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December 11, 2006

(Filed Electronically)

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Food and Drug Administration
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PETITION FOR STAY OF ACTION

On behalf of Purdue Pharma L.P. ("Purdue"), the undersigned submit this petition under 21 C.F.R. §§ 10.35, 314.94(a)(12)(viii)(C)(1), 314.107, 21 U.S.C. § 355(j)(5)(B)(iii), and the cases and authorities cited in the attached Plaintiffs' Motion for Order of the Statutory 30-Month Stay Under the Hatch-Waxman Act ("Motion"), requesting that the Commissioner of Food and Drugs stay the potential grant of effective approval of the abbreviated new drug application ("ANDA") # 77-822 submitted by Mallinckrodt, Inc. ("Mallinckrodt") seeking approval for oxycodone hydrochloride extended release tablets, 10, 20, 40, and 80 mg.

I. Decision Involved

The potential grant of effective approval by FDA of ANDA # 77-822 submitted by Mallinckrodt seeking approval for oxycodone hydrochloride extended release tablets, 10, 20, 40, and 80 mg.

II. Action Requested

By this Petition for Stay, the undersigned hereby request that FDA stay any pending action to grant effective approval of ANDA # 77-822 until after the United States District Court for the Southern District of New York ("District Court") has ruled on the pending Motion filed on behalf of Purdue¹ on December 9, 2006. A copy of the

¹ For simplicity, Purdue and its affiliates, The P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P., will be referred to as "Purdue" in this Petition.

KLEINFELD, KAPLAN AND BECKER, LLP

Dockets Management Branch
December 11, 2006
Page 2 of 9

Motion is attached hereto as Attachment A. The Motion seeks an Order from the Court of a 30-month stay of approval of ANDA # 77-822 under 21 U.S.C. § 355(j)(5)(B)(iii), starting from the date Purdue received a letter from Mallinckrodt purporting to provide notice of Mallinckrodt's filing, with ANDA #77-822, of a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification").

III. Statement of Grounds

A. Introduction

This Petition for Stay involves a unique set of circumstances resulting from various decisions and orders by the District Court and the United States Court of Appeals for the Federal Circuit ("Federal Circuit") declaring certain Purdue patents unenforceable and enjoining their enforcement – which decisions and orders were ultimately vacated based on a reversal by the Federal Circuit of the underlying District Court decision.

The need for this Petition for Stay arises from the fact that, during the time period in which Purdue was prevented from taking action to enforce its patent rights, Mallinckrodt filed its ANDA # 77-822, including a Paragraph IV Certification with respect to the relevant Purdue patents. Mallinckrodt's Paragraph IV Certification, as explained in its subsequent notice letter to Purdue, was based solely on the collateral estoppel effect of the decisions and orders by the District Court and Federal Circuit that have now been reversed on appeal and/or vacated. However, despite the fact that the collateral estoppel defense relied upon by Mallinckrodt has now been eliminated, Mallinckrodt has not submitted a new patent certification or provided Purdue with a new notification letter describing any legal or factual grounds on which it believes a Paragraph IV Certification might now truthfully be based. Therefore, as a result of this sequence of actions, and inactions, it appears that Mallinckrodt may intend to take unwarranted advantage of the now-vacated District Court decisions and orders in an attempt to circumvent the statutory 30-month stay provided in the Hatch-Waxman Act for ANDA applicants seeking to market generic products prior to expiration of listed patents.

In order to invoke the legal and equitable powers of the District Court to assure that the issue of infringement by the pending Mallinckrodt products can be properly litigated and resolved prior to their effective approval and launch, as contemplated by the Hatch-Waxman Act, Purdue initiated an infringement action against Mallinckrodt in the District Court on November 9, 2006, within 45 days of the date on which Purdue could first bring such an action without violating the now-vacated District Court orders, including several collateral estoppel orders based on the underlying District Court decision. Purdue has now also, on December 9, 2006, filed its Motion, requesting the District Court to order that the filing of the November 9, 2006 action against Mallinckrodt warrants invocation of the remaining portion of the statutory 30-month stay,

KLEINFELD, KAPLAN AND BECKER, LLP

Dockets Management Branch
December 11, 2006
Page 3 of 9

running from October 4, 2005, the date on which Purdue received notice of Mallinckrodt's original Paragraph IV Certification.

