *See Univ. of W. Va. Bd. of Tr. v. Vanvoorhies*, 278 F.3d 1288, 1295, 61 USPQ2d 1447, 1453 (Fed. Cir. 2002). In addition, review here would be *de novo* in any event because this case centers on an issue of statutory construction, which is a pure question of law. *See Abbott Labs. v. Novopharm Ltd.*, 104 F.3d 1305, 1308, 41 USPQ2d 1535, 1537 (Fed. Cir. 1997).

II. DR. REDDY'S PROPOSED AMLODIPINE MALEATE DRUG PRODUCT INFRINGES THE "RIGHTS DERIVED" FROM PFIZER'S '909 PATENT, AS EXTENDED BY SECTION 156

The question here is whether Dr. Reddy's proposed amlodipine maleate drug product infringes the "rights derived" from Pfizer's '909 patent as extended by Section 156. There is no dispute that Pfizer's '909 patent, as issued, covers this proposed amlodipine maleate drug product. (A173 ("The parties, Pfizer and DRL, agree that the drug product defendants seek to make – amlodipine maleate – is covered by Pfizer's ['909] patent")) Nor is there any dispute that Pfizer took all steps legally necessary under the Hatch-Waxman Act to extend its '909 patent, or that such an extension was granted. (A169) The only issue is whether the

patent term extension granted by the PTO applies to the amlodipine maleate drug product and allows Pfizer to exclude it from the market. It plainly does.

A. Section 156 Extends “The Term Of The Patent” And Thus Allows Pfizer To Exclude The Marketing Of Amlodipine Maleate

The district court here held that the Section 156 extension applies only to the precise product on which the patentee obtained FDA approval, and not to other salts of the same drug that are also within the claims of the patent and that have the same use as the product approved by the FDA. This holding is contrary to the text of the statute. *See Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 756 (1975) (“The starting point in every case involving construction of a statute is the language itself.”).

While having an “approved product” is an eligibility condition for a patent term restoration, subsection (a) of Section 156 does not provide exclusivity only to that particular “approved product.” On the contrary, Section 156(a) uses the broader term “product” (as well as the more limited term “approved product”) and, without qualification, expressly extends “[t]he term of a patent” itself. 35 U.S.C. § 156(a). *Accord*, H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. at 2670 (“The new section provides for *the extension of the normal 17 year term of a . . . patent if a product* which is the subject of the patent is required by Federal law to be approved before it is commercially marketed.”) (emphasis added).

Since the statutory text extends “the term of the” ‘909 patent itself, and not just the protection for one of the products covered by that patent (*e.g.*, amlodipine besylate), then Dr. Reddy’s proposed marketing of amlodipine maleate infringes the ‘909 patent, as extended. Dr. Reddy’s concedes that its proposed amlodipine maleate product is covered by the existing ‘909 patent, and that that patent’s term was extended by the PTR. With these concessions, under the plain terms of Section 156(a), there is unlawful infringement.

B. The Limitation In Section 156(b) Is Inapplicable To Dr. Reddy’s Proposed Marketing Of Amlodipine Maleate

Contrary to the district court’s conclusion, the limitation on the patent extension set forth in subsection (b) of Section 156 does not absolve Dr. Reddy’s of its infringement. The limitation in subsection (b) of Section 156 is not on the scope of what compositions are covered by the patent upon extension. Rather, subsection (b) simply limits “the rights derived from” the patent — including the right to exclude others from making, using, selling, offering to sell, or importing the invention “claim[ed] in the patent” — to any “use approved” for the product.

Specifically, Section 156(b) provides that, “in the case of a patent which claims a product,” the “rights derived” from an extended patent term are limited to “any *use* approved for the product.” 35 U.S.C. § 156(b) (emphasis added). The statutory text does not limit the patent extension to the product approved by the

FDA. Rather, even as limited, the text extends the claims of the patent subject to any “use approved.”

Thus, while Pfizer’s patent term extension is limited by subsection (b) of Section 156, it is limited only insofar as Pfizer would seek to exclude a different “use” than one previously approved by the FDA. But that limitation is no impediment to Pfizer’s infringement claim against Dr. Reddy’s, since Dr. Reddy’s proposed amlodipine maleate product is indicated for exactly the same uses (treatment of hypertension, chronic stable angina, and vasospastic angina) as those for which Norvasc® is itself approved. (*Compare A276 with A722*)

In other words, Section 156(a) extended all of the claims of Pfizer’s ‘909 patent, including the claims of the patent that cover amlodipine maleate, as well as amlodipine besylate (or any other salt of amlodipine for that matter). While the “rights derived” from the ‘909 patent are “limited to any use approved,” Norvasc® is approved for *exactly the same uses* that Dr. Reddy’s proposed amlodipine maleate drug product would have — treatment of hypertension, chronic stable angina, and vasospastic angina. Thus, the Section 156(b) “use” limitation provides Dr. Reddy’s with no safe haven from its clear infringement of Pfizer’s ‘909 patent, as the rights derived from the patent include not only the exclusive right to market Norvasc®, but also the right to exclude other compositions claimed by the ‘909 patent that are indicated for the same uses approved for Norvasc®.

