DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

Memorandum to File

From: Jay Sitlani, ORP/CDER

Date: October 30, 2015

Re: NDA 208090, Xtampza ER (oxycodone extended-release) Capsules: status of 30-month stay of approval

This memorandum was prepared in conjunction with the Office of Chief Counsel to address the status of the 30-month stay of approval for NDA 208090, Xtampza ER (oxycodone extended-release) Capsules.

Background

At issue is whether dismissal of a patent infringement action for lack of personal jurisdiction, which is later vacated[1] and transferred to another venue, terminates a 30-month stay of approval of a 505(b)(2) application. Collegium Pharmaceutical, Inc. ("Collegium"), sponsor of NDA 208090, argues that the 30-month stay for this drug was terminated. Purdue Pharma L.P. ("Purdue") argues that the stay remains in effect. For the reasons described below, we conclude that the 30-month stay currently is in effect.

Statutory and Regulatory Background

Under section 505(c)(3)(C) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), if a 505(b)(2) applicant makes a certification under section 505(b)(2)(A)(iv) and provides notice as described in section 505(b)(3), and within 45 days an "action is brought for infringement of the patent that is the subject of the certification," a 30-month stay of approval results. The statute provides specific circumstances, relating to different types of court decisions, which terminate the stay. The relevant language states:

[1] As described below, *supra* note 17, the relevant order is not expressly characterized as vacating the earlier dismissal order.

the approval [of the (b)(2) application] may be made effective upon the expiration of the thirty-month period[2] beginning on the date of the receipt of the notice provided under subsection (b)(3) of this section or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed—

(I) if the judgment of the district court is appealed, the approval shall be made effective on—

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271 (e)(4)(A) of title 35;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

[2] In certain circumstances for drugs subject to 5-year statutory exclusivity, not applicable here, a 7 ½ year period applies. *See* FD&C Act § 505(c)(3)(E)(ii); 21 C.F.R. 314.107(b)(3)(i)(B).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

Neither the above-quoted statutory text nor the implementing regulation at 21 C.F.R. 314.107[3] expressly address a circumstance in which the infringement case is dismissed without substantively addressing the patent claims and where that dismissal was subsequently vacated and the court case reinstated. In the preamble to the proposed "Abbreviated New Drug Applications and 505(b)(2) Applications" regulation ("MMA proposed rule"), FDA recently stated:

> The MMA's amendments to section 505(c)(3)(C)(i), (c)(3)(C)(ii), (j)(5)(B)(iii)(I), and (j)(5)(B)(iii)(II) of the FD&C Act clarify the timing of approval of a 505(b)(2) application or ANDA, respectively, in relation to a settlement order or consent decree stating that the patent that is the subject of the paragraph IV certification is invalid or not infringed. However, the statute does not address whether a 30-month stay may be terminated and a 505(b)(2) application or ANDA approved if the court enters an order of dismissal without a finding of patent infringement—a scenario that FDA encounters frequently. We are proposing to add § 314.107(b)(3)(viii) to codify FDA's policy that court entry of an order of dismissal, with or without prejudice, of patent infringement litigation that was timely initiated in response to notice of a paragraph IV certification will terminate the 30-month period (or 7½ years where applicable) if such order does not state a finding of patent infringement. It is appropriate that a 30-month stay terminates under these circumstances because the statutory purpose of the stay is to allow time for claims of patent infringement to be litigated prior to approval of the potentially infringing drug product. If the patent owner or exclusive patent licensee dismisses the patent infringement action on terms that the court considers proper (see Fed. R. Civ. P. Rule 41(a)(2)), then there should be no further delay of approval of a 505(b)(2) application or ANDA otherwise eligible for approval.[4]

Factual Background

In this case, Collegium has filed a 505(b)(2) application for an extended release oxycodone product that relies upon FDA's finding of safety and/or effectiveness for Purdue's OxyContin (NDA 022272). Collegium sent notice of its paragraph IV certification to Purdue, and Purdue initiated two infringement actions within 45 days, giving rise to a 30-month stay of approval under section 505(c)(3)(C) of the FD&C Act.

