United States Court of Appeals for the Federal Circuit

03-1339

THE ARNOLD PARTNERSHIP,

Plaintiff-Appellant,

v.

Jon Dudas, Acting Under Secretary of Commerce for Intellectual Property
and Acting Director, Patent and Trademark Office,
and NICHOLAS P. GODICI, Commissioner for Patents,

Defendants-Appellees.

Christopher N. Sipes, Covington & Burling, of Washington, DC, argued for plaintiff-appellant.

Linda Moncys Isacson, Associate Solicitor, Office of the Solicitor, United States Patent and Trademark Office, of Arlington, Virginia, argued for defendants-appellees. With her on the brief were John M. Whealan, Solicitor; and Raymond T. Chen, Associate Solicitor.

Donald O. Beers, Arnold & Porter, of Washington, DC, for amicus curiae GlaxoSmithKline. With him on the brief was David E. Korn. Of counsel on the brief was Scott A. Chambers, Patton Boggs, LLP, of McLean, Virginia.

Appealed from: United States District Court for the Eastern District of Virginia

Judge Leonie M. Brinkema

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DECIDED: March 24, 2004

Before RADER, BRYSON, and DYK, Circuit Judges.

RADER, Circuit Judge.

On summary judgment, the United States District Court for the Eastern District of Virginia ruled that the United States Patent and Trademark Office (PTO) properly denied an application for extending the term of U.S. Patent No. 4,587,252 under 35 U.S.C. § 156. Arnold P'ship v. Rogan, 246 F. Supp. 2d 460 (E.D. Va. 2003). Because the district court did not err in upholding the PTO's interpretation of § 156, this court affirms.

I.

The Arnold Partnership (Arnold) is the owner of record for the '252 patent, which claims compositions comprising hydrocodone (or a salt thereof) and ibuprofen (or a salt thereof) as well as methods of treating pain with those compositions.[1] The '252 patent was filed on December 18, 1984,

was issued on May 6, 1986, and is due to expire on December 18, 2004. The commercial embodiment of the '252 patent is Vicoprofen® – a combination of hydrocodone bitartrate (a salt of hydrocodone) and ibuprofen. Because these components had only been available separately, the Food and Drug Administration (FDA) required a New Drug Application (NDA) before clearing Vicoprofen for the market.

The marketing applicant for Vicoprofen, Knoll Pharmaceuticals (Knoll), filed an Investigational New Drug Application (IND) with FDA on December 30, 1986. Knoll later filed an NDA on April 25, 1996, which FDA approved on September 23, 1997. Abbott Labs has since succeeded Knoll as both the exclusive licensee of the '252 patent and the holder of the Vicoprofen NDA.

On November 20, 1997, Arnold filed an application with the PTO for patent term restoration under 35 U.S.C. § 156. The PTO denied the application solely because Vicoprofen did not comply with the "first commercial marketing" requirement of § 156(a)(5)(A). The PTO reasoned that both hydrocodone and ibuprofen had been marketed previously either alone or in combination with other active ingredients. For this reason, the PTO determined the patent was not eligible for patent term extension to compensate for the period of regulatory review. In particular, hydrocodone bitartrate had been marketed in conjunction with various other active ingredients, including acetaminophen and aspirin. Ibuprofen had been marketed alone.

Arnold then filed suit in the United States District Court for the Eastern District of Virginia challenging the PTO's denial under the Administrative Procedure Act (APA). Arnold argued that the combination of hydrocodone and ibuprofen was an active ingredient within the meaning of § 156. According to Arnold, the statute permits extension of a combination drug product when the combination itself had not been previously on the market. Specifically, Arnold argued that the statute examines a drug product as a whole and not on a component-by-component basis. Because hydrocodone and ibuprofen were never marketed previously in combination with one another, Arnold argued that the patent claiming the two in combination deserves an extension. The district court, however, agreed with the PTO's interpretation of the statute and affirmed the agency's denial of an extension to the '252

patent.

II.

This court reviews a district court's grant of summary judgment without deference, reapplying the same standard as the district court. Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1353 (Fed. Cir. 1998). Because Arnold brought this case under the APA, this court may reverse the PTO's final decision denying patent term extension if the decision is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); see also Dickinson v. Zurko, 527 U.S. 150, 154 (1999). An abuse of discretion occurs if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors. In re Gartside, 203 F.3d 1305, 1315-16 (Fed. Cir. 2000).

This court reviews statutory interpretation, the central issue in this case, without deference. Merck & Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996). When construing a statute, the language of the statute controls its meaning. Ardestani v. Immigration & Naturalization Serv., 502 U.S. 129, 135 (1991). The statutory language on patent term extensions states:

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

* * *

(f) For purposes of this section:

(1) The term "product" means:

(A) A drug product.

* * *

(2) The term "drug product" means the active ingredient of—

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) . . .

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 (2004).

In rejecting the application for a patent term extension, the PTO asserted that Arnold did not satisfy the fifth condition under subsection (a) – the "first commercial marketing requirement." That subsection refers to "the product," a term defined in subsection (f). Subsection (f) defines "the product" as "a drug product." The subsection further defines "a drug product" as "the active ingredient of a new drug . . . product . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient." Thus, in simple terms, the statute permits extension for a patent claiming an active ingredient of a new drug product.