C. Barring Infringement By Dr. Reddy's Amlodipine Maleate Product Promotes The Purposes Of The Hatch-Waxman Act

Barring infringement by Dr. Reddy's proposed amlodipine maleate product best promotes the purposes of the Hatch-Waxman Act. There is no dispute that Pfizer first invented amlodipine and its salts, claimed those products in its '909 patent, and even conducted the clinical trials and testing upon which Dr. Reddy's seeks to rely in its paper NDA. Nor is there any dispute that Dr. Reddy's seeks FDA approval to have amlodipine maleate used for exactly the same uses for which the FDA has already approved amlodipine besylate. In order to serve Hatch-Waxman's purpose of providing meaningful incentives for innovative activities, the patent right must include both the right to practice one embodiment of the invention in Norvasc® (amlodipine besylate) and the right to exclude other embodiments also claimed by the patent (such as Dr. Reddy's proposed amlodipine maleate product) that would have the same uses and thus take market share away from Pfizer's patented invention.

The House Report confirms that Section 156 was intended to protect patent holders in such circumstances. As noted above, that Report indicates that Section 156 was designed to "create a new incentive for increased expenditures for research and development" in pharmaceuticals and related fields, by providing "compensation for the loss of patent term due to government review," which in turn will lead to "increased expenditures for research and development, and

ultimately in more innovative drugs.” H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. at 2648, 2651. That Report further indicates that Congress specifically chose to use in subsection (a) the terminology “[t]he term of a patent which *claims a product*” to describe what was being extended, in order to make clear that, “in the case of a product patent which ‘claims’ a broad genus of compounds, the patent owner could prevent others from making, using or selling *any compound* which is a species of that genus.” H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. at 2670 (emphasis added). In other words, to promote innovation, the statute specifically contemplated that the statutory right to exclude would apply to all salts of a compound claimed by the patent, not just the specific salt approved by the FDA.

The “use” limitation in Section 156(b) is not to the contrary. As the legislative history confirms, from the outset, that limitation was aimed solely at preventing a patent holder from seeking to apply an extended patent to exclude others from marketing a product for uses different than the uses approved by the FDA. *See* H.R. Rep. No. 97-696, at 10 (1982) (“[I]f a chemical is subjected to regulatory review for new drug uses, but is also marketed for other commercial uses, the patent term extension would apply only to the new drug uses for which regulatory review was required.”); *see also* H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. at 2672 (Section 156(b) limits the patent holder’s right to exclude “to any use of the approved product which was approved”). Nothing in the

legislative history suggests that this provision was intended to limit protection to only the specific product approved by the FDA.

On the contrary, so limiting the patent extension would wholly defeat the purposes of Section 156. That provision was designed “to erase the de facto reduction of [a] patent term” (*AbTox*, 122 F.3d at 1029, 43 USPQ2d at 1553) and “to recover a portion of the market exclusivity lost during the lengthy process of development and FDA review” (*Glaxo*, 110 F.3d at 1568, 42 USPQ2d at 1262). Allowing a generic manufacturer such as Dr. Reddy’s to escape the claims of the ‘909 patent by simply changing the salt used in an approved product such as Norvasc® would essentially deprive pioneer drug manufacturers such as Pfizer of the economic benefits of the PTR. Instead of having an additional period of market exclusivity, an approved product such as Norvasc® would face direct competition during the extended term from a variant of the same therapeutic entity that (as here) the pioneer drug manufacturer itself studied, invented, and patented. This is hardly different than having no patent term extension at all. As a consequence, if Section 156 were so construed, the Hatch-Waxman Act would provide little of the incentive for new drug research and development that it was intended to provide. Such a self-defeating construction should be resisted. See *Kokoszka v. Belford*, 417 U.S. 642, 650 (1974) (the court should endeavor to give

the statute “such a construction as will carry into execution the will of the Legislature”) (internal quotation marks omitted).

D. The Statutory Scheme Confirms That Section 156 Is Best Read As Extending Patent Coverage To All Salt Forms Claimed By The Patent And Marketed For The Same Use

That Section 156 extends patent coverage to all salts claimed by the patent and marketed for the same use approved by the FDA is further confirmed by the statutory scheme itself. At every turn, that statutory scheme contemplates patents that claim particular uses, not particular products, and evidences congressional intent to extend patent protection to pioneer drug manufacturers against competition from chemical entities beyond just the approved product itself.

First, “the interplay between section 156 and section 271(e)” (*AbTox*, 122 F.3d at 1029, 43 USPQ2d at 1552-53) confirms that Section 156(b) is an approved “use” limitation, not an “approved product” limitation. Section 271(e), which was added by Section 202 of the Hatch-Waxman Act, legislatively overruled the holding of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 211 USPQ 937 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), and provided that generic drug companies’ pre-application research activities did not constitute infringing “uses” of patented inventions. 35 U.S.C. § 271(e)(1). At the same time, however, Section 271(e) established that infringement by an ANDA or paper NDA turns on the “use” approved by the FDA. *See Warner-Lambert Co. v. Apotex Corp.*, 316

F.3d 1348, 1356, 65 USPQ2d 1481, 1485 (Fed. Cir. 2003) (“The FDA does not grant across-the-board approval to market a drug,” but instead “grants approval to make, use, and sell a drug *for a specific purpose for which that drug has been demonstrated to be safe and efficacious.*”) (emphasis added). Accordingly, interpreting the PTR provision of Section 156(b) as only imposing a “use approved” limitation, and not an “approved product” limitation, creates an appropriate “use” fit between the two sections. *See Eli Lilly*, 496 U.S. at 674 (holding that the Court’s interpretation “appears to create a perfect ‘product’ fit between the two sections” of the Hatch-Waxman Act at issue there). Indeed, the Supreme Court has instructed that the Hatch-Waxman Act should be interpreted to avoid any “disequilibrium” between “front-end” (PTR) patent adjustments and “back-end” (*Roche v. Bolar*) adjustments. 496 U.S. at 672. Since Dr. Reddy’s benefited from the “back end” adjustment by being able to use amlodipine during Pfizer’s patent term in order to develop its amlodipine maleate product, Pfizer’s “complementary” patent term restoration is thus properly understood to extend to that amlodipine product as well. *Id.* at 673.