The chart below summarizes the relevant events pertaining to these actions:

[3] FDA has proposed revisions to 21 C.F.R. 314.107 to reflect the revisions to section 505(c)(3)(C) made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), but the regulation has not yet been amended.

[4] Proposed Rule, Abbreviated New Drug Applications and 505(b)(2) Applications, 80 Fed. Reg. 6802, 6864 (Feb. 6, 2015).

Date	Action
3/24/15	Purdue files an infringement action in the U.S. District Court for the District of Delaware ("D. Del.") (15-cv-00260).[5]
3/26/15	Purdue files an infringement action in the U.S. District Court for the District of Massachusetts ("D. Mass.") (15-cv-11294).[6]
4/6/15	Collegium moves to dismiss D. Del. action for lack of personal jurisdiction; seeks transfer to the U.S. District Court for the Southern District of New York ("S.D.N.Y.").[7]
7/23/15	Purdue voluntarily dismisses D. Mass. action under Federal Rule of Civil Procedure 41(a)(1)(A)(i).[8]
8/6/15	D. Del. dismisses action for lack of personal jurisdiction.[9]
8/6/15	Collegium files declaratory action in S.D.N.Y. seeking a determination of non-infringement and invalidity (15-cv-06179).
8/6/15	Purdue files infringement action in D. Mass. (15-cv-13099).[10]
8/7/15	Purdue files motion for "re-argument" in D. Del to vacate dismissal.[11]
9/4/15	Appeal of D. Del. decision filed in the U.S. Court of Appeals for the Federal Circuit (15-1990) (pending).
10/7/15	D. Del. issues an order to vacate its dismissal and transfers venue of the action to D. Mass.[12]

The Delaware district court's August 6, 2015 order granted in part and denied in part Collegium's motion to dismiss for lack of personal jurisdiction, or in the alternative, transfer venue to the Southern District of New York. The memorandum opinion explained that the court lacked personal jurisdiction over Collegium and the case should be dismissed under Federal Rule of Civil Procedure 12(b)(2).[13] The court denied Collegium's request to transfer venue to the Southern District of New York, reasoning that personal jurisdiction over Collegium should exist in Massachusetts, and Purdue could pursue its "protective lawsuit" filed in that district.[14] The court did not appear to be aware that Purdue had, approximately two weeks earlier, voluntarily dismissed the Massachusetts case. Neither party asserts that the decision reached the merits of the infringement claims asserted in Purdue's complaint.[15]

[5] Case 15-cv-00260, Docket No. 1.
[6] Case 15-cv-11294, Docket No. 1.
[7] Case 15-cv-00260, Docket Nos. 8, 9.
[8] Case 15-cv-11294, Docket No. 14.
[9] Case 15-cv-00260, Docket Nos. 29, 30.
[10] Case 15-cv-13099, Docket No. 1.
[11] Case 15-cv-00260, Docket Nos. 32, 33.
[12] Case 15-cv-00260, Docket No. 38.
[13] Case 15-cv-00260, Docket No. 29, at 4-11.
[14] *Id.* at 11-12.
[15] Counsel for Collegium argues, in a footnote, that Purdue has "admitted" that another district court in separate litigation found that the listed patents at issue were invalid, and this concession should serve to terminate the 30-month stay. *See* Letter from Kurt R. Karst, to Elizabeth Dickinson & Kim Dettelbach (Oct. 9, 2015), at 2-3, n.1 ("Oct. 9 Karst Letter"). Even if Collegium's characterization is valid, we interpret section 505(c)(3)(C)(i) to terminate a stay only when the court decision is in the action that gave rise to the stay in the first place. The reference to "the district court" in clause (i) is read most naturally to refer to the court adjudicating the action described immediately above in paragraph (C).

