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In Re: Patent Term Extension
Application for
U.S. Patent No. 8,327,844

October 13, 2020

FINAL DETERMINATION DENYING PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. § 156 FOR U.S. PATENT NO. 8,327,844

This is in response to the Request for Reconsideration of Decision on Patent Term Extension (PTE) Application filed on March 27, 2020, in support of the application for extension of the patent term of U.S. Patent No. 8,327,844 (the '844 patent) under 35 U.S.C. § 156 filed in the United States Patent and Trademark Office (USPTO) on November 17, 2017. The application was filed by OptiNose AS ("OptiNose" or "Applicant"), the patent owner of record. Extension is sought based upon the premarket review under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) of XHANCE® (fluticasone propionate), a combination drug/device product for which fluticasone propionate is the active ingredient of the drug component and for which the device component is described as an exhalation delivery system for the treatment of nasal polyps.

A determination has been made that the '844 patent is **NOT** eligible for PTE based upon the regulatory review period (RRP) of XHANCE®. Therefore, Applicant's PTE application is **DENIED**.

Please note that a PTE application for U.S. Patent No. 6,715,485 was filed concurrently, pursuant to the provisions of 37 CFR 1.785.

A. PROCEDURAL BACKGROUND

1. On December 11, 2012, the USPTO issued the '844 patent to Per Gisle Djupesland. It is assigned to OptiNose.

2. On November 18, 2016, OptiNose submitted a New Drug Application (NDA) pursuant to section 505(b)(2) of the FFDCA for XHANCE® (fluticasone propionate) nasal spray for treatment of nasal polyps.[1] The NDA was assigned NDA No. 209022.

3. On September 18, 2017, at 12:13 P.M., Eastern Time, the Food and Drug Administration (FDA) transmitted an approval letter for NDA No. 209022 to Mr. Alan Traettino, Vice President,

[1] See the FDA's approval letter for NDA 209022, which is Exhibit C of the November 17, 2017 PTE application ("This new drug application provides for the use of Xhance (fluticasone propionate) nasal spray for the treatment of nasal polyps ….").

Regulatory Affairs, at OptiNose. Mr. Traettino acknowledged receipt of the approval letter at 12:59 P.M. on September 18, 2017. The approval letter granted OptiNose permission to commercially market or use XHANCE® (fluticasone propionate) nasal spray as a treatment for nasal polyps.

4. On November 17, 2017, Applicant filed a PTE Application under 35 U.S.C. § 156(d)(1) to extend the term of the '844 patent based on the FDA's regulatory review of XHANCE®.

5. On August 28, 2018, pursuant to the Memorandum of Understanding Between the USPTO and the FDA,[2] the USPTO requested assistance from the FDA in confirming that XHANCE® was approved pursuant to NDA 209022. The USPTO's letter additionally asked the FDA to clarify the following three issues:

a. whether the approval of XHANCE® constituted the first permitted commercial marketing or use of the product as required by 35 U.S.C. § 156(a)(5)(A), as the term "product" is defined in 35 U.S.C. §156(f)(1), given that the active ingredient, fluticasone propionate, was previously approved by the FDA as far back as December 14, 1990, for the product CUTIVATE®;

b. given that there is no statutory category of "product" identified as "combination of drug/device," whether XHANCE® was reviewed as a drug product, as that term is defined in 35 U.S.C. § 156(f)(2)(A), having the active ingredient fluticasone propionate; and

c. whether the PTE was timely filed within the sixty-day period beginning on the date the product was approved, as set forth in 35 U.S.C. § 156(d)(1), given that the PTE application identified September 18, 2017, as the date the product received approval, which would make the November 17, 2017 filing date for the PTE application untimely.

6. On October 4, 2018, Applicant sent a letter to the FDA asking the FDA to endorse Applicant's position that the earliest date XHANCE® could be deemed to have received permission was September 19, 2017, rather than September 18, 2017. On November 29, 2019, the FDA in response explained that it cannot endorse Applicant's account of events and the approval letter was transmitted on September 18, 2017, at 12:13 P.M.

7. On November 29, 2019, the FDA communicated its findings to the USPTO. The FDA provided the following information:

a. The FDA confirmed that NDA No. 209022 did not represent the first permitted commercial marketing or use of the active ingredient fluticasone propionate of XHANCE®.

b. XHANCE® is a drug-device combination product. The device constituent part is a metered dose nasal spray for delivery of the drug constituent. The primary mode of action of XHANCE® is the drug, and the regulatory review under NDA No. 209022 was under section 505 of the FFDCA.

c. The FDA also confirmed the approval letter for NDA No. 209022 was transmitted by e-mail by Dr. Phuong Nina Ton, senior regulatory project manager in the FDA Center for Drug Evaluation and Research, Division of Pulmonary, Allergy, and Rheumatology Products, on September 18, 2017, at 12:13 P.M. to Mr. Alan Traettino, Vice President,

[2] See 52 Fed. Reg. 17830, May 12, 1987.

> Regulatory Affairs, at OptiNose. The FDA letter also noted that Mr. Traettino acknowledged receipt of Dr. Ton's e-mail and the attached copy of the NDA 209022 XHANCE® approval letter on Monday, September 18, 2017, at 12:59 P.M.

