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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,674,860

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JAN 09 2014
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DENIAL OF PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. 156 FOR U.S. PATENT No. 5,674,860

This is in response to the application for extension of the patent term of U.S. Patent No. 5,674,860 (the '860 patent) under 35 U.S.C. § 156 filed in the United States Patent and Trademark Office (USPTO) on September 19, 2006. The patent term extension application (PTE Application) was filed by AstraZeneca AB (Applicant) the owner of record of the patent. Extension was sought based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) for a human drug product known by the tradename SYMBICORT® and having the active ingredients budesonide and formoterol fumarate dihydrate. The application indicated that SYMBICORT® had been approved for commercial use and sale by the Food and Drug Administration (FDA) on July 21, 2006.

A determination has been made that the '860 patent is **NOT** eligible for patent term extension based upon the regulatory review period of SYMBICORT®. Therefore, Applicant's PTE application is **DENIED**.

PROCEDURAL BACKGROUND

(1) On October 7, 1997, the USPTO issued the '860 patent to Christer C.G. Carlin et al. It is assigned to AstraZeneca AB.

(2) On July 21, 2006, FDA approved New Drug Application (NDA) No. 21-929, thereby granting permission for commercial marketing or use of SYMBICORT® (budesonide and formoterol fumarate dihydrate). Applicant received notice of this approval at 4:36 PM on July 21, 2006 (after the close of business).

(3) On September 19, 2006, Applicant filed a PTE Application under § 156 to extend the term of the '860 patent based on FDA regulatory review of SYMBICORT®.

(4) On June 20, 2007, pursuant to the Memorandum of Understanding Between the USPTO and the FDA, see 52 Fed. Reg. 17830, May 12, 1987, the USPTO requested assistance from the FDA (USPTO Letter to FDA) in determining eligibility of the '860 patent for patent term extension based on the regulatory review period of SYMBICORT®. The USPTO indicated in its letter that "[s]ince budesonide and formoterol [fumarate dihydrate] have been previously approved individually, their use in a combination product does not appear to comply with 35 U.S.C. § 156(a)(5)(A), *i.e.*, the approval of SYMBICORT® would not

appear to constitute the first permitted commercial marketing or use of the product as required by 35 U.S.C. § 156(a)(5)(A)."

(5) On December 6, 2007, the FDA communicated their findings to the USPTO (FDA letter). The FDA indicated that SYMBICORT® (budesonide and formoterol fumarate dihydrate) had been subject to regulatory review under NDA 21-929 in accordance with section 505 of the FFDCA, and confirmed that NDA 21-929 did not represent the first permitted commercial marketing or use of the active ingredients of SYMBICORT® (budesonide and formoterol fumarate dihydrate).

(6) On June 13, 2008, the USPTO dismissed Applicant's request for extension of the term of the '860 patent filed under the provisions of 35 U.S.C. § 156(d)(1).

(7) On December 16, 2008, Applicant filed a Response to the Notice of Final Determination of June 13, 2008 (Reconsideration Request I) pursuant to the provisions of 37 C.F.R. § 1.750.

(8) On June 24, 2011, Applicant filed an additional Response to the Notice of Final Determination of June 13, 2008 (Reconsideration Request II) to address the timeliness issue in light of the district court decision in *The Medicines Company v. Kappos*, 731 F.Supp. 2d 470 (E.D. Va. 2010).

DECISION

The USPTO has considered the arguments made by Applicant in its Reconsideration Request and finds the arguments regarding compliance with 35 U.S.C. § 156(a)(5)(A) to be unpersuasive. With respect to the arguments regarding the failure to comply with the timing requirement for filing an application in 35 U.S.C. § 156(d)(1), the USPTO finds the arguments in the Reconsideration Request II to be persuasive in light of the amendments to § 156(d)(1) and the district court decision in *The Medicines Company v. Kappos*, 731 F.Supp. 2d 470 (E.D. VA. 2010) as discussed below. Thus, the USPTO will address Applicant's arguments regarding compliance with 35 U.S.C. 156(a)(5)(A) in turn.