This Petition for Stay is being filed simultaneously with the Motion, in order to request that the FDA, consistent with the intent and purposes of the Hatch-Waxman Act and the public interest reflected in the balance struck in that Act, stay action to grant effective approval of Mallinckrodt's ANDA # 77-822, until the District Court has ruled on the pending Motion. Failure to grant the requested stay would be inconsistent with the orderly resolution of patent disputes provided for in the Act, resulting in further substantial and irreparable harm to Purdue through premature approval of yet another generic product that infringes the Purdue patents.

A more detailed explanation follows of the factual and procedural history and of the grounds for this Petition for Stay.

B. Factual Background: Purdue's Patents and The Pending Motion

Purdue's Patents.

Purdue is the holder of NDA # 20-553 for OxyContin® (oxycodone hydrochloride controlled release) Tablets ("OxyContin"). Four unexpired patents are listed in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for OxyContin, including United States Patent Nos. 5,549,912, 5,508,042, and 5,656,295 ("the '912, '042, and '295 Patents").² See Current Orange Book Excerpts, attached as Attachment B. Three companies currently hold approved ANDA's for generic versions of OxyContin: Endo Pharmaceuticals, Inc. ("Endo") (ANDA # 75-923), Teva Pharmaceuticals USA, Inc. ("Teva") (ANDA ## 76-168, 76-610), and Impax Laboratories, Inc. ("Impax") (ANDA ## 76-318, 76-446). Each of these three companies included Paragraph IV Certifications with respect to the '912, '042, and '295 Patents in their ANDA's, and Purdue sued each company for patent infringement within 45 days of receiving notice of those Paragraph IV Certifications, thus triggering the statutory 30-month stay of approval under 21 U.S.C. § 355(j)(5)(B)(iii). The ANDA's were approved following now-vacated disposition of patent litigation in the District Court, as described below, and expiration of applicable periods of 180 day generic exclusivity.

² The fourth unexpired patent listed in the Orange Book, U.S. Patent Number 5,266,331, has not been the subject of a lawsuit brought against applicants seeking to market a generic version of OxyContin.

KLEINFELD, KAPLAN AND BECKER, LLP

Dockets Management Branch
December 11, 2006
Page 4 of 9

The January 2004 Decision.

In January 2004, the District Court issued an Opinion and Order in the patent litigation against Endo, holding the '912, '042, and '295 Patents infringed by Endo, but unenforceable due to inequitable conduct ("Endo Unenforceability Order"). The District Court also enjoined Purdue from further enforcement of the '912, '042, and '295 Patents ("Endo Injunction").³ Purdue promptly filed a Notice of Appeal to the Court of Appeals for the Federal Circuit ("Federal Circuit") seeking relief from the Endo Injunction. Purdue also moved the District Court to suspend the Endo Injunction, but the court denied Purdue's motion on February 17, 2004. The next month, the Federal Circuit also denied Purdue's motion for a stay of the Endo Injunction pending the appeal.

On June 25, 2004, the District Court issued a Memorandum Order in the infringement litigation against Teva, granting Teva's motion for summary judgment of unenforceability of the '912, '042, and '295 Patents based on the collateral estoppel effect of the Endo Unenforceability Order ("Teva Collateral Estoppel Order").⁴ Similarly, on January 5, 2005, the District Court issued an Order granting a motion by Impax for summary judgment of unenforceability of the '912, '042, and '295 Patents based on the collateral estoppel effect of the Endo Unenforceability Order ("Impax Collateral Estoppel Order").⁵

In June 2005, the Federal Circuit issued an Opinion affirming the Endo Unenforceability Order.⁶ Purdue promptly filed a petition for panel rehearing and rehearing *en banc*.

³ See *Purdue Pharma L.P. v. Endo Pharms., Inc.*, Civil Action Nos. 00-CV-8029 (SHS), 01-CV-2109 (SHS), and 01-CV-8177 (SHS) 2004 U.S. Dist. LEXIS 10; 70 U.S.P.Q. 2d (BNA) 1185 (S.D.N.Y. Jan. 5, 2004).