8. On January 28, 2020, the USPTO issued a decision dismissing Applicant's PTE application, the entire contents of which are expressly incorporated herein.

9. On March 27, 2020, Applicant submitted a Request for Reconsideration of the USPTO's January 28, 2020 dismissal.

B. DECISION

In the decision of January 28, 2020, the USPTO determined that the '844 patent is not eligible for PTE based upon the RRP of XHANCE®. The Request for Reconsideration summarized the Office's position in the following manner:

> **First**, the product is considered to be a drug product and as such fails to comply with 35 U.S.C. § 156(a)(5)(A), because XHANCE® (fluticasone propionate) does NOT represent the first permitted commerical marketing or use of the product. The active ingredient fluticasone propionate has been previously approved in multiple new drug applications (NDAs), as reflected in the USPTO letter to the FDA dated August 28, 2018; and the FDA Letter dated November 29, 2019. **Second**, the patent does not claim the product, which, for a product reviewed under section 505 of the FFDCA is a drug product, which is defined in section 156(f) as the active ingredient, the patent fails to recite the active ingredient, fluticasone propionate, in any patent claim. **Third**, if the product were considered to be a medical device and did comply with 35 U.S.C. § 156(a)(5)(A), then the term extension would be zero days since both periods of 35 U.S.C. §§ 156(g)(3)(B)(i) and 156(g)(3)(B)(ii) are zero. **Fourth**, the patent term application was not timely filed as required under 35 U.S.C. § 156(d)(1). The filing of the present application for patent term extension on November 17, 2017, is untimely as the sixty-day period would have begun on September 18, 2017, and ended on November 16, 2017. [Emphasis added.][3]

In the Request for Reconsideration of March 27, 2020, Applicant contends that its PTE application was timely, because the date of permission for marketing was no earlier than September 19, 2017. Applicant also contends that the first three reasons summarized above for denying eligibility "relate to the PTE eligibility of the Patents-at-Issue based on the fact that XHANCE® was reviewed as a drug product, not as a medical device."[4] According to Applicant, the '844 patent is eligible for PTE, because it claims "the medical device component of XHANCE® (or methods of using said device), which was the first permitted commercial marketing or use of the medical device component that could only be approved under a pre-market approval (PMA)," *i.e.*, could only be approved under an application under section 515.[5]

The Office has considered Applicant's arguments, which are addressed in detail below, but has not found them persuasive. In summary, the application was not timely because approval was transmitted to Applicant on September 18, 2017. Furthermore, 35 U.S.C. § 156(f)(1) provides:

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[3] See page 6 of the Request for Reconsideration.
[4] *Id.*
[5] See page 2 of the Request for Reconsideration.

> 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.

Regardless of whether XHANCE® is treated as a drug product under 35 U.S.C. § 156(f)(1)(A) or a medical device under 35 U.S.C. § 156(f)(1)(B), the requirements of 35 U.S.C. §156 are not met.[6] Therefore, for the reasons that follow, the PTE application for the '844 patent is **DENIED**.

I. The PTE Application for the '844 Patent Was Untimely Filed

Applicant agrees that the FDA approved the XHANCE® NDA on September 18, 2017,[7] that the FDA transmitted the approval letter for the XHANCE® NDA via email at 12:13 pm on September 18, 2017, that Applicant acknowledged receipt of the emailed approval letter at 12:59 PM on September 18, 2017,[8] and that the approval letter was not invalid.[9]

Applicant's position is that the approval letter as transmitted by email at 12:13 PM on September 18 did not constitute a "valid" or "verifiable" permission.[10] Applicant notes that, under FDA regulations, an electronic record or transmission, such as the emailed approval letter, must include a time stamp to constitute a verifiable record. Though the approval letter transmitted by email at 12:13 PM on September 18 included a signature and date, it did not include a time stamp. Thus, according to Applicant, the record of the permission was verifiable only to the extent that it shows a transmission occurred on September 18 with no indication of what time on September 18 the transmission occurred.[11] Applicant therefore concludes that the 60-day clock must start no earlier than the next day, i.e., September 19, 2017. Sixty days from September 19, 2017, would make the November 17, 2017 filing date of the PTE application timely.

Applicant's argument is not persuasive.

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[6] 35 U.S.C. § 156(f) does not provide for a "combination of drug/device" statutory category of product.

[7] See page 2 of the March 27, 2020 Request for Reconsideration ("…OptiNose agrees with FDA that the XHANCE® NDA was approved on September 18, 2017 (and that FDA emailed a copy of the approval letter to OptiNose at 12: 13 PM on the same day)….").

[8] See pages 3-4 of the Request for Reconsideration ("FDA approved NDA No. 209022 on September 18, 2017. FDA emailed OptiNose a copy of the NDA Approval Letter at 12:13 PM on September 18, 2017, and an OptiNose employee acknowledged receipt of the email at or around 12:59 PM that same day.").

[9] See fn. 21 at page 27 of the Request for Reconsideration ("To be clear, the missing time stamp does not make the NDA Approval Letter invalid ….").

[10] See page 19 of the Request for Reconsideration ("… FDA did not 'transmit' a valid 'permission' prior to 4:30 PM EST on September 18, 2017, because the NDA Approval Letter lacked a time-stamped signature, as required under FDA rules, to constitute a 'verifiable record' of a 'permission' for commercial marketing. See 21 C.F.R. § 314.3. OptiNose thus had no 'trustworthy, reliable' indication of permission prior to 4:30 PM, only evidence that the NDA was or would be approved sometime on September 18, 2017. See 21 C.F .R. § 11.1. Therefore, the 60-day filing period started at earliest on September 19, 2017, ….").

