No. 2009-1362

In the
United States Court of Appeals
for the Federal Circuit

ORTHO-MCNEIL PHARMACEUTICAL, INC.,
and ORTHO-MCNEIL, INC.,

Plaintiffs-Appellees,

and

DAIICHI SANKYO CO., LTD.,

Plaintiff-Appellee,

v.

LUPIN PHARMACEUTICALS, INC.
and LUPIN LTD.,

Defendants-Appellants.

Appeal from the United States District Court for the District of New Jersey
in case no. 06-CV-4999, Chief Judge Garrett E. Brown, Jr.

PETITION FOR REHEARING *EN BANC* OF DEFENDANTS-APPELLANTS LUPIN PHARMACEUTICALS, INC. AND LUPIN LTD.

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CERTIFICATE OF INTEREST

Counsel for Defendants-Appellants Lupin Pharmaceuticals, Inc. and Lupin Ltd. certifies the following:

1. The full name of every party or amicus represented by me is:

Lupin Pharmaceuticals, Inc. and Lupin Ltd.

2. The name of the real parties in interest represented by me is:

Lupin Pharmaceuticals, Inc. and Lupin Ltd.

3. All parent 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:

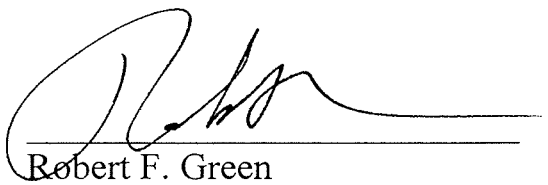
Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Ltd. Lupin Ltd. has no parent corporation, and no publicly held company owns 10 percent or more of Lupin Ltd.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

LEYDIG, VOIT & MAYER, LTD.
Robert F. Green
Christopher T. Griffith
Saumil H. Mehta

STERNS & WEINROTH
Karen A. Confoy

Dated: June 8, 2010



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Lupin Ltd.

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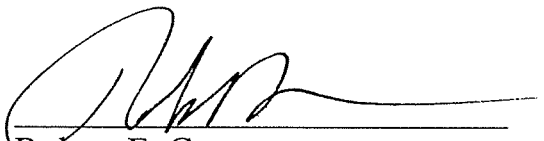
STATEMENT OF COUNSEL UNDER RULE 35(b)

Based on my professional judgment, I believe this appeal requires an answer to the following precedent-setting question of exceptional importance:

Whether an enantiomer of a previously approved racemate qualifies as a newly approved *active ingredient* for purposes of eligibility for a patent term extension under the provisions of 35 U.S.C. § 156, even though such an enantiomer of a previously approved racemate has been determined *not* to qualify as a newly approved *active ingredient* for purposes of eligibility for five years of FDA new product exclusivity in accordance with 21 U.S.C. §§ 355(c)(3)(E)(ii) and 355(j)(5)(F)(ii), and such determination has been made by the U.S. Food and Drug Administration ("FDA"), interpreting the same term, "active ingredient," as used in a statutory provisions enacted as part of the same legislation, the "Hatch-Waxman Act."



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Attorney of Record for
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and Lupin Ltd.

INTRODUCTION

U.S. Patent No. 5,053,407 ("the '407 patent") was granted a patent term extension by the U.S. Patent and Trademark Office ("USPTO") based upon the regulatory delay associated with the FDA approval of LEVAQUIN®, which contains levofloxacin as the active ingredient. But rather than being a newly approved active ingredient, levofloxacin was present as an active ingredient in a previously-FDA-approved product, FLOXIN®.