⁴ See *Purdue Pharma L.P. v. Teva Pharms. USA, Inc.*, Civil Action Nos. 01-CV-8507 (SHS), 01-CV-11212 (SHS), and 03-CV-2312 (SHS) (S.D.N.Y.).

⁵ See *Purdue Pharma L.P. v. Impax Labs., Inc.* Civil Action No. 02-CV02803 (SHS) (S.D.N.Y.). The Court also issued a collateral estoppel order in litigation between Purdue and Roxane Laboratories, Inc., holder of NDA 20-932 for an oxycodone product substantially similar to OxyContin® ("Roxane Collateral Estoppel Order"). Although Roxane did not make statutory patent certifications in that NDA with respect to any Purdue patents, Purdue initiated an infringement action against Roxane subsequent to FDA's purported approval of the Roxane application – which approval is no longer in effect. See FDA Docket No. 99P-1589.

⁶ *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, 410 F.3d 690 (Fed. Cir. 2005).

KLEINFELD, KAPLAN AND BECKER, LLP

Dockets Management Branch
December 11, 2006
Page 5 of 9

Mallinckrodt's ANDA Filing.

By letter dated September 30, 2005, and received by Purdue on or about October 4, 2005, Mallinckrodt informed Purdue that it had filed its ANDA # 77-882 seeking approval to market generic versions of OxyContin and that the ANDA contained Paragraph IV Certifications to all patents listed in the Orange Book for OxyContin. With respect to the '912, '042, and '295 Patents, the sole basis for Mallinckrodt's claim that the patents were invalid, unenforceable, or would not be infringed by Mallinckrodt's oxycodone hydrochloride tablets was the alleged collateral estoppel effect of the Endo Unenforceability Order and the Federal Circuit's June 2005 Opinion affirming the Endo Unenforceability Order. *See* the September 30, 2005 notice letter, included as Exhibit 1 to the Motion, which is Attachment A to this Petition.

At the time of the Mallinckrodt ANDA filing and its notice letter, Purdue was precluded from suing Mallinckrodt for infringement of the '912, '042, and '295 Patents due to the Endo Unenforceability Order and Endo Injunction, and the various Collateral Estoppel Orders. Accordingly, Purdue was unable to sue Mallinckrodt for infringement within 45 days of its receipt of notice from Mallinckrodt and to invoke, at that time, its statutory right to a 30-month stay of approval of ANDA # 77-882 pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). *See* Declaration of Philip C. Strassburger, accompanying the Motion, which is Attachment A to this Petition.

The February 2006 Federal Circuit Vacatur.

In February of this year, the Federal Circuit, ruling on Purdue's petition for panel rehearing and rehearing *en banc*, withdrew its June 7, 2005 Opinion and issued a new Opinion vacating the Endo Unenforceability Order, affirming the District Court finding that Endo infringed the Purdue patents, and remanding for further proceedings.⁷ On March 29, 2006, the District Court adopted the Federal Circuit's February 1, 2006 Opinion and formally vacated its judgment of unenforceability and its injunction against enforcement of the '912, '042, and '295 Patents.⁸ On October 3, 2006, Purdue and Impax filed a Proposed Stipulated Order seeking vacatur of the Impax Collateral Estoppel Order. On October 12, 2006, the District Court vacated the Teva Collateral Estoppel Order in all respects. On October 17, 2006, Purdue and Roxane filed a Proposed Stipulated Order with the District Court seeking vacatur of the Roxane Collateral Estoppel Order.⁹

⁷ *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, 483 F.3d 1123 (Fed. Cir. 2006).

⁸ *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*, No. 00 Civ. 8029, 2006 U.S. Dist. LEXIS 15321 (S.D.N.Y. March 29, 2006).

⁹ The orders vacating the Impax and Roxane Collateral Estoppel Orders were entered by the Court on November 24, 2006.

KLEINFELD, KAPLAN AND BECKER, LLP

Dockets Management Branch
December 11, 2006
Page 6 of 9

With the Federal Circuit's February 1, 2006 Opinion and the subsequent vacatur of the Endo Unenforceability Order and Endo Injunction, as well as the District Court's vacatur of the Collateral Estoppel Orders, the '912, '042, and '295 Patents are once again presumed valid and are enforceable.

The November 9, 2006 Suit Against Mallinckrodt.

No longer prohibited from enforcing