[11] See pages 25-26 of the Request for Reconsideration ("Because FDA emailed the NDA Approval Letter with a signature containing a date, but not a time stamp, FDA did not 'transmit' a verifiable record of official 'permission' prior to 4:30 PM EST on September 18, 2017. In addition, OptiNose was put on notice that its NDA was approved on September 18, 2017, but did not 'receive permission' to begin commercial marketing before the 4:30 PM EST cutoff. Thus, the PTE filing period did not start until the following day, September 19, 2017.").

There is no requirement in 35 U.S.C. § 156 or any other statute that the transmitted permission be time-stamped. Instead, the relevant language in 35 U.S.C. § 156 appears in paragraph (d)(1) and reads as follows:

> "…such an application may only be submitted within the sixty-day period beginning on the date the product received permission…"; and
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> "For purposes of determining the date on which a product receives permission …, 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."

It is undisputed that FDA "transmitted" the September 18 approval letter via email prior to 4:30 PM ET (specifically at 12:13 PM ET) on September 18 and Applicant acknowledged receipt of the emailed approval letter at 12:59 PM on September 18. It also is undisputed that, at every opportunity, Applicant has relied on the September 18 approval letter as constituting "permission" to commercially market or use XHANCE® as of September 18, 2017.[12] Thus, under 35 U.S.C. § 156, the date on which XHANCE® "received permission" is September 18, 2017.

As Applicant admits, the fact that the September 18 approval letter does not include a time-stamp does not make it an invalid permission.[13] As noted by Applicant, the purpose of FDA's regulations concerning time-stamps in the context of electronic records is to ensure the authenticity and integrity of the electronic record.[14] Applicant has not provided evidence that the approval letter was inauthentic or lacked integrity or that the lack of a time-stamp on the approval letter transmitted at 12:13 PM on September 18, 2017, negatively impacted the authenticity or integrity of the approval letter in any way. For example, Applicant has not offered any evidence that the lack of a time-stamp caused the Applicant or anyone else to question the authenticity or integrity of the approval letter. Further, while Applicant acknowledged receipt of the emailed approval letter at 12:59 PM on September 18, Applicant did not request that the FDA retransmit the approval letter with a time-stamp. Applicant has not provided evidence that the lack of a time-stamp caused Applicant or anyone else to be unsure of, and/or to not rely on, September 18 as the official date of permission to commercially market or use XHANCE®. As

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[12] See, e.g., page 3 of the November 17, 2017 PTE application ("The approved product received permission for commercial marketing or use under Section 505(b)(2) of the FFDCA (21 U.S.C. § 355(b)(2)) on September 18, 2017."); fn. 4 on page 3 of FDA's November 29, 2019 letter to Applicant's counsel ("We also note the there could be significant consequences to false statements made in the amendment to the OptiNose Initial Public Offering statement, which focused on the XHANCE approval and stated: 'On September 18, 2017, the U.S. Food and Drug Administration, or FDA, approved our new drug application, or NDA, for XHANCE for the treatment of nasal polyps in patients 18 years of age or older.' See UNITED STATES SECURITIES AND EXCHANGE COMMISSION: AMENDMENT NO. 1 TO FORM S-1 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933: OPTINOSE, INC., (Oct. 3, 2017) pages 1, 72; https://www.sec.gov/Archives/edgar/data/1494650/000104746917006175/a2233379zs-1a.htm.

[13] See fn. 21 at page 27 of the Request for Reconsideration ("To be clear, the missing time stamp does not make the NDA Approval Letter invalid ….").

[14] See page 21 of the Request for Reconsideration ("…the administrative history of the time requirement shows that it was deliberately included in the regulations to ensure the 'authenticity' and 'integrity' (*see*, *e.g.*, 21 C.F.R. § 11.30) of the electronic record." [Italics in original.]).

already noted, at every opportunity, Applicant has relied on the September 18 approval letter as constituting "permission" to commercially market or use XHANCE® as of September 18, 2017.

At pages 21-22 of the Request for Reconsideration, Applicant states:

> "Thus, the language of the 21 C.F.R. § 11 and the administrative record leading to its enactment make abundantly clear that the time-stamp is an important and essential requirement for establishing the timing of electronically signed documents …."

And at page 27 of the Request for Reconsideration, Applicant states:

> "When an electronic record's authenticity is or may be at issue–for example, when it is necessary to determine the ***time of day*** that an electronic product permission is deemed to have been received under 35 U.S.C. § 156(d)(l)–the time stamp rule becomes critical." [Emphasis in original.]

But the timing of the transmission of the September 18 approval letter at 12:13 PM is without dispute. Likewise, it is indisputable that the FDA signed the approval letter no later than 12:13 PM on September 18. In this regard, while the lack of a time-stamp may not indicate when exactly on or prior to the 12:13 PM transmission time the approval letter was signed, the inclusion of "{See appended electronic signature page}" in the signature block at page 4 of the approval letter, and the fact that the signature page transmitted at 12:13 PM on September 18 both states "This is a representation of an electronic record that ***was*** signed electronically and this page is the manifestation of the electronic signature" [emphasis added] and is dated "09/18/2017" renders it indisputable that the approval letter was signed no later than 12:13 PM on September 18.