Second, treating the entire patent, and not some subpart thereof, as being extended by Section 156 – limited only by “use,” and not by “product” – also harmonizes Section 156 with the exclusivity provisions of the Patent Laws. It is axiomatic that the claims of the patent, not the identity of any particular

composition or product covered by the patent, define the right to exclude. *See, e.g., Teleflex, Inc. v. Ficoso N.A. Corp.*, 299 F.3d 1313, 1324, 63 USPQ2d 1374, 1380 (Fed. Cir. 2002) (“[T]he claims define the scope of the right to exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim.”) (quoting *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1248, 48 USPQ2d 1117, 1120 (Fed. Cir. 1998)). Those claims define the “metes and bounds” of the patent’s right to exclude and put the public on notice of what it may not practice. *See, e.g., Int’l Visual Corp. v. Crown Metal Mfg. Co.*, 991 F.2d 768, 774, 26 USPQ2d 1588, 1592 (Fed. Cir. 1993) (Lourie, J., concurring) (quoting *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538, 20 USPQ2d 1456, 1458 (Fed. Cir. 1991)). Yet, if patent term extensions were limited to “the approved product,” as the district court ruled, the infringement inquiry would ask not whether the accused composition is covered by the language of the claims, but whether the accused composition is the same as “the approved product.” That concept is completely foreign to patent-infringement jurisprudence. *See, e.g., ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1578, 221 USPQ 929, 933 (Fed. Cir. 1984) (“Infringement is determined on the basis of the claims, not on the basis of a comparison with the patentee’s commercial embodiment of the claimed invention.”).

The point is well illustrated by the '909 patent itself. None of that patent's claims is drawn specifically to particular salts of amlodipine. Rather, they are written more generally to cover all types of dihydropyridine compounds and their acid addition salts. (A168, col. 30, lines 2-66) There is no textually grounded way to read any claim of that patent as covering *only* amlodipine besylate.

The district court's interpretation of Section 156 thus requires the conclusion that the Hatch-Waxman Act created a new patent and infringement regime where the claims of the patent itself are irrelevant. Such a "fundamental departure from traditional rules" cannot be justified absent a "plainly stated" command from Congress. *Kremer v. Chem. Constr. Corp.*, 456 U.S. 461, 485 (1982). *See also United States v. U.S. Gypsum Co.*, 438 U.S. 422, 437 (1978) ("Congress will be presumed to have legislated against the background of our traditional legal concepts . . . and 'absence of contrary direction [will] be taken as satisfaction with widely accepted definitions, not as a departure from them.'") (quoting *Morrisette v. United States*, 342 U.S. 246, 263 (1952)) (bracketed language added in *U.S. Gypsum*); *Koyo Seiko Co. v. United States*, 36 F.3d 1565, 1572 (Fed. Cir. 1994) (similar); *Gibraltar Fin. Corp. v. United States*, 825 F.2d 1568, 1575 (Fed. Cir. 1987) (similar).

No such unambiguous command can be found anywhere in the Hatch-Waxman Act. The text specifically talks both of extending the term of the patent

and the “rights derived” from the patent. The limitation in subsection (b) is on “uses,” consistent with FDA practice and longstanding patent tradition and doctrine. And the House Report specifically disclaimed that Section 156(b) was to work a fundamental change to patent law. *See* H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. at 2672 (aside from the limitation of subsection (b), “all provisions of the patent law apply to the patent during the period of extension”). In these circumstances, the statute cannot properly be read to work the radical change that the district court’s approach requires.

E. The District Court’s Stated Reasons For Limiting Pfizer’s PTR Only To The “Approved Product” Are Unsound

The district court offered several reasons – many of which it characterized as “implicit” in the case law or “inherent” in the statute – to support its judgment that “the only product eligible for the benefit of PTE is amlodipine besylate, the active ingredient in Norvasc[®].” (A22) None of these reasons is persuasive.

First, citing *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 38 USPQ2d 1347 (Fed. Cir. 1996), the district court held that it was “implicit” in certain identified language in that opinion “that only one drug product per patent is allowed an extension under the Hatch-Waxman Act.” (A8-9) That holding is not sound.

Merck was not an infringement suit; it was a dispute between patent holders and the PTO. *Merck* involved the interplay between two statutes, the Hatch-Waxman Act and the Uruguay Round Agreement Act (URAA), the latter of which

amended Section 154 of the Patent Laws “to harmonize the term provision of United States patent law with that of our leading trading partners which grant a patent term of 20 years from the date of filing of the patent application” (*Merck*, 80 F.3d at 1547, 38 USPQ2d at 1349), and therefore allowed certain patents in force or applied for prior to the effective date of the URAA “to keep or to enjoy the 17-year term from issuance of the patent or a 20-year from filing term, whichever is longer.” *Merck*, 80 F.3d at 1548, 38 USPQ2d at 1350. The question in *Merck* was whether a patent that was in force on the effective date of the URAA *only because* it had obtained an initial Section 156 extension could avail itself of a second Section 156 patent term extension on its newly recalculated term. This Court held that such a patent could not get a second Section 156 extension. *Merck*, 80 F.3d at 1552, 38 USPQ2d at 1354.