This statutory language requires this court to examine a drug product patent's eligibility for extension on a component-by-component, or an ingredient-by-ingredient basis. The final phrase in subsection (f) – "including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient" – emphasizes this point. This final phrase of subsection (f) shows that the statute refers to a drug product on a component-by-component basis, not as a whole.

A closer examination of this statutory language confirms this meaning. The subsection uses the disjunctive to show that the drug product may consist of either a single active ingredient or an active ingredient in combination with another active ingredient. Thus, the statute places a drug product with

two active ingredients, A and B, in the same category as a drug product with a single active ingredient. In both instances, those active ingredients individually qualify for examination under the first permitted marketing requirement. To extend the term of a patent claiming a composition comprising A and B, either A or B must not have been previously marketed. In other words, at least one of the claimed active ingredients must be new to the marketplace as a drug product. In this respect, the district court's opinion correctly summarizes: "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 this first active ingredient." Arnold P'ship, 246 F. Supp. 2d at 464-65. This court has not found any statutory history that contradicts this straightforward reading of the statute, particularly none that would qualify as a "most extraordinary showing" to "justify a limitation on the 'plain meaning' of the statutory language." Garcia v. United States, 469 U.S. 70, 75 (1984).

Section 1 of title 1 of the United States Code does not change this meaning of the statutory language. This section provides some general guidance for the meaning of the Code, including "words importing the singular include and apply to several persons, parties, or things." This general guidance, however, includes in the same section the following caveat, "unless the context indicates otherwise." In this case, the context of 35 U.S.C. § 156 does not permit the singular term "active ingredient" to embrace the plural.

In addition, this court considers, but rejects, an alternative reading of § 156. Under this reading, § 156 only prohibits term extensions on a patent claiming drug product AB when the drug product AB itself has been previously approved. In other words, this reading would not examine the combination independent of its separate ingredients for prior marketing. Thus, as in this case, the patent for combination drug product AB could receive an extension because the combination has not received prior approval, even though drug product A and drug product B have separate, prior approvals. Under this alternative, incorrect reading, the words "in combination with" refer to a different drug product. The statute, however, does not state "in combination with the active ingredient of a different drug," but states without limitation "in combination with another active ingredient." Therefore, the language of the

statute is not susceptible to this alternative incorrect reading.

This court also considers the effect of subsection (c), which states, in part, that the term extension of an eligible patent "shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued." 35 U.S.C. § 156(c). Because each combination drug product receives only one regulatory review period, this passage might suggest that the combination as a whole is the approved product, not the individual components. To the contrary, however, this court has already rejected an argument that the presence of "approved product" compels a definition in harmony with the product approved by FDA. See Fisons plc v. Quigg, 876 F.2d 99, 101 (Fed. Cir. 1989). In any event, a vague implication in subsection (c) cannot override the unambiguous language in the remainder of the section. Rather, this court reads the two sections together to reach the meaning in this opinion.

This court also weighs into its calculation the understanding that FDA requires a NDA for combination drugs. FDA does not approve these combination drugs on a component-by-component basis, but on the basis of an evaluation of the whole drug combination. Thus, this court understands that its reading of § 156 does not perfectly overlay with FDA's practices and regulations. Because the Patent Act and the Food, Drug, and Cosmetic Act do not exhibit a perfect overlap of policies and protections, § 156 may not supply the same term protections for combination drugs as for noncombination drugs. This court, however, must follow the directions of the law, not its own conceptions of the best way to make the law achieve certain policy objectives. Indeed, this court agrees with the following observation of the district court:

> Although we are not unsympathetic with plaintiff's argument that defendants' interpretation of the Act creates a financial disincentive to pharmaceutical companies' development of new therapeutic drugs for consumers, whether plaintiff's interpretation of § 156(f)(2) would create a "better balanced policy" for applying the Act in parity with the FDA's discharge of its own statutory enforcement responsibilities is an issue appropriately addressed to Congress.

Arnold P'ship, 246 F. Supp. 2d at 466 n.3.

This court also addresses briefly whether synergistic combination drug patents qualify for a patent term extension under § 156. Although the PTO notes that it has not taken a position on the effect

of synergy on a combination drug patent's eligibility for term extension, the facts of this case seem to indicate otherwise. The patent at issue states: "The combination [of hydrocodone and ibuprofen] provides an analgesic effect greater than that obtained by increasing the dose of either constituent administered alone. The adverse effects produced by such combination are considered to be less than those produced by an equi-analgesic dose of one of the constituents." '252 patent, col. 1, ll. 27-32; see also id. at col. 2, ll. 1-5, 12-17, 25-28. Moreover, this court doubts that synergistic effects are an appropriate distinction for term extension policies, particularly where the statutory language does not distinguish at all between synergistic and nonsynergistic combinations.

III.

Because the district court did not err in upholding the PTO's decision to deny Arnold's application for extension of the '252 patent's term, this court affirms.

COSTS

Each party shall bear its own costs.

AFFIRMED

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[1] In a separate litigation, the United States District Court for the Northern District of Illinois determined on summary judgment that the claims of the '252 patent are invalid for obviousness. Knoll Pharm. Co. v. Teva Pharms. USA, Inc., No. 01 C 1646, 2002 U.S. Dist. LEXIS 17201 (N.D. Ill. Sept. 12, 2002); Knoll Pharm. Co. v. Teva Pharms. USA, Inc., No. 01 C 1646, 2002 U.S. Dist. LEXIS 23983 (N.D. Ill. Dec. 9, 2002). The patentee has separately appealed that judgment to this court.