In fact, there is no evidence Applicant even noticed the lack of a time-stamp until the timeliness of the PTE application became an issue. On page 3 of the November 17, 2017 PTE application, in section 3 titled "The Date of Permission for Commercial Marketing under 37 C.F.R. § 1.740(a)(3)," Applicant states: "The approved product ***received permission*** for commercial marketing or use under Section 505(b)(2) of the FFDCA (21 U.S.C. § 355(b)(2)) on September 18, 2017." [Emphasis added.] This language mirrors the language of 35 U.S.C. 156 and leaves no room for the argument advanced in the Request for Reconsideration of a different approval date and receipt date. The language also contradicts Applicant's statement at page 4 of the Request for Reconsideration that the PTE application merely stated "that the product was 'approved' on September 18, 2017."

Applicant asserts at page 4 of the Request for Reconsideration that "[a]lthough not stated explicitly, both [PTE] applications clearly assumed September 19, 2017, to be the starting date for the 60-day clock under § 156(d)(1)." The record provides no reasonable basis to accept this assertion. Given that the starting date for the 60-day clock under 35 U.S.C. § 156(d)(1) is the date the product received permission, the assertion directly contradicts the statement made at page 3, section 3, of the November 17 PTE application that the approved product "received permission" on September 18. The assertion also is inconsistent with the table at page 1 of the "NDA 209022 Chronology 18-Nov-2016-17-Oct-2017" section of Exhibit G of the PTE application. As noted on page 9, section 11, of the PTE application, Section G provides a list of the correspondence between Applicant and the FDA during the NDA phase. Unlike the row for

the date "11-Sept-2017," which indicates under the "Additional Comment(s)" column that a "[l]etter from FDA dated 06-Sept-2017 [was] received via U.S. mail on 11-Sept-2017," the row for the September 18 XHANCE® approval letter is blank under the "Additional Comment(s)" column.

For the foregoing reasons, XHANCE® "received permission" within the meaning of 35 U.S.C. § 156(d)(1) on September 18, 2017. Accordingly, the 60-day clock under 35 U.S.C. § 156(d)(1) for submitting a PTE application for XHANCE® terminated on November 16, 2017. Applicant's PTE application submitted on November 17, 2017, is thus untimely.

II. The Requirements of 35 U.S.C. § 156 Are Not Met When XHANCE® Is Treated as a Drug Product under 35 U.S.C. § 156(f)(1)(A)

When XHANCE® is treated as a drug product under 35 U.S.C. § 156(f)(1)(A), 35 U.S.C. § 156(f)(2)(A) states that "[t]he term "drug product" means the active ingredient of 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)." It is undisputed that the active ingredient in XHANCE® is fluticasone propionate. Therefore, when XHANCE® is treated as a drug product, the "product" for purposes of 35 U.S.C. § 156 is fluticasone propionate, and the '844 patent does not satisfy the statutory requirements for PTE because (a) the '844 patent does not "claim" fluticasone propionate and (b) approval of XHANCE® does not represent the first permitted commercial marketing or use of fluticasone propionate.

(a) 35 U.S.C. § 156(a) is not met when the "product" is fluticasone propionate

Under 35 U.S.C. § 156(a), a patent may be eligible for PTE if it "claims a product, a method of using a product, or a method of manufacturing a product." Thus, when XHANCE® is treated as a drug product, the '844 patent may be eligible for PTE if it "claims" fluticasone propionate. As explained below, the '844 patent does not "claim" fluticasone propionate.

The issue of whether a patent "claims" a product, within the meaning of 35 U.S.C. § 156(a), has been addressed in *Hoechst-Roussel Pharmaceuticals Inc.* v. *Lehman*, 109 F.3d 756 (Fed. Cir. 1997) and *Angiotech Pharm. Inc.* v. *Lee*, 191 F. Supp. 3d 509 (E.D. Va. 2016). In *Hoechst-Roussel*, the Federal Circuit explained that "in order for a patent to 'claim' a product, the patentee must have satisfied numerous tests of patentability, including, *inter alia*, a disclosure of the best mode of making the claimed product, and a description which would enable a person skilled in the art to make and use the claimed invention."[15] In addition, in *Angiotech*, the Eastern District of Virginia interpreted *Hoechst-Roussel* as standing "for the proposition that for purposes of § 156(a), a patent does not claim all products that directly infringe the patent claims."[16] Instead, "for a patent to qualify for a patent term extension, the patent must claim the

[15] *Id.* at 758-9.
[16] *Angiotech*, 191 F. Supp. 3d at 526.

particular product that underwent FDA review."[17] The '844 patent fails each of these tests and thus fails to "claim" fluticasone propionate.

At page 6, the November 17, 2017 PTE application states that "at least claims 1, 14-16, 23, 26-29, 35, 36, 39, 40, 43, 44, 46 and 50 of the '844 patent claim both a method of delivering (using) the drug product and a method of using the medical device components of the approved drug/device combination product." The analysis of the '844 patent's eligibility for PTE when the product is the medical device component of XHANCE® is addressed at section III of this decision. Here we address the '844 patent's eligibility for PTE when the product is fluticasone propionate.