Purdue immediately filed a motion for reargument, in which it argued that Collegium had consented to personal jurisdiction in Delaware. In response to Purdue's motion for reargument, the Delaware district court issued a memorandum order on October 7, 2015 vacating the August 6, 2015 order.[16] The order explains that although Collegium stated in oral argument that "it would consent to jurisdiction in Delaware if necessary to avoid starting from scratch in Massachusetts," Collegium "did not formally consent to jurisdiction." The court ordered, however, "that rather than dismissal, the case shall be transferred to the District of Massachusetts, which was the intended destination in the first instance."[17]

The parties have submitted correspondence providing their characterization of the relevant facts and legal theories in support of their positions. On August 7, 2015, Collegium submitted a letter to FDA stating that dismissal of the Massachusetts and Delaware actions terminated the 30-month stay.[18] On October 6, Peter Mathers, counsel for Purdue, submitted a letter to FDA's Office of Chief Counsel arguing that, to date, no action had occurred that would terminate the 30-month stay.[19] Purdue argued that there was "no entry of a settlement order, consent decree or court judgment finding that the patents that underlay that action are invalid or not infringed." Purdue also argued that the "Delaware action continues to be litigated."

On October 7, 2015, Kurt Karst, counsel for Collegium, submitted a letter to FDA's Office of Chief Counsel arguing that both patent infringement actions filed by Purdue within the statutory 45-day period "have been dismissed by the courts, terminating any 30-month litigation stay."[20] Collegium argued that "[w]here no timely filed patent infringement action remains pending, there can be no 30-month stay."[21] Collegium supported this statement by referencing the MMA proposed rule passage described above. Later, on October 7, counsel for Purdue emailed the October 7, 2015 order to FDA's Office of Chief Counsel and asserted that "[b]ased on today's order, the original complaint, and the infringement claims raised therein, continue to be litigated and the 30-month stay continues in effect."[22]

On October 9, 2015, Kurt Karst, counsel for Collegium, submitted a second letter to FDA's Office of Chief Counsel. The letter asserted that "the controlling statute, FDA precedent, and FDA guidance all dictate that once a suit is dismissed for any reason, the 30-month litigation stay terminates and is not revived by a subsequent reversal or vacatur."[23] Collegium argued that the

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[16] Case 15-cv-00260, Docket No. 38, at 3. The order explains that a "motion for reargument" is the "functional equivalent" of a motion to alter or amend judgment under Fed. R. Civ. P. 59(e). *Id.* at 1.
[17] *Id.* at 3. We note that the order does not expressly state that the August 6, 2015 order was "vacated." Both parties characterize the October 7 order as vacating or "apparent[ly]" vacating the August 6, 2015 order, however, and we will adopt that terminology here. *See* Oct. 9 Karst Letter at 2; Email from Peter Mathers, to Elizabeth Dickinson & Kim Dettelbach (October 7, 2015) ("Oct. 7 Mathers Email").
[18] Letter from John F. Weet, PhD, to Sharon Hertz, M.D., FDA, Center for Drug Evaluation and Research (Aug. 7, 2015).
[19] Letter from Peter Mathers to Elizabeth Dickinson & Kim Dettelbach, FDA, Office of Chief Counsel (Oct. 6, 2015).
[20] Letter from Kurt R. Karst to Elizabeth Dickinson & Kim Dettelbach, FDA, Office of Chief Counsel (Oct. 7, 2015).
[21] *Id.* at 2-3.
[22] Oct. 7 Mathers Email.
[23] Oct. 9 Karst Letter at 1.

result is "compelled by the statute's plain language," citing to section 505(c)(3)(C)(i).[24] Collegium argued that FDA has previously taken the view that "vacatur of a judgment terminating a 30-month stay . . . by itself has no effect on FDA's ability to approve an application."[25] Collegium also cited to FDA's approval of a 505(b)(2) application for an oxaliplatin injection product and the U.S. District Court for the District of Columbia's decision rejecting a challenge to the approval.[26]

Discussion

The precise issue here is whether the Delaware district court's dismissal of the infringement action for lack of personal jurisdiction terminated the 30-month stay, even though the district court later vacated that decision and the patent issues continue to be litigated. We conclude that the stay remains in effect.