Although the district court found determinative *Merck*’s statement that “the restoration period of the patent does not extend to all products protected by the patent but only to the product on which the extension was based” (*id.* at 1547, 38 USPQ2d at 1349), this sentence is in fact not conclusive of the issue in this case. *Merck*’s statement that the restoration period extends “only to the product on which the extension was based” is naturally understood to mean only that eligibility for a patent term extension is determined by reference to a single product (*see* 35 U.S.C. § 156(a)(4), (5)), and that the length of the restored term is

measured by reference to the regulatory review period for that product. Moreover, *Merck's* observation that the restoration period “does not extend to all products protected by the patent” is fully consistent with the understanding that the patentee’s right to exclude nonetheless extends to any product that is put to an FDA-approved use. In short, the sentence in *Merck* can be read just as easily to extend the “rights derived” from the patent’s extension to the “use approved” for the product (as the statute says) as it can to apply them only to the “approved product” itself (as the district court held).

In all events, this language in the *Merck* opinion is clearly *dicta*. A statement in a judicial opinion is *dicta* and not binding where it is “unnecessary to the Court’s decision.” *Kastigar v. United States*, 406 U.S. 441, 455 (1972); *see also Smith v. Orr*, 855 F.2d 1544, 1550 (Fed. Cir. 1988) (“[I]t is well established that a general expression in an opinion, which expression is not essential to the disposition of the case, does not control a judgment in a subsequent proceeding.”). The decision in *Merck* plainly did not depend on whether Section 156(b)(1) is interpreted as having an “approved product” limitation or only a “use” limitation. Indeed, the location of the cited language in Section “I” of the opinion, which contains an introductory and cursory summary of the patent term provisions of the Hatch-Waxman Act, confirms that the sentence was not viewed as critical to the Court’s reasoning. Accordingly, it should not be controlling here.

Second, the district court assumed that Section 156(a) “takes away” certain patent rights as a condition of the PTR and, on that assumption, determined that reading subsection (b) as a provision that “gives back” what subsection (a) took away would contravene the “plain meaning of the statute.” (A10) But the district court was wrong to assume that Section 156(a) “takes away” any rights. Rather, as demonstrated above, although it imposes rigorous eligibility conditions, subsection (a) broadly extends “[t]he term of a patent which claims a product,” without limitation. It thus “takes away” nothing. It is Section 156(b) that “takes away,” and its *only* limitation is a “use approved” limitation, not an “approved product” limitation.

Third, stating that “inherent in the wording of the subsection is that ‘product’ means ‘approved product’” (A11), the district court concluded that there is an “inherent,” even though unexpressed, limitation of Section 156(b) to “approved products.” That conclusion is both incorrect and irrelevant.

The conclusion that Section 156(b) is limited to the “approved product” is contrary to the language of Section 156(b). That provision states in its last sentence that, for purposes of that subsection, “the term ‘product’ *includes* an approved product.” (Emphasis added.) The use of the word “includes” means that there are other products includable beyond the “approved product” enumerated.

See United States v. New York Tel. Co., 434 U.S. 159, 169 (1977) (a phrase

introduced by the words “to include” does “not restrict or purport to exhaustively enumerate”); *Fed. Land Bank of St. Paul v. Bismarck Lumber Co.*, 314 U.S. 95, 100 (1941) (“the term ‘including’ is not one of all-embracing definition, but connotes simply an illustrative application of the general principle”); *see generally* 2A Norman J. Singer, *Sutherland Statutory Construction* § 47.07, at 231 (6th ed. 2000).

If Section 156(b) were limited to the “approved product,” the last sentence of subsection (b) would have employed the word “means,” as it did elsewhere in the statute, such as when it provided that “the term ‘product’ means . . . [a] drug product.” 35 U.S.C. § 156(f)(1); *see also id.* § 156(f)(2)-(3), (6)-(8) (each defining what a term used in the Act “means”). This deliberate “distinction in th[e] use” of “[t]he terms ‘means’ and ‘includes’” shows that “these words [have] a different sense.” *Helvering v. Morgan’s, Inc.*, 293 U.S. 121, 125 n.1 (1934) (“[W]here ‘means’ is employed, the term and its definition are to be interchangeable equivalents,” whereas “the verb ‘includes’ imports a general class, some of whose particular instances are those specified in the definition.”); *see also New York Tel. Co.*, 434 U.S. at 169 n.15.

Thus, contrary to the district court’s reasoning, “the term ‘product,’” as used in subsection (b), is broader than *just* an “approved product,” and includes other amlodipine salts covered by the claims of the patent; indeed, this Court has already

held that the term “product” as used in Section 156 does not mean the same thing as “approved product.” See *Fisons plc v. Quigg*, 876 F.2d 99, 101, 10 USPQ2d 1869, 1870 (Fed. Cir. 1989). That understanding is confirmed by Section 156(a)’s correlative distinction between the “product(s)” covered by the claims of a patent and the “approved product” referred to in paragraphs (4) and (5) of that subsection, as well as by Section 156(b)(3)’s distinction between “the approved product” (35 U.S.C. § 156(b)(3)(A)), and “the product” (35 U.S.C. § 156(b)(3)(B)).