The PTE application selected claim 1 to demonstrate the manner in which at least one patent claim reads on the product. Claim 1 recites:

> 1. A method of delivering a substance to the nasal airway of a subject, comprising the steps of:
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> sealing one of the nostrils of a subject to an outlet of a delivery unit such as to prevent the escape of a gas flow through the one nostril;
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> closing the oropharyngeal velum of the subject; and
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> delivering a gas flow entraining a substance through the outlet at such a driving pressure as to flow around the posterior margin of the-nasal septum and out of the other nostril of the subject, wherein the gas flow entraining a substance is provided by actuation of a supply unit device.

At pages 6-7 of the PTE application, Applicant takes the position that claim 1 reads on fluticasone propionate because claim 1 recites a "substance" and:

> "(1) the 'substance' can be a medicament (column 3, line 1) or a pharmaceutical (column 5, line 33, column 6, lines 45-46); 2) The 'medicament' can be a steroid (column 1, lines 65-67); 3) The 'pharmaceutical' can be a steroid (column 5, lines 40-41); 4) fluticasone propionate is a corticosteroid *(see* XHANCE™ Packaging Insert (PI)); and 5) corticosteroids are generally known to be 'steroids' by those skilled in the art.)."

Claim 1 and the explanation provided at pages 6-7 of the PTE application are insufficient to meet the requirement in 35 U.S.C. § 156(a) that the '844 patent must "claim" fluticasone propionate. Moreover, none of the other claims of the '844 patent "claims" fluticasone propionate in accordance with 35 U.S.C. § 156(a). Indeed, the specification of the '844 patent never mentions fluticasone propionate. Thus, the '844 patent is unable to satisfy the *Hoechst-Roussel* tests of providing a disclosure of the best mode or written description with respect to fluticasone propionate. Nor is the '844 patent able to satisfy *Angiotech's* particularity test. At best, claim 1 (or any claim) of the '844 patent claims a method that can deliver a myriad of different

[17] *Id.*

substances to the nasal airway of a subject, of which fluticasone propionate may be but one such substance.[18]

Hence, the '844 patent is ineligible for PTE under 35 U.S.C. § 156(a) when the "product" is fluticasone propionate.

(b) 35 U.S.C. § 156(a)(5)(A) is not met when the product is fluticasone propionate

Applicant acknowledges in the PTE application that the active ingredient, fluticasone propionate, was previously approved as far back as October 19, 1994.[19] Thus, Applicant does not dispute that the approval of XHANCE® does not represent the first permitted commercial marketing or use of fluticasone propionate pursuant to 35 U.S.C. § 156(a)(5)(A).[20] Accordingly, the '844 patent is not eligible for PTE in view of 35 U.S.C. § 156(a)(5)(A) when the "product" is fluticasone propionate.

III. The Requirements of 35 U.S.C. § 156 Are Not Met When XHANCE® Is Treated as a Medical Device under 35 U.S.C. § 156(f)(1)(B)

At page 2 of the Request for Reconsideration, Applicant contends that the '844 patent is eligible for PTE, because it claims "the medical device component of XHANCE® (or methods of using said device), which was the first permitted commercial marketing or use of the medical device component that could only be approved under a pre-market approval (PMA)." According to Applicant, "§ 156 must be construed as 'classifying' XHANCE® also as a Class III medical device approved under a regulatory review period that would make it eligible for PTE."[21]

When the "product" in accordance with 35 U.S.C. § 156(f)(1)(B) is the medical device component of XHANCE®, the '844 patent is not eligible for PTE because at least five different statutory requirements—35 U.S.C. § 156(a), (a)(4), (a)(5)(a), (d)(1), and (g)(3)—have not been satisfied since a regulatory review period for the product has not yet been completed.

(a) 35 U.S.C. § 156(a) is not met when the product is the medical device component of XHANCE®

At page 6, the November 17, 2017 PTE application states that "at least claims 1, 14-16, 23, 26-29, 35, 36, 39, 40, 43, 44, 46 and 50 of the '844 patent claim both a method of delivering (using) the drug product and a method of using the medical device components of the approved

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[18] In *Angiotech*, the court determined that the patent at issue did not claim the product at issue (Zilver PTX) under 35 U.S.C. § 156(a), because the patent did not particularly claim Zilver PTX and instead merely claimed "a method that can be performed by a number of products, of which the Zilver PTX is but one." 191 F. Supp. 3d at 527.

[19] See page 3, item 4, of the PTE application. In fact, per the November 29, 2019 letter from the FDA to the USPTO, fluticasone propionate had been approved by the FDA as far back as December 1990.

[20] The FDA is also in agreement. See the November 29, 2019 letter from the FDA to the USPTO, which states at page 1: "FDA records also indicate that XHANCE does NOT represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(a)(5)(A)." [Emphasis in original.]

[21] See page 7 of the Request for Reconsideration. Applicant's contention that the nasal delivery device component of XHANCE® is a Class III device is addressed at section IV of this decision.

drug/device combination product." The PTE application selected claim 1 to demonstrate the manner in which at least one patent claim reads on the product. Claim 1 recites:

> 1. A method of delivering a substance to the nasal airway of a subject, comprising the steps of:
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> sealing one of the nostrils of a subject to an outlet of a delivery unit such as to prevent the escape of a gas flow through the one nostril;
>
> closing the oropharyngeal velum of the subject; and
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> delivering a gas flow entraining a substance through the outlet at such a driving pressure as to flow around the posterior margin of the-nasal septum and out of the other nostril of the subject, wherein the gas flow entraining a substance is provided by actuation of a supply unit device.