A. Approval of NDA 21-929 for SYMBICORT on July 21, 2006 at 4:36 PM Means the PTE Application Submitted on September 19, 2006 is Timely

The time period for submission of an application for patent term extension is set by statute. The statute provides, "such an application may only be submitted within the sixty-day period ***beginning on the date*** the product received permission under the provision of law under which the applicable regulatory review period occurred . . . ." 35 U.S.C. § 156(d)(1) (emphasis added). Thus, day one of the sixty-day period starts on the date the product receives permission for commercial marketing or use.

As originally determined in the USPTO communication to FDA of June 20, 2007, the

present PTE application was filed on day 61 when counting day one of the sixty-day period as the date the product was approved. However, the words, "beginning on the date" were at issue in *The Medicines Company v. Kappos* from 2010. The ruling of the district court was codified in section 37 of the Leahy-Smith America Invents Act which added the following sentence to the patent term extension provisions of § 156:

> For purposes of determining the date on which a product receives permission under the second sentence of this paragraph, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to receive such permission on the next business day. For purposes of the preceding sentence, the term "business day" means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under section 6103 of title 5.

35 U.S.C. § 156(d).

In their Reconsideration Request II, Applicant argued that the USPTO, in their determination from 2007, erroneously applied the calendar day interpretation. Since the USPTO's initial determination of June 2007, the district court determined that the term "date" as used in § 156(d)(1) means business day. Moreover, the Leahy-Smith America Invents Act of 2011 revised 35 U.S.C. § 156(d)(1) by adding language regarding how to determine the start the count of the sixty-day period set forth in 35 U.S.C. 156(d)(1) when the approval of the regulated product is received after the regulating agency's close of business. Because Applicant received their approval after 4:30 PM on July 21, 2006, the date which triggers the sixty-day period of § 156(d)(1) is July 22, 2006. Thus, the PTE application filed on September 19, 2006 is considered timely.

B. Permission For Commercial Marketing Or Use of SYMBICORT® Is Not The First Permitted Commercial Marketing Or Use As Required By 35 U.S.C. 156(a)(5)(A)

In order for the regulatory review of a drug product to give rise to patent term extension for a patent claiming such product under the provisions of 35 U.S.C. § 156, the permission for the commercial marketing or use of the product must be the first permitted commercial marketing or use of the product under the provision of law under which the regulatory review period occurred. Here, the permission for commercial marketing or use of each of the active ingredients of SYMBICORT® does not constitute the first permitted commercial marketing or use of either budesonide or formoterol fumarate dihydrate. Thus, Applicant's PTE application must be **denied**.

1. Section 156(f) recites that an active ingredient of a new drug is, "as a single entity or in combination with another active ingredient"

Applicant argues that because the drug product SYMBICORT® is a synergistic combination of budesonide and formoterol fumarate dihydrate, it constitutes a single active ingredient. Reconsideration Request I at 1. Applicant asserts that the USPTO's reliance on *In re Alcon*, 13 USPQ2d 1115 (Comm's Pat. & Trademarks 1989) is in error because the holding in *In re Alcon* is inconsistent with *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990). Applicant further argues that the *Alcon* decision by the Commissioner was based on a faulty interpretation of the legislative history of 35 U.S.C. § 156(a)(5)(A). Reconsideration Request at 1.

First, Applicant's analysis of the language of section 156(f) is flawed. Applicant glosses over the clear language of section 156(f) which provides that the active ingredient of a new drug may exist as **a single entity or in combination with another active ingredient**. When Congress provided a definition of "product" for purposes of determining which kinds of products, when subject to a regulatory review period and claimed in a patent, would give rise to patent term extension, the definition indicated that a new drug had either an active ingredient as a single entity or multiple active ingredients which are in combination with one another. See § 156(f)(2)(A). The language of section 156(f) recites that the term "product," means "a drug product," which in turn, means "the active ingredient of a new drug . . . as a single entity or in combination with another active ingredient." Applying the statutory language here, a drug product, SYMBICORT®, means the active ingredient (budesonide) of a "new drug" in combination with another active ingredient (formoterol fumarate). There is no escaping the plain language that the statute contemplates an active ingredient as a single entity in a new drug or an active ingredient in combination with another active ingredient in a new drug. To conclude that a single active ingredient can be a combination of two or more active ingredients would render superfluous the statutory language "or in combination with another active ingredient.