FLOXIN® contained ofloxacin, a racemate comprised of 50% levofloxacin (S(-)-ofloxacin) and 50% R(+)-ofloxacin. *A17, A18, A917, A1170, A1193, A1194*, *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.,* 348 F. Supp. 2d 713, 720-21 (N.D.W.V. 2004), *aff'd,* 161 Fed. Appx. 944 (Fed. Cir. 2005). Despite the prior marketing of levofloxacin in FLOXIN®, the FDA decided to consider levofloxacin a new active ingredient for patent term extension purposes under 35 U.S.C. § 156(a), and the PTO granted the extension. *A44, A1888*. The patent term extension, however, is invalid because the FDA approval of LEVAQUIN® was not the "first permitted commercial marketing" of levofloxacin as an active ingredient.

The district court and the panel upheld the FDA and PTO decisions, based on the "long-standing term-extension policy of the FDA and the PTO" (*Slip op. at 7; See also A26*), but apparently without considering whether this policy is an

abuse of discretion. The FDA and PTO abused their discretion when they applied two conflicting interpretations to the same words—"active ingredient"—in the same legislation—the "Hatch-Waxman Act."[1] Thus, the district court and the panel erred in failing to consider the important legal issue: what the term "active ingredient" means and how it should be applied to enantiomers. The Court should grant this petition for rehearing *en banc* to adopt and apply a consistent definition of "active ingredient" and to reverse the district court's determination that the patent term extension was properly based on the approval of LEVAQUIN®, which contained the previously approved enantiomer, levofloxacin, as its active ingredient.

ARGUMENT

This case turns on statutory construction and whether the FDA and PTO have construed the relevant statutory provisions correctly and consistently. When the FDA and PTO base their decisions on an erroneous interpretation of the law, they have abused their discretion. *See In re Gartside*, 203 F.3d 1305, 1315-16 (Fed. Cir. 2000). Contrary to the panel's opinion, whether the agencies have applied their constructions for many years is not important. A long-standing but incorrect agency statutory interpretation should still be remedied by the court. *See*

[1] The "Hatch-Waxman Act" is formally known as the "Drug Price Competition and Patent Term Restoration Act of 1984."

In re McDaniel, 293 F.3d 1379, 1385 (Fed. Cir. 2002) ("deference is not appropriate where the agency's interpretation is 'plainly erroneous or inconsistent with the regulation.' "); *see also Demahy v. Wyeth Inc.*, 2008 WL 4758615, at *1, *11 (E.D. La. Oct. 27, 2008) (FDA's inconsistent interpretation of its own unambiguous regulation is only entitled to deference to the extent that it has the "power to persuade").

The FDA apparently considers a single enantiomer of a previously-marketed racemic mixture of enantiomers to be a new "active ingredient" for determining patent term extension eligibility under 35 U.S.C. § 156(a), but considers the same single enantiomer *not* to be a new "active ingredient" for determining new product exclusivity under 21 U.S.C. §§ 355(c)(3)(E)(ii) and 355(j)(5)(F)(ii). This inconsistent application defies both logic and proper rules of statutory construction.

A. The FDA Must Apply a Consistent Definition of "Active Ingredient" in the Patent Term Extension Provisions of 35 U.S.C. § 156 and in the New Product Exclusivity Provisions of 21 U.S.C. § 355

The term "active ingredient" should be considered to have the same meaning when it appears in the patent term extension provisions of the Hatch-Waxman Act, codified at 35 U.S.C. § 156, and in the new product exclusivity provisions of the Hatch-Waxman Act, codified at 21 U.S.C. §§ 355(c)(3)(E)(ii) and 355(j)(5)(F)(ii). When the same term appears in multiple locations in the same Congressional Act, it is generally considered to have the same meaning each time. *See*)*Voracek v.*

Nicholson, 421 F.3d 1299, 1304 (Fed. Cir. 2005 ("identical words used in different parts of the same act are intended to have the same meaning" under the "normal rule of statutory construction") (*citing Gustafson v. Alloyd Co.*, 513 U.S. 561, 570 (1995), *quoting Dep't of Revenue of Or. v. ACF Indus., Inc.*, 510 U.S. 332, 342 (1994)).