At page 7 of the PTE application, Applicant takes the position that claim 1 reads on the medical device component of XHANCE® because claim 1 recites a "delivery unit" and:

> "The delivery of fluticasone propionate to the nasal airway is via a 'delivery unit' and an actuation of a supply unit. The delivery unit can be a nosepiece which includes an outlet through which the gas flow is in use delivered to the one nostril and a sealing member for sealing the one nostril to the outlet such as in use to prevent the escape of the gas flow through the one nostril (column 2, lines 58-62)."

Claim 1 and the explanation provided at page 7 of the PTE application are insufficient to meet the requirement in 35 U.S.C. § 156(a) that the '844 patent must "claim" the medical device component of XHANCE® (or use of the medical device component). The '844 patent does not satisfy *Angiotech*'s particularity test. The '844 patent claims a method of delivering a substance to the nasal airway of a subject which is not limited to any particular device. The '844 patent broadly encompasses the use of any number of devices capable of administering a spray to a nasal airway. As the *Angiotech* court reasoned, just because a product may infringe a claim does not mean that the patent claims that product for purposes of 35 U.S.C. § 156(a).[22] At best, claim 1 (or any claim) of the '844 patent claims a method that can be performed by a number of products, of which the medical device component of XHANCE® is but one.[23]

The claims of the '844 patent broadly provide for a method of delivery of a substance to the nasal airway of a subject with any device, but it is important to note that not all devices capable of substance delivery to the nasal airway qualify for term extension under Title II of Hatch-Waxman. The intent of Hatch-Waxman was not to provide relief for all regulatory actions.[24] The only structure of the device that is provided in Claim 1 is an "outlet" which the method requires to be sealed to one of the nostrils". There is no description of how the XHANCE® device is covered by the patent and the XHANCE® device component is not linked to the claim language.

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[22] See *Angiotech* at 528.

[23] In *Angiotech*, the court determined that the patent at issue did not claim the product at issue (Zilver PTX) under 35 U.S.C. § 156(a), because the patent did not particularly claim Zilver PTX and instead merely claimed "a method that can be performed by a number of products, of which the Zilver PTX is but one." *Id.* at 527.

[24] See *Id.* at 528.

Hence, the '844 patent is ineligible for PTE in view of 35 U.S.C. § 156(a) when the "product" is the medical device component of XHANCE®.

(b) 35 U.S.C. § 156(a)(4) is not met when the product is the medical device component of XHANCE®

35 U.S.C. § 156(a)(4) provides that the term of a patent which claims a product shall be extended if "the product ***has been subject to*** a regulatory review period before its commercial marketing or use." [Emphasis added.] 35 U.S.C. § 156(g) sets out the meanings of the term "regulatory review period" for purposes of 35 U.S.C. § 156.[25] When the "product" is the medical device component of XHANCE®, 35 U.S.C. § 156(g)(3)(B) defines the RRP as follows:

> The regulatory review period for a medical device is the sum of —
>
> (i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
>
> (ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

Even if the date of submission of the Investigational New Drug Application for XHANCE® is considered to represent "the date a clinical investigation on humans involving the device was begun" in 35 U.S.C. § 156(g)(3)(B)(i), "an application … with respect to the device under section 515" has not been submitted, as 35 U.S.C. § 156(g)(3)(B)(i) also requires. Nor has an application under section 515 been approved, as required by 35 U.S.C. § 156(g)(3)(B)(ii). Therefore, when the text of 35 U.S.C. § 156(g)(3)(B) is considered in the most favorable light to Applicant, the RRP remains ongoing when the "product" is the medical device component of XHANCE®. The statutory language in 35 U.S.C. § 156(a)(4) stating "the product ***has been subject to*** a regulatory review period before its commercial marketing or use" has not and cannot be met. Accordingly, the '844 patent is not eligible for PTE in view of 35 U.S.C. § 156(a)(4) when the "product" is the medical device component of XHANCE®.

(c) 35 U.S.C. § 156(a)(5)(A) is not met when the product is the medical device component of XHANCE®

35 U.S.C. § 156(a)(5)(A) requires "the permission for the commercial marketing or use of the product ***after such regulatory review period*** … [to be] the first permitted commercial marketing or use of the product under the provision of law ***under which such regulatory review period occurred***." [Emphasis added.] As noted in section B.III.b above, when considering the medical device component of XHANCE® as the product, the applicable RRP is the RRP of 35 U.S.C. § 156(g)(3), and it is, at best, ongoing. Accordingly, the statutory language in 35 U.S.C.

[25] "For purposes of this section, the term "regulatory review period" has the following meanings:"

§ 156(a)(5)(A) stating "***after*** such regulatory review period" and "such regulatory review period ***occurred***" has not and cannot be met. Thus, the '844 patent is not eligible for PTE in view of 35 U.S.C. § 156(a)(5)(A) when the "product" is the medical device component of XHANCE®.