As described in the MMA proposed rule, "the statute does not address whether a 30-month stay may be terminated and a 505(b)(2) application or ANDA approved if the court enters an order of dismissal without a finding of patent infringement."[27] FDA's general policy has been that a court entry of an order of dismissal, with or without prejudice, of patent infringement litigation that was timely initiated in response to notice of a paragraph IV certification will terminate the 30-month period if the order does not state a finding of patent infringement. In the proposed MMA rule, FDA explained that "[i]t is appropriate that a 30-month stay terminates under these circumstances because the statutory purpose of the stay is to allow time for claims of patent infringement to be litigated prior to approval."[28]

To our knowledge, FDA has not addressed a case in which the order of dismissal (without a finding of patent infringement) was vacated, and the infringement action giving rise to the 30-month stay remains pending at the time FDA is ready to act on the 505(b)(2) application. Under the unique and specific facts at issue here, [29] we have determined that the 30-month stay remains in effect. The purpose of the above-described general policy is to interpret the statutory ambiguity in section 505(c)(3)(C) in a manner that furthers Congress' intent – to allow the parties time to litigate claims of patent infringement. As described in the MMA proposed rule, in the common example where the patent owner or exclusive patent licensee dismisses the patent infringement action voluntarily on terms that the court considers proper, and the litigation thereby ends, Congress' intent is served by terminating the stay. In this case, because the Delaware district court ultimately determined that its dismissal was not proper and the order of

[24] *Id.* at 2.
[25] *Id.* at 3 (citing FDA, Guidance for Industry Court Decisions, ANDA Approvals, and 180-day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act (Mar. 2000) ("Court Decision Guidance").
[26] *Id.* at 4 (citing *Sanofi-Aventis v. FDA,* 725 F. Supp. 2d 92 (D.D.C. 2010), Memorandum, Approval of ANDAs After Entry of Judgment by District Court and Stay of Judgment by Federal Circuit, Martin Shimer, Branch Chief, Regulatory Support Branch FDA/Office of Generic Drug (Aug. 7, 2009) ("Shimer Memorandum")).
[27] 80 Fed. Reg. at 6864.
[28] *Id.*
[29] We note that FDA evaluates the status of the 30-month stay only at the time a 505(b)(2) application is otherwise ready for approval.

dismissal was vacated, and the original infringement action giving rise to the stay remains pending, Congress' intent is served by considering the stay to be in effect.
Collegium argues in its October 9 letter that the outcome of this matter is dictated by the plain language of section 505(c)(3)(C)(i), FDA's approach described in the Court Decision Guidance, FDA's approval of the above-referenced 505(b)(2) application for oxaliplatin, and the district court's decision in *Sanofi-Aventis v. FDA*. We disagree. Collegium does not point to any evidence that the August 6, 2015 decision reached the substance of Purdue's patent infringement claims. Upon reviewing the memorandum opinion, we conclude that the court addressed only the jurisdictional and procedural issues of personal jurisdiction and venue. Thus, we do not believe that the order and opinion constitute the type of substantive decisions described in section 505(c)(3)(C)(i), and therefore this matter is not governed by the plain language of section 505(c)(3)(C)(i). Accordingly, Collegium misplaces its reliance on the Court Decision Guidance, FDA's approval of oxaliplatin, and the *Sanofi-Aventis* case, all of which are premised on a substantive court decision of patent invalidity or infringement.[30] Instead, as described above, we believe that the statute does not address the effect of an order of dismissal without a finding of patent infringement. Under the unique facts of this matter, where the court dismissed the relevant action for lack of personal jurisdiction and then vacated that decision before the time FDA is ready to act on the 505(b)(2) application, we believe that the 30-month stay should remain in effect for the reasons described above.

Conclusion

For the reasons described above, we conclude that the 30-month stay currently is in effect for NDA 208090 and FDA cannot grant final approval to this application at this time.

[30] *See Sanofi-Aventis*, 643 F. Supp. 2d at 86 (interpreting FD&C Act § 505(c)(3)(C)(i)(I)); Shimer Memorandum, at 2-5 (interpreting FD&C Act § 505(j)(5)(B)(iii)(I)). The Court Decision guidance concerned the pre-MMA version of section 505(j)(5)(B)(iii)(I), which stated "if before the expiration of [the 30-month period] the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision."

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/s/

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