This Court has applied the principle to a similar situation in *Pfizer, Inc. v. Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361, 1366 (Fed. Cir. 2004). *While deciding the meaning of the term "active ingredient" in the context of determining the proper scope of a patent term extension under Section 156(f)*, this Court turned to the FDA regulation that relates to the five year Hatch-Waxman exclusivity period for "new" active ingredients:

> As we observed, 35 U.S.C. § 156(f) defines the drug product as including 'any salt or ester of the active ingredient.' *See Abbott Laboratories, Inc. v. Young,* 920 F.2d 984, 985-89 (D.C. Cir. 1990). The FDA ruled 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 (F.D.A. Oct. 3, 1994). The FDA has defined '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).

Hence, this Court has specifically relied upon the FDA's regulations relating to *new product exclusivities* to construe the same term "active ingredient" as used

in the *patent term extension* provisions of § 156(f)(2). This indicates the Court understands that "active ingredient" is defined the same in both provisions. Accordingly, the term "active ingredient" should be construed to have the same meaning when it appears in the patent term extension provisions of the Hatch-Waxman Act, codified at 35 U.S.C. § 156(a), and in the new product exclusivity provisions of the Hatch-Waxman Act, codified at 21 U.S.C. §§ 355(c)(3)(E)(ii) and 355(j)(5)(F)(ii).

Following the logic of the Court's analysis in *Pfizer*, "active ingredient" has the same meaning for patent term extensions as for new product exclusivities, so the FDA must be incorrect when it considers "active ingredient" to have different meanings in the two provisions.

A decade ago the FDA formalized its position that a single enantiomer of a previously approved racemate is not considered a "new" active ingredient, in the context of the five-year new product exclusivity under 21 U.S.C. §§ 355(c)(3)(E)(ii and 355(j)(5)(F)(ii). *See* 54 Fed. Reg. 28872 at 28898 (July 10, 1989). According to the FDA, enantiomers, such as the levofloxacin "active ingredient" in LEVAQUIN®, do not qualify for new product exclusivity if the corresponding racemic mixture containing that enantiomer was previously approved as a drug. *Id.*

Notably, no request was made for LEVAQUIN® to be granted such five-year new product exclusivity, as it was clear that under the FDA's long-standing policy,

LEVAQUIN® did not represent the first FDA approval of levofloxacin as an "active ingredient." Levofloxacin was the "active ingredient" in LEVAQUIN® and was also present as an "active ingredient" in FLOXIN®.

Paradoxically, though, when the FDA determined levofloxacin's eligibility for a patent term extension, the FDA decided that levofloxacin *was* a new "active ingredient," different from the "active ingredient" in FLOXIN®. Contrary to the Court's discussion in *Pfizer* and to the standard rules of statutory construction, the FDA adopted two directly conflicting definitions of "active ingredient" and applied them to different aspects of the same situation.

The panel failed to address the dichotomy in the FDA's definition of "active ingredient," instead noting only that the FDA's patent term extension policy was long-standing. This long-standing policy, however, contradicted the FDA's other long-standing policy relating to new product exclusivity. *See* 54 Fed. Reg. 28872 at 28897-98 (July 10, 1989). A discrepancy like this leads to discordant and inequitable results, such as in the case here. The FDA should be required to apply the definition of "active ingredient" consistently to both the patent term extension provisions and the new product exclusivity provisions of the Hatch-Waxman Act.

B. For Both Patent Term Extension and New Product Exclusivity Purposes, a Single Enantiomer of a Previously-Marketed Racemate is not a New "Active Ingredient" because the Enantiomer is Present as an "Active Ingredient" in the Racemate

As discussed above, levofloxacin is not a new active ingredient because it was present as an ingredient in FLOXIN®, which contained levofloxacin and R(+)-ofloxacin. Section 156(a) of the Hatch-Waxman Act states that in order to qualify for a patent term extension, the commercial marketing or use of a "product" must be the first permitted (*i.e.,* FDA-approved) commercial marketing or use of the product in the United States. 35 U.S.C. § 156(a)(5). The term "product" is defined in the statute as a "drug product," the latter in turn being defined as an "active ingredient." 35 U.S.C. § 156(f)(1) & (2). *See also Fisons PLC v. Quigg*, 876 F.2d 99, 102 (Fed. Cir. 1989). The "active ingredient" may be present "as a single entity or in combination with another active ingredient." 35 U.S.C. § 156(f)(2). The FDA has defined "active ingredient" as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man of or animals." 21 C.F.R. § 210.3(b)(7).