Second, contrary to Applicant's reading of the Commissioner's decision in *In re Alcon*, the decision did not limit patent term extension to situations where FDA granted permission for marketing or use of "New Chemical Entities," as that term is defined, for purposes of exclusivity, in 21 U.S.C. 355(c)(3)(E)(ii) and 21 U.S.C. 355(j)(5)(F)(ii) and its implementing regulation at 21 C.F.R. 318.108. Rather, the *Alcon* decision discusses that the data available to Congress at the time of the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) related to the costs and patent coverage of what was referred to as new molecular entities.

Alcon involved an extension application for a patent based on the regulatory review of Tobradex, a combination product of tobramycin and dexamethasone. Since only tobramycin was claimed in the patent, the Commissioner held that the permission for commercial marketing or use of tobramycin must constitute the first permitted commercial marketing or use in the Tobradex product in order to give rise to eligibility for extension of Alcon's patent. Although dexamethasone had not been approved prior to the approval of Tobradex, because the Alcon patent didn't claim dexamethasone, compliance with 35 U.S.C. 156(a)(5)(A) regarding dexamethasone was irrelevant.

Accordingly, because the approval of the combination product did not constitute the first permitted commercial marketing or use of tobramycin which was the only component of the combination product which was claimed in Alcon's patent, the approval of Torbradex did not constitute the first permitted commercial marketing or use requirement of 35 U.S.C. 156(a)(5)(A) and extension was denied.

Applicant further opines that the USPTO's interpretation of *In re Alcon* is inconsistent with *Glaxo Operations UK Ltd. v. Quigg*. Although the court in *Glaxo* indicated that patent term extension was not limited to "new chemical entities" as that term is used in 21 C.F.R. 314.108, the issue in *Glaxo* did not address combination products. *Glaxo* addressed a separate question, *i.e.*, whether the active ingredient in a drug product is: (*i*) the underlying active chemical moiety, or (*ii*) the formulation of that active moiety, *e.g.*, as a salt or ester, as it actually exists in the approved drug product. The case confirmed that the active ingredient is not the underlying chemical moiety, but the actual formulation of that moiety as it appears in the approved drug product. Here, the USPTO has considered the actual formulation of budesnoide as an active ingredient in combination with formoterol fumarate dihydrate as an active ingredient.

Additionally, Applicant indicates that the USPTO does not dispute the synergistic effect of SYMBICORT®. Reconsideration Request I at 1. Such statement is true, but unavailing. While such properties and information regarding synergy are perhaps relevant for patentability purposes, there is no basis in 35 U.S.C. 156 for considering whether a drug product containing two active ingredients acts synergistically to achieve a specific pharmacological effect. Rather, the relevant inquiry for purposes of section 156 is whether the drug product represents the first commercial marketing or use of that product. When a drug product contains two active ingredients, at least one of those ingredients must constitute the first permitted commercial marketing or use as required by 35 U.S.C. § 156(a)(5)(A). Budesonide was first approved for commercial marketing or use in the drug products Entocort EC, Pulmicort and Rhinocort. For example, Rhinocort was approved on February 14, 1994. Formoterol fumarate dihydrate was first approved for commercial marketing or use in the drug product Foradil. Foradil was approved on February 16, 2001. Because both budesonide and formoterol fumarate dihydrate had been previously approved, neither can constitute the first permitted commercial marketing or use for compliance with§ 156(a)(5)(A).

2. Determining Compliance with 35 U.S.C. 156(a)(5)(A) Requires Analysis Of A Product On An Active Ingredient-By-Active Ingredient Basis

Applicant argues that the USPTO has erroneously relied on the Federal Circuit's decision in *Arnold P'ship v. Dudas*, 262 F.3d 1338 (Fed. Cir. 2004). Reconsideration Request I at 1-2 Applicant also claims support for the argument that SYMBICORT® is a drug with a single active ingredient by reference to MPEP 2751 and states that this section of the MPEP supports treating a combination of two active ingredients as a single active ingredient where synergy can be shown. Reconsideration Request I at 2.

Applicant acknowledges that "the active ingredients of the Approved Product have each been separately approved for marketing or use by the U.S. Food and Drug Administration." PTE

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