The district court’s conclusion that Section 156(b)(1) refers to the “approved product” is in any event irrelevant. As explained above, the limitation on the patentee’s right to exclude, imposed by Section 156(b), is determined by reference to the “use approved for,” not the composition of, the “product.” Even if the word “product” in Section 156(b)(1) meant only “approved product,” the statutory right to exclude would still literally and properly extend to all “uses” approved for that approved product, not just to the “approved product” itself. Therefore, Pfizer still would be entitled to enforce its patent rights during the extension period to exclude a competitor, such as Dr. Reddy’s, seeking to market a product claimed by the patent having the same use as Pfizer’s approved product.

Fourth, the district court erroneously endorsed Dr. Reddy’s argument that the “use” limitation “was included ‘to effectuate its goal to compensate innovators only for what was actually lost in the regulatory review period, that is the right to

sell their product for use approved by the government.” (A11, quoting A1075)

This conclusion is also unsound.

To begin with, the language quoted by the district court was attorney argument in Dr. Reddy’s brief — and not congressional source material. Moreover, while preliminary versions of the bill would have limited “[t]he rights derived from any claim of any patent extended” to “the scope of such claim which relates to the product subject to regulatory review” and “to the uses of the product which may be regulated by the” FD&C Act, H.R. Rep. No. 97-696, at 15 (1982); *see also id.* at 10 (summarizing same); S. 255, 97th Cong., § 155(a)(1) (1981) (similar), these bills did *not* pass. Thus, they provide no proper basis for inferring that the statute that *was* in fact enacted somehow means the same thing as those earlier, differently worded, proposals. *See Chickasaw Nation v. United States*, 534 U.S. 84, 91 (2001) (“We ordinarily will not assume that Congress intended to enact statutory language that it has earlier discarded in favor of other language.” (internal quotation marks omitted)); *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987) (“Few principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language.” (internal quotation marks omitted)).

Furthermore, interpreting the Hatch-Waxman Act to preserve the patentee's right to exclude products claimed by the patent that are for the same "use approved" by the FDA is much more consistent with the goal of compensating patentees "for what was actually lost in the regulatory review period." During the pendency of an NDA for a patented new drug, the patentee is prevented from marketing as a drug *any* embodiments of its invention (not just the one submitted for FDA approval), thereby "actually los[ing]" a period of market exclusivity for *all* such embodiments. By contrast, to the extent that an invention can be marketed for non-regulated commercial uses at the beginning of the patent term, the patentee "actually los[es]" nothing with respect to such non-pharmacological uses during the pendency of the regulatory approval process. During that time, the patentee is free to market its invention for those non-regulated uses, and it can exclude others from marketing any patented product for such non-regulated uses. It is for this reason that the Hatch-Waxman Act makes the approved "use" of the product the touchstone for the applicability of patent rights during the extension term. Accordingly, from the perspective of compensation, it is more accurate to limit the patentee's rights during the extension term only to the "use" that required FDA approval.

Fifth, for similar reasons, the district court erroneously concluded that reading Section 156(b) as only imposing a "use" limitation "contravenes the policy

behind the statute.” (A12) The supposed “policy” identified by the district court was the policy of “one extension, per product, per patent,” which in turn was based on the theory that the Hatch-Waxman Act required patent owners to “choose one product and one product alone from the multiple terms in its patent” for extension.

(A12) But no such policy can properly be gleaned from the language or history of the Hatch-Waxman Act.

There is certainly a “one extension per patent” policy on the face of the statute (*see* 35 U.S.C. § 156(a)(2)), but nothing that suggests that the policy is one extension per patent *limited to* one particular approved product covered by the patent. Moreover, the limitation set forth in Section 156(b) is based on the “use” approved for the product (as defined by Section 156(f)), not on the approved product itself.

Indeed, all of the discernible policies of the patent term extension provision are to grant patent extensions to protect the patent holder’s exclusive “use” rights for an appropriately extended period of time and thereby to create more incentives for pioneer pharmaceutical manufacturers (like Pfizer) to invest in research and development. Those policies would be severely undermined by reading the Act so narrowly as to allow a generic manufacturer (like Dr. Reddy’s) to simply change the salt in a pioneer drug product and then market that product for exactly the same uses as the pioneer drug manufacturer’s approved product.

Sixth, the district court also erred in relying on language contained in Section 2750 of the MPEP that states: “[I]f the patent claims other products in addition to the approved product, the exclusive patent rights to the additional products expire with the original expiration date of the patent.” (A13) Like the language in *Merck*, this language does not address whether the right to exclude that does not expire continues to apply to any patented product with the same “use” as the approved product, or just to the “approved product” itself. In any event, the MPEP is nothing more than an instruction manual for patent examiners who make no determinations, when evaluating eligibility for patent restoration, regarding the scope of patent extensions as part of their charge under Section 156(a); any persuasive value that the MPEP might otherwise have is therefore exceedingly limited here. Furthermore, by its own terms, the MPEP lacks the force of law (it does not even bind the PTO, *see Litton Sys., Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1439, 221 USPQ 97, 106 (Fed. Cir. 1984)), and it therefore is not entitled to deference by the courts, even in the event of statutory ambiguity. *See Merck*, 80 F.3d at 1549-50, 38 USPQ2d at 1351 (even PTO determinations receive no deference, except as to procedures within the PTO). Finally, as this Court has of course steadfastly recognized, the MPEP must be disregarded when, as here, it contradicts the Patent Laws. *See, e.g., In re Recreative Techs. Corp.*, 83 F.3d 1394, 1397-98, 38 USPQ2d 1776, 1778 (Fed. Cir. 1996).