The Hatch-Waxman Act uses the same term, "active ingredient," in both the new product exclusivity provisions and the patent term extension provisions. Thus, the same rationale can be applied to patent term extension eligibility for single enantiomers as was applied to new product exclusivity eligibility. Applying

the FDA's definition of "active ingredient" from 21 C.F.R. § 210.3(b)(7), levofloxacin has pharmacological activity, as does R(+)-ofloxacin, so both are "active ingredients." *A17, A1193, Ortho-McNeil,* 348 F. Supp. 2d at 721, 751. The racemic mixture of levofloxacin and R(+)-ofloxacin has the combined activity of both enantiomers, so levofloxacin was present as an "active ingredient" in FLOXIN®.

This situation is analogous to one in which a drug product contains a combination of active ingredients, and then a patent term extension is sought for a later product containing only one of those ingredients. As this Court has noted, 35 U.S.C. § 156 "requires this Court to examine a drug product patent eligibility for extension on a component-by-component, or an ingredient-by-ingredient basis." *See Arnold Partnership v. Dudas*, 362 F.3d 1338, 1341 (Fed. Cir. 2004). Quoting the district court, the Court explained:

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

Id. (internal citation omitted).

Levofloxacin and R(+)-ofloxacin were present in FLOXIN®, essentially as a combination of "active ingredients." Accordingly, since levofloxacin was an "active ingredient" in the earlier-marketed FLOXIN®, LEVAQUIN® cannot be the

first commercial marketing of levofloxacin, and cannot support either a patent term extension or new product exclusivity under the Hatch-Waxman Act.

CONCLUSION

For the foregoing reasons, Lupin respectfully requests that the Court grant the petition for this case to be reheard *en banc*.

Respectfully submitted,

Dated: June 8, 2010

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ADDENDUM

Federal Circuit Opinion
Dated May 10, 2010

United States Court of Appeals for the Federal Circuit

2009-1362

ORTHO-MCNEIL PHARMACEUTICAL, INC.,
and ORTHO-MCNEIL, INC.,

Plaintiffs-Appellees,

and

DAIICHI SANKYO CO., LTD.,

Plaintiff-Appellee,

v.

LUPIN PHARMACEUTICALS, INC.
and LUPIN LTD.,

Defendants-Appellants.

George F. Pappas, Covington & Burling LLP, of Washington, DC, for plaintiffs-appellees Ortho-McNeil Pharmaceutical, Inc. et al. With him on the brief were Jeffrey B. Elikan and Gary Rubman.

Henry B. Gutman, Simpson Thacher & Bartlett LLP, of New York, New York, argued for plaintiff-appellee Daiichi Sankyo Company, Ltd. With him on the brief were Robert A. Bourque and Noah M. Leibowitz. Of counsel on the brief were Mark Boland, Michael R. Dzwonczyk and Keiko K. Takagi, Sughrue Mion, PLLC, of Washington, DC.

Robert F. Green, Leydig, Voit & Mayer, Ltd., of Chicago, Illinois, argued for defendants-appellants. With him on the brief was Christopher T. Griffith.

Howard S. Scher, Trial Attorney, Appellate Staff, Civil Division, United States Department of Justice, of Washington, DC, for amicus curiae United States. With him on the brief were Tony West, Assistant Attorney General, and Scott R. McIntosh, Attorney. Of counsel on the brief were James A. Toupin, General Counsel, Office of the General Counsel, United States International Trade Commission, of Washington, DC, and Raymond T. Chen, Deputy General Counsel and Solicitor, Office of the Solicitor, United States Patent and Trademark Office, of Arlington, Virginia.