(d) 35 U.S.C. § 156(d)(1) is not met when the product is the medical device component of XHANCE®

35 U.S.C. § 156(d)(1) requires the PTE application to "be submitted within ***the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred*** for commercial marketing or use." [Emphasis added.] As noted in section B.III.b above, when considering the medical device component of XHANCE® as the product, the applicable RRP is the RRP of 35 U.S.C. § 156(g)(3), and it is, at best, ongoing, i.e., it has not "occurred." Nor has the medical device component of XHANCE® received permission under section 515, which is the relevant provision of law with respect to 35 U.S.C. § 156(g)(3). Thus, the 60-day period in 35 U.S.C. § 156(d)(1) has not yet begun when the product is the medical device component of XHANCE®. Accordingly, an application for PTE based on the product being the medical device component of XHANCE® is premature.

(e) 35 U.S.C. § 156(g)(3) is not met when the product is the medical device component of XHANCE®

As noted in section B.III.b above, when considering the medical device component of XHANCE® as the product, the RRP is the RRP of 35 U.S.C. § 156(g)(3), and it is, at best, ongoing, i.e., it has not "occurred." With no RRP under 35 U.S.C. § 156(g)(3) having occurred, the RRP for the medical device component of XHANCE®, which is the sum of the periods defined in 35 U.S.C. § 156(g)(3)(B)(i) and (ii), cannot be calculated or is at best zero days. Thus, any patent term extension under 35 U.S.C. § 156(c) based on such a RRP would also be zero days.

IV. A Regulatory Review under Section 515 Did Not Occur

As shown above, the requirements of 35 U.S.C. § 156 are not met, regardless of whether XHANCE® is treated as a drug product or a medical device. Applicant argues that when XHANCE® is treated as a medical device, the requirements of 35 U.S.C. § 156 are met, because XHANCE® "was reviewed under the same safety and efficacy requirements as would be applied to any other Class III medical device subject to a PMA."[26] In other words, Applicant argues that the medical device component of XHANCE® was subjected to a RRP which should be deemed to satisfy the requirements of 35 U.S.C. § 156(g)(3), regardless of the FDA having identified the review as a section 505 review.[27]

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[26] See, e.g., page 12 of the Request for Reconsideration and fn. 5 at page 18 of the PTE application.

[27] At page 16 of the Request for Reconsideration, Applicant states: "OptiNose's PTE applications identified these dates with respect to § 156(g)(1)(B) for a drug since the application was reviewed as an NDA, but because XHANCE® is a combination drug-device product, these dates are identical to the dates under § 156(g)(3)(B) for the

The Office has considered this additional argument, but has not found it persuasive because (a) there was no section 515 regulatory review and (b) an equivalent of a section 515 review is not permitted by statute and did not occur in any event.

(a) A regulatory review under section 515 did not in fact occur

There is no basis to conclude that a RRP under section 515 in fact occurred. Nothing on the record supports a conclusion that a section 515 review actually occurred. For example, neither the FDA's approval letter[28] nor the FDA's November 29, 2019 letter to the USPTO indicates that the FDA reviewed XHANCE® under section 515.

Moreover, Applicant had a statutory pathway by which to challenge the FDA's determination that the "primary mode of action" (PMOA) of XHANCE® is that of a drug.[29] Applicant knew that fluticasone propionate had been previously approved under section 505 and a section 505 approval for XHANCE® thus would not provide PTE eligibility in view of 35 U.S.C. § 156(a)(5)(A).[30] It would have been reasonable for Applicant, pursuant to 21 U.S.C. § 353(g)(1)(F), to challenge the FDA's PMOA determination for XHANCE®. Alternatively, Applicant could have asked the FDA to confirm on the record that XHANCE® would be receiving simultaneous review under sections 505 and 515. It appears that Applicant opted not to take either step and instead accepted the FDA's PMOA determination. Applicant's assertion that the medical device component of XHANCE® received a section 515 review is unavailing because it is not supported by the actual record of review at the FDA.

(b) XHANCE® was not subject to an equivalent section 515 review

To the extent Applicant's argument is that the medical device component of XHANCE® was subjected to a RRP that is the equivalent of a section 515 review, such an argument is also unavailing. There is no evidence to conclude that the RRP to which XHANCE® was subjected to is the equivalent of a section 515 review. Even if such evidence existed, the statute does not provide for PTE for a review equivalent to a section 515 review. Further, the text of the statute lacks any ambiguity which might suggest that the requirements of 35 U.S.C. § 156(g)(3) can be satisfied by a review equivalent to a section 515 review.

Throughout the Request for Reconsideration, and especially at pages 6-12, Applicant appears to argue that, because the device component of XHANCE® "retained its 'regulatory identity,'" the device component of XHANCE® was subjected to a regulatory review that was the equivalent of a section 515 review.[31] Yet while Applicant goes to great lengths in these sections of the Request

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medical device component. Time associated with regulatory review counts for a parallel review of both the drug component and the medical device component."

[28] See Exhibit C of the PTE application.

[29] See 21 U.S.C. § 353(g)(1)(F).

[30] See page 3, item 4, of the PTE application.