Seventh, and finally, the district court erred in declining to give any interpretive significance to the fact that an earlier version of the Hatch-Waxman Act contained a limitation of the rights under a PTR to both “approved use” and “approved product.” (A13-14) This legislative history confirms that the statute as enacted does *not* limit the PTR to the “approved product” itself, but rather to the “uses approved for the product” – as it was only the “uses” language that survived the enactment process. That Congress considered, but chose not to enact, a limitation of PTR rights to both “approved uses” *and* “approved product” is powerful evidence that Section 156(b) as written only limits the “rights derived” under a PTR to the “use approved” for the regulated product, not to the specific “approved product” itself.

III. THE APPROVED PRODUCT INCLUDES AMLODIPINE MALEATE

The district court also erred in holding that, as a matter of law, the “approved product” here does not include amlodipine maleate. It surely does.

A. The “Approved Product” Includes “Any Salt” Of Amlodipine

Section 156(a) defines “approved product” by reference to Section 156(a)(4) and (5): A patent is eligible for a PTR if it claims a product (Section 156(a), first clause), and, *inter alia*, if the product “has been subject to a regulatory review period before its commercial marketing or use” (Section 156(a)(4)), and if “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” (Section 156(a)(5)(A)). Thus, the “approved product” is a “product,” as defined in Section 156(f), that has undergone the requisite regulatory review. *See Fisons plc*, 876 F.2d at 100, 10 USPQ2d at 1870 (“[a]pplying the definition of ‘product’ in section 156(f) to the extension requirement of section 156(a)(5)(A)”). So understood, Pfizer’s “approved product” – *i.e.*, Norvasc® – encompasses amlodipine maleate.

Section 156(f)(2) defines “product” 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.” 35 U.S.C. § 156(f)(2). As this Court has made clear, an “active ingredient” under Section 156(f)(2) is one that has therapeutic activity and is “present in the drug product when administered.” *Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756, 759 n.3, 42 USPQ2d 1220, 1223 n.3 (Fed. Cir. 1997). The amlodipine ion in both Norvasc® and amlodipine maleate satisfies this test: As the parties’ respective experts agreed, the amlodipine ion has therapeutic activity in the body and is present in the drug when administered. (A625-26; A628; A1113-14; A1115; A1118) Moreover, amlodipine maleate and amlodipine besylate are both salts containing the amlodipine ion; and the salt counterions in amlodipine maleate and amlodipine besylate do not

themselves have therapeutic activity. (A622; A624-25) Rather, each salt form incorporates that “active ingredient.” *See also* 21 C.F.R. § 60.3(b)(10) (“*Human drug product* means the active ingredient of a new drug or human biologic product (as those terms are used in the [FD&C] 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.”). Indeed, Section 156(f)(2)(A) by its terms states that the “product” legally encompasses “any salt” forms of the “active ingredient” as well. Accordingly, both amlodipine maleate and amlodipine besylate are encompassed by the “approved product.”

This construction of Section 156 is compelled by the FDA’s construction and application of 21 U.S.C. §§ 355(c)(3)(D) and 355(j)(5)(D), which are parallel provisions contained in Title I of the Hatch-Waxman Act. Section 156(f)(2) expressly links the two titles together by instructing that certain definitions in Section 156, including much of the language at issue here, carry the same meaning “as those terms are used in the Federal Food, Drug, and Cosmetic Act.” And, following the mandate of the D.C. Circuit in *Abbott Labs. v. Young*, 920 F.2d 984, 985-89, 17 USPQ2d 1027, 1028-30 (D.C. Cir. 1990), the FDA determined that “the term ‘active ingredient’ as used in the phrase ‘active ingredient (including any salt or ester of the active ingredient)’ means active moiety.” *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg.

50,338, 50,358 (Oct. 3, 1994). For these purposes, the FDA defines “active moiety” as “the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . responsible for the physiological or pharmacological action of the drug substance.” 21 C.F.R. § 314.108(a). Under this definition, there is no question that, in applying the data-exclusivity provisions of the Hatch-Waxman Act – which, like Section 156, are intended to encourage pharmaceutical innovation (*see, e.g., Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1333, 6 USPQ2d 1565, 1566 (D.C. Cir. 1988)) – the FDA would prohibit the approval during the exclusivity term of any product containing amlodipine or any of its salts, including amlodipine maleate.

The FDA’s determination concerning the “regulatory review period” for Norvasc® further confirms this conclusion and demonstrates that the “approved product” includes amlodipine maleate as well as amlodipine besylate. Under Section 156, the FDA is charged with computing the “regulatory review period for the approved product.” *See* 35 U.S.C. § 156(c), (d), & (g). Section 156(g)(1)(B) defines the “regulatory review period” for a new drug as including the period beginning on the date when an Investigational New Drug Application (IND) becomes effective “for the approved product” and ending on the date when an NDA is submitted for that drug. *See id.* § 156(g)(1)(B)(i). Here, the FDA computed that the regulatory review period for the ‘909 patent began on July 8,

1983, when Pfizer's IND for amlodipine *maleate* became effective, included the time of testing and trials of amlodipine, amlodipine maleate, and amlodipine besylate, and ended when Pfizer's NDA for Norvasc® was approved. (A1340; *see* A1296-97) This administrative determination, which deserves judicial respect in accordance with the congressional delegation to the FDA, demonstrates that the "approved product" encompasses both amlodipine maleate *and* amlodipine besylate.