Appealed from: United States District Court for the District of New Jersey

Chief Judge Garrett E. Brown, Jr.

Sankyo Co. and exclusively licensed to Ortho-McNeil Pharmaceutical, Inc. and Ortho-McNeil, Inc. (collectively "Ortho").[1] The '407 patent is directed to an enantiomer of a racemic compound that had previously been approved by the Food and Drug Administration (FDA). On cross-motions for summary judgment, the district court agreed with the positions of the Patent and Trademark Office (PTO) and the FDA, and held that the statutory requirements for term extension were met for the '407 patent.

The district court enjoined Lupin from infringement during the extended term of the patent. We affirm the district court's judgment.

BACKGROUND

The '407 patent is for an antimicrobial compound having the common name levofloxacin. Levofloxacin is the levorotatory enantiomer (also designated the S(-) enantiomer) of the racemate ofloxacin, which is a known antimicrobial product. A racemate consists of equal amounts of spatial isomers called enantiomers, molecules that are mirror images of each other. Due to their spatial orientation, enantiomers are optically active and are characterized by whether they rotate plane-polarized light clockwise (dextrorotatory) or counter-clockwise (levorotatory). Although enantiomers and their racemates have the same chemical composition, they may differ in their physical, chemical, or biological properties. See, e.g., Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1081 (Fed. Cir. 2008) (discussing possible differences among enantiomers and their racemates).

The record states that the inventors at Daiichi Sankyo tried unsuccessfully, over several years, to separate the constituent enantiomers from the racemate ofloxacin.

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[1] Ortho-McNeil Pharm., Inc. v. Lupin Pharm., Inc., Civ. No. 06-4999, 2009 WL 1228448 (D.N.J. May 1, 2009).

They eventually produced the substantially pure enantiomers by direct synthesis from stereospecific starting materials. The inventors then determined that levofloxacin has properties that are significantly superior to those of ofloxacin. The '407 patent describes this synthesis, and presents data showing that levofloxacin is more effective as an antimicrobial agent, more rapidly available for biological effectiveness, and has lower acute toxicity and thus may be administered in higher doses than ofloxacin. See Ortho-McNeil Pharm. Inc. v. Mylan Labs., Inc., 348 F. Supp. 2d 713, 754 (N.D.W. Va. 2004) ("[L]evofloxacin is pharmaceutically superior to ofloxacin in virtually every relevant aspect."), aff'd, 161 F. App'x 944 (Fed. Cir. 2005).

The '407 patent issued on October 1, 1991. In 1996, after Ortho satisfied the regulatory requirements, the FDA approved levofloxacin for commercial marketing and use as the product having the brand name Levaquin®. Daiichi Sankyo then applied for extension of the patent term, in accordance with 35 U.S.C. §156. The PTO consulted with the FDA, as provided in their Memorandum of Understanding, 52 Fed. Reg. 17,830 (FDA May 12, 1987) (observing that "while it is the responsibility of the Commissioner of Patents and Trademarks to decide whether an applicant has satisfied these six conditions [of 35 U.S.C. §§156(a)(1)–(5) and 156(d)(1)], FDA possesses expertise and records regarding" some of these conditions). The FDA duly advised the PTO that regulatory approval for levofloxacin had been granted, stating that:

> A review of the Food and Drug Administration's official records indicates that this product [LEVAQUIN] was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. §156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. §156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F.2d 392 (Fed. Cir. 1990).

Ortho-McNeil, Civ. No. 06-4999, slip op. at 6 (alteration in original). The PTO concluded that extension of the patent term was warranted, and the PTO and FDA collaborated in calculation of the applicable extension of 810 days, in accordance with §156(d)(2)(A). See In re Patent Term Extension Application for U.S. Patent No. 5,053,407 (PTO Aug. 4, 1999).