[31] For example, in fn. 7 at pages 8-9 of the Request for Reconsideration, Applicant states: "21 U.S.C. § 353(g)(8)(C) appears to contemplate that a consulting agency center in charge of reviewing Class III medical devices may complete a 'premarket review' of the medical device component of a product under § 360(e), while another agency center may complete a 'premarket review' of the drug component as an NDA under§ 355." At page

for Reconsideration to make a hypothetical case for a review that is the equivalent of a section 515 review, the record does not in any way demonstrate that an equivalent section 515 review actually happened.

Furthermore, even assuming *arguendo* that the requirements of 35 U.S.C. § 156(g)(3) could be satisfied by a review equivalent to a section 515 review, to the extent the device component of XHANCE® was reviewed during the FDA's section 505 review, Applicant has cited no evidence that such a review was equal to a section 515 review. Applicant's argument that the device component of XHANCE® was subjected to the equivalent of a section 515 review depends on the device component being a Class III device. But Applicant has not set forth any evidence in support of the position that the device component of XHANCE® is the type of medical device that the FDA would classify as a Class III medical device. Applicant's assertion in footnote 5 at page 18 of the PTE application is conclusory; there is no evidence the nasal delivery device, if reviewed separately, would qualify as a Class III device or that it underwent such a review.

A Class III designation is usually reserved for devices that sustain or support life, are implanted, or present potential unreasonable risk of illness or injury.[32] For example, implantable pacemakers, stents and breast implants are the type of devices classified as Class III, and, according to the FDA, only 10% of medical devices fall under this category.[33]

In fact, the nasal delivery device of XHANCE® does not appear to be the type of device that is classified under Class III. The constituents of XHANCE® consist of a well-known drug, fluticasone propionate, and a nasal delivery device. Given the parameters by which the FDA classifies devices, there is no basis to conclude that XHANCE® was treated as anything more than a Class II device when undergoing review under the FFDCA.[34] A Class II device undergoes a section 510(k) review.[35] 35 U.S.C. § 156 does not provide for PTE based on a section 510(k) review of a medical device.

Since there is no evidence that Applicant's nasal delivery device qualifies as a Class III medical device, or would meet the PMA requirement of section 515, then there is no basis to conclude that the review the medical device component of XHANCE® underwent should be treated as a section 515 review.

The holding and reasoning in *Angiotech* is unavailing to the Applicant. A point of distinction between *Angiotech* and the present case is that the stent device in *Angiotech* was actually

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12 of the Request for Reconsideration, Applicant states "Here, even though FDA identified the drug component of XHANCE® as the PMOA and the product was reviewed for FDA's convenience under an NDA, the device component maintained its 'regulatory identity' and was reviewed under the same safety and efficacy requirements as would be applied to any other Class III medical device subject to a PMA."

[32] See https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device (last visited July 16, 2020).

[33] See https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing (last visited July 16, 2020).

[34] See https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing (last visited July 16, 2020) ("Most medical devices are considered Class II devices.").

[35] See https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device (last visited July 16, 2020) ("If your device is classified as Class I or II, and if it is not exempt, a 510(k) will be required for marketing.").

reviewed as a Class III medical device and in fact underwent a section 515 review.[36] The district court's interpretation of the plain statutory language in *Angiotech* did not untether 35 U.S.C. § 156(f)(1)(B) from 35 U.S.C. § 156(g)(3). Therefore, when XHANCE® is treated as a medical device, it must meet the plain statutory language of 35 U.S.C. § 156(g)(3) and have been subjected to a section 515 review, which did not happen.[37]

Finally, the text of the statute lacks any ambiguity suggesting that a review equivalent to a section 515 review could be interpreted to meet the statutory requirements of a section 515 review as set forth in 35 U.S.C. § 156(g)(3)(B)(i) and (ii). The statute refers to submissions under section 515 and dates related thereto. 35 U.S.C. § 156(g)(3) only provides for PTE based on a section 515 review. The statute has no language that addresses equivalents of a section 515 review. There is no ambiguity - it provides for section 515 review and nothing else. Even if the record contained evidence sufficient to establish that the RRP to which XHANCE® was subjected to is the equivalent of a section 515 review, the Office has no authority to rewrite the language of 35 U.S.C. § 156(g)(3)(B)(i) and (ii) in order to provide for PTE in instances where the "product" is a medical device and review of the product was not under section 515.

C. CONCLUSION

Thus, for the reasons stated above, the USPTO finds that the '844 patent is not eligible for PTE based on the FDA's approval of XHANCE®. As such, the application for term extension of the '844 patent is **DENIED** as failing to comply with 35 U.S.C. § 156.

This is a **final** agency action within the meaning of 5 U.S.C. § 704 for purposes of seeking judicial review.

Any correspondence from the Applicant with respect to this matter should be submitted via the USPTO's patent electronic filing systems (EFS-Web or Patent Center) and should be addressed as follows:

Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

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[36] *Id.* at 517.

[37] See 35 U.S.C. § 156(g)(3)(B)(i) ("…and ending on the date an application was initially submitted with respect to the device under section 515…"). See 35 U.S.C. § 156(g)(3)(B)(ii) ("…the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act…").

Telephone inquiries related to this determination should be directed to Ali Salimi at (571) 272-0909.

/Brian E. Hanlon/
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Office of the Deputy Commissioner
for Patent Examination Policy

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Attention: Beverly Friedman

RE: XHANCE® (fluticasone propionate)
Docket No.: FDA-2018-E-4326