B. The District Court's Contrary Reasoning Is Unsound

The district court, however, held as a matter of law that the "active ingredient" in Norvasc®, and thus the "approved product" to which the PTR purportedly was limited, is amlodipine *besylate*. In so holding, the district court made much of Dr. Reddy's claim that Pfizer had told the PTO that the active ingredient in Norvasc® is amlodipine besylate. (A18-20) The district court further viewed this legal conclusion as compelled by *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 13 USPQ2d 1628 (Fed. Cir. 1990), which, according to the district court, "explicitly rejected the argument offered by the [PTO Commissioner] that active ingredient . . . was synonymous with active moiety." (A17) The district court's reasoning is unsound.

First, the district court's reliance on selected statements made by Pfizer to the FDA and to the PTO was improper. On a Rule 12(b)(6) motion, "[d]isputed

issues are construed favorably to the complainant, and all reasonable inferences are drawn in favor of the complainant.” *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 988 F.2d 1157, 1161, 26 USPQ2d 1038, 1041 (Fed. Cir. 1993) (citing *United States v. Mississippi*, 380 U.S. 128, 143 (1965)). Yet, in placing controlling weight on selected Pfizer statements, the district court improperly ignored many other statements in the PTR application and elsewhere that refer to “amlodipine” itself as the “active ingredient” of Norvasc®.

For example, when Pfizer in its PTR application described “the activities undertaken during the applicable regulatory review period with respect to the approved product” (as required by Section 156(d)(1)(D)) and the “significant activities” “during the applicable regulatory review period with respect to the approved product (as required by 37 C.F.R. § 1.740(11)), Pfizer provided the PTO with a table entitled “Brief Description of Representative Significant Activities During the Regulatory Review Period for *Amlodipine*.” (A1302, emphasis added) The accompanying table – which sets forth 29 pages of studies on amlodipine, amlodipine maleate, and amlodipine besylate – contains no fewer than 63 references to “amlodipine.” (A1302-30) So too, Pfizer’s PTR application was required to include “[a] statement that the patent claims the approved product” and to show how the claims “read on” “[t]he approved product.” 37 C.F.R. § 1.740(9).

And, here too, Pfizer identified “amlodipine” as the “approved product” at least 14 times. (A1288-92)

All of this demonstrates, as Pfizer’s expert explained in his declaration, that even Pfizer’s references to “amlodipine besylate” necessarily refer to the amlodipine molecule itself, and the ion form of amlodipine. (A625-26) Indeed, this understanding is confirmed by Dr. Reddy’s *own* representations on its Internet web page, which define the amlodipine maleate salt as comprising the amlodipine molecule. (A777) On a Rule 12(b)(6) motion, the district court should not have selectively relied upon certain statements made by Pfizer, when the totality of the record demonstrates that those statements actually support Pfizer’s submission that the amlodipine ion, not just amlodipine besylate, is the active ingredient in Norvasc®.

Perhaps more critically, the question whether amlodipine maleate and amlodipine besylate are separate “active ingredient[s]” should be a legal question not subject to resolution by reference to Pfizer’s representations. It is uncontroverted, and, indeed, incontrovertible, that maleate and besylate are salts of amlodipine. For purposes of Section 156, the only question is whether those salts can themselves be separate “active ingredient[s].” That legal question is for a court to decide, regardless of statements allegedly made about the matter by Pfizer.

Second, the district court's treatment of *Glaxo* was overbroad. The case should not be read to render each salt of a single ion with therapeutic activity to be a separate "active ingredient" within the meaning of Section 156(f).

At issue in *Glaxo* was whether cefuroxime axetil, an ester of cefuroxime contained in Glaxo's antibiotic Ceftin®, could be the "first . . . permitted product" under Section 156(a)(5)(A), since the FDA had previously approved two products containing salts of cefuroxime. 894 F.2d at 393, 13 USPQ2d at 1629. The PTO Commissioner contended that Ceftin® was not entitled to a Section 156 extension, because the ester was converted, *in vivo*, into the same "active moiety," cefuroxime, as the previously approved products. *Id.* at 394, 13 USPQ2d at 1629. In so contending, the Commissioner conceded that this "active moiety" was "*not present in Ceftin Tablets.*" *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224, 1227 n.7, 10 USPQ2d 1100, 1103 n.7 (E.D. Va. 1989) (emphasis added). The district court in *Glaxo* ruled that, since "Cefuroxime [acid] itself is not present at all in Ceftin Tablets; it is therefore not an 'ingredient.'" *Id.* at 1227, 10 USPQ2d at 1103. This Court affirmed, endorsing the district court's opinion as "properly appl[ying] the operative terms of the Act," and holding that the "plain language" of the statute defeated the claim that an entity not present in the drug was an "active ingredient." 894 F.2d at 393, 395-97, 13 USPQ2d at 1628, 1630-32.