Lupin invoked the litigation procedures of 21 U.S.C. §355(j)(2)(A)(vii)(IV) (Paragraph IV certification). In the district court, Lupin stipulated to the validity, enforceability, and infringement of the '407 patent, contesting only whether the '407 patent is entitled to the term extension.[2] The district court held that the extension was properly granted.

DISCUSSION

The grant of summary judgment receives plenary review on appeal. Int'l Visual Corp. v. Crown Metal Mfg. Co., 991 F.2d 768, 770 (Fed. Cir. 1993). Similarly, statutory interpretation receives plenary review. Madison Galleries, Ltd. v. United States, 870 F.2d 627, 629 (Fed. Cir. 1989). The relevant statutory provisions include:

> 35 U.S.C. §156(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 . . . , if--
>
> * * * *
>
> (a)(4) the product has been subject to a regulatory review period before its commercial marketing or use;
>
> (a)(5)(A) except as provided in subparagraph (B) or (C) [not here relevant], 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;
>
> * * * *
>
> §156(f) For purposes of this section:
>
> (1) The term "product" means:
>
> (A) A drug product.

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[2] Validity of the '407 patent had previously been sustained. See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 348 F. Supp. 2d 713 (N.D.W. Va. 2004), aff'd., 161 F. App'x 944 (Fed. Cir. 2005).

* * * *

(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), . . .

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

The '407 patent claims the enantiomer levofloxacin as a new product and for use as an antimicrobial agent. Regulatory review of the drug product containing levofloxacin as active ingredient was required by the FDA, and permission for sale and use had been granted. The issue is whether this was the first permitted commercial marketing or use of levofloxacin, as required by 35 U.S.C. §156(a)(5)(A), for the racemate had previously been marketed. The district court held that the extension was in conformity with the practices of the PTO and the FDA with respect to enantiomers, and that the PTO's determination that levofloxacin is a different "product" than the racemate ofloxacin must be afforded "great deference," see Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 399 (Fed. Cir. 1990) ("[W]e will give great deference to the Commissioner's determinations as to which patented chemical compounds fall within Congress' definition of 'products,' but little or no deference to the Commissioner's surmise of Congress' intent in framing its definition.").

Lupin argued in the district court, and again on this appeal, that the PTO and the FDA have incorrectly interpreted the statute insofar as enantiomers are concerned. Lupin argued that an enantiomer is half of its racemate, and thus that the enantiomer levofloxacin was an "active ingredient" or component of the previously marketed racemate ofloxacin. Thus Lupin argued that levofloxacin is the same "drug product" as ofloxacin, and that since ofloxacin had been previously approved by the FDA, permission to market and use

levofloxacin was not "the first permitted commercial marketing or use of the product" as required by §156(a)(5)(A).

Ortho responded that an enantiomer has consistently been recognized, by the FDA and the PTO, as a different "drug product" from its racemate. Ortho pointed out that levofloxacin was viewed by the FDA as a new product requiring full regulatory approval, and that levofloxacin was viewed by the PTO as separately patentable. The FDA practices were explained by Dr. David Lin, a former acting Division Director in the FDA's Division of New Drug Chemistry, declaring that "in each and every instance in which it has considered the question, the FDA has described a racemate as a single active ingredient, distinct from its enantiomers, and each enantiomer as a single active ingredient distinct from the other and from the racemate," Lin Decl. ¶20, J.A. 1280 (including examples and Orange Book descriptions, at Lin Decl. Ex. C, J.A. 1278-1439). Nor does Lupin challenge the separate patentability of the enantiomer levofloxacin. Lupin also does not dispute that the federal approval for Levaquin® is the first permitted marketing of levofloxacin as a separate enantiomer. We discern no basis for challenging these established FDA and PTO practices. The FDA and PTO practices are in accordance with Glaxo, where the court held that "product" as used in §156(a) is the active ingredient present in the drug. See 894 F.2d at 393–95 (extending term of patent on a new separately patentable ester, although salts of the same acid had previously been approved).