Glaxo is thus entirely distinguishable. Unlike *Glaxo*, this case concerns the scope of claims of an extended patent, not eligibility for patent term restoration. Moreover, unlike *Glaxo*, this case does not involve a claim that a composition not present in a drug is an “active ingredient.” Here, there is no dispute that the amlodipine ion *is* present in Norvasc®. (A619-29) It thus can be, and is, an “active ingredient.” Indeed, since maleate and besylate are both salts of amlodipine, *Glaxo*’s “plain language” reasoning (894 F.2d at 396, 13 USPQ2d at 1631) counsels that amlodipine be treated as the “active ingredient” since, as noted above, Section 156(f) on its face distinguishes between “the active ingredient” and “any salt or ester” of the “active ingredient.” 35 U.S.C. § 156(f)(1).

The district court’s contrary construction of Section 156(f) and *Glaxo* is not only wrong, it is also in tension with the D.C. Circuit’s later decision in *Abbott Labs.* and with how the FDA construes and applies the “active ingredient” language. *Abbott Labs.* held that adopting a construction of such “active ingredient” language like that adopted by the district court here “fails to serve any conceivable statutory purpose”; and that such a “farfetched” construction “produc[es] . . . a windfall depending on an accident of chemical nomenclature.” 920 F.2d at 989, 17 USPQ2d at 1031. Similarly, as noted above, for these purposes, the FDA has construed the “active ingredient” language to refer to the “active moiety,” which it in turn has defined as the “ion . . . responsible for the

physiological or pharmacological action of the drug substance” excluding its salts. 21 C.F.R. § 314.108(a). There is no statutory basis for construing the “active ingredient” in Section 156(f)(2) differently than the FDA and the D.C. Circuit have construed it in 21 U.S.C. § 355(j)(5)(D)(i) & (v). *See, e.g., Communications Workers of Am. v. Beck*, 487 U.S. 735, 754 (1988) (“[O]nly the most compelling evidence” would demonstrate “that Congress intended the nearly identical language of these two provisions to have different meanings.”). The Court should reject any such overbroad construction of *Glaxo*.

Indeed, if the district court’s interpretation of Section 156(b) as containing an “approved product” limitation, and not a “use” limitation, were to control, that would make it all the more critical that the “active ingredient” language in Section 156(f)(2)(A) be construed consistently with 21 U.S.C. §§ 355(c)(3)(D) and 355(j)(5)(D) to apply to any combination of a salt with a therapeutic entity like amlodipine. As noted above, the legislative purpose of Section 156 was to extend pioneer drug manufacturers’ market exclusivity in order to increase the incentives for innovation; Congress recognized that “[l]esser profits might result in less research on new drugs.” *Glaxo*, 894 F.2d at 396, 13 USPQ2d at 1631. Reading Section 156(b) as only imposing a “use” restriction is consistent with that goal of giving pioneering drug manufacturers a meaningful extension of their exclusionary rights. Similarly, Section 156(f)(2)(A)’s definition of “drug product” should be

read to encompass the “active moiety” and its various salts and esters; this conclusion would have the similar effect of creating a PTR having meaningful exclusionary rights. But in no event should both Section 156(b) *and* Section 156(f)(2)(A) be read so restrictively that a generic manufacturer (like Dr. Reddy’s) can successfully pirate a product invented, tested, and patented by a pioneer drug manufacturer (like Pfizer) and use it to compete with a product that is distinguishable only by its use of a different salt. *See Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1577, 38 USPQ2d 1705, 1712-13 (Fed. Cir. 1996) (recognizing that, in the context of the Process Patent Amendments Act, 35 U.S.C. § 271(g), a product’s “conversion to a salt [or an] ester” is “a minor chemical conversion,” not a “material change”). To do so would render the PTR provision of the Hatch-Waxman Act virtually valueless.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

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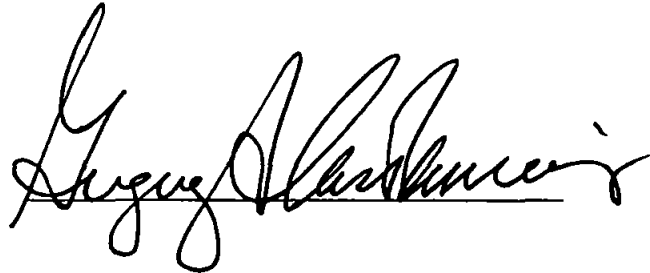
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CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of March, 2003, two bound copies of the foregoing BRIEF FOR PLAINTIFF-APPELLANT PFIZER INC. were caused to be served via Federal Express, to:

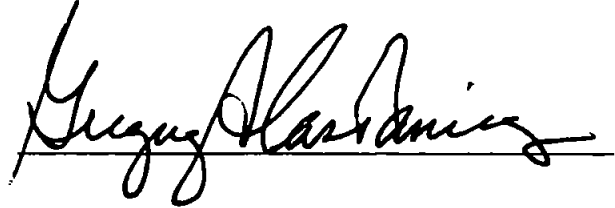
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A handwritten signature in black ink, appearing to read "Gregory A. Kamin", written over a horizontal line.

CERTIFICATE OF COMPLIANCE

In accordance with Federal Rule of Appellate Procedure 32(a)(7)(B) & (C), I certify that this brief complies with the type-volume limitation and contains 13,752 words. In preparing this certificate, I have relied on the word count of the word processing system used to prepare this brief.



Gregory A. Hartman