Lupin presses the argument that the status of enantiomers with respect to eligibility for term extension was legislatively changed in 2007, in the statute that changed the FDA policy concerning data exclusivity for new enantiomer products. See 21 U.S.C. §355(u)(1) (Supp. II 2008). The new provision authorizes an applicant "for a non-racemic drug

containing as an active ingredient (including any ester or salt of the active ingredient) a single enantiomer that is contained in a racemic drug approved in another application" to, under certain conditions, "elect to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug." Id. Lupin argues that by specifically allowing an applicant to "elect" this separate treatment for enantiomers, Congress expressed its understanding that enantiomers were the same active ingredient as the racemate for all other purposes, including patent term extension.

No support for this theory appears in the legislative record, or elsewhere. Lupin's interpretation would change the long-standing term-extension policy of the FDA and the PTO; such a far-reaching change is not achieved by legislative silence. See Young v. Cmty. Nutrition Inst., 476 U.S. 974, 983 (1986) ("This failure to change the scheme under which the FDA operated is significant, for a congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress." (internal quotation marks omitted)); Daewoo Electronics Co. v. Int'l Union of Electronic, Electrical, Technical, Salaried & Machine Workers, 6 F.3d 1511, 1522 (Fed. Cir. 1993) (unrelated amendments to a statute without change in the provisions at issue is "evidence that the policy of the [agency] comports with congressional intent").

We affirm the district court's ruling that the '407 patent on levofloxacin was properly granted the statutory term extension, for the enantiomer is a different drug product from the racemate ofloxacin, and was subject to regulatory approval before it could be commercially marketed and used.

II

Based on Lupin's admissions of infringement, validity, and enforceability, the district court granted Ortho's motion to enjoin Lupin from making, using, offering to sell, selling, or importing levofloxacin in bulk or tablet form during the extended term of the '407 patent. Lupin argues that the injunction is improperly broad. Ortho states, and Lupin does not contradict, that Lupin did not object to the scope of the injunction when it was presented to the district court as a proposed order, and did not move for modification or raise any other objection when the order was entered by the district court. Although Lupin appears to have waived objection to the injunction, in the interest of completeness we have reviewed Lupin's challenge.

The grant of an injunction and its scope are reviewed for abuse of discretion. Ortho Pharm. Corp. v. Smith, 959 F.2d 936, 945 (Fed. Cir. 1992). Lupin argues that the extension of a patent term under 35 U.S.C. §156(b) applies only to sale and use of the patented product, and that the extended term does not encompass any other exclusionary patent rights, such as making or importing the patented product. Thus Lupin argues that the district court's injunction is improper as a matter of law.

It is recognized that an extended patent term does not apply to unrelated uses of an FDA-approved product. See Pfizer Inc. v. Dr. Reddy's Labs., Ltd., 359 F.3d 1361, 1366 (Fed. Cir. 2004) ("The 'rights derived' provision of §156(b) specifically limits the extension to 'any use approved for the product,' which means that other, e.g., non-pharmaceutical uses, are not subject to the extension."). Lupin does not assert that levofloxacin has any non-pharmaceutical uses. The district court did not abuse its discretion in issuing an injunction commensurate with the patent rights of exclusion, see 35 U.S.C. §271(a) (infringement

includes making, using, selling, and importing the patented invention). The scope of the injunction is sustained.

AFFIRMED

Certificate of Service

CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing PETITION FOR REHEARING EN BANC were served June 8, 2010, *via* overnight courier, on the following:

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The undersigned hereby further certifies that the original and 18 true copies of the foregoing PETITION FOR REHEARING EN BANC were filed with the Clerk of the Court on June 8, 2010, *via* overnight courier.

Dated: June 8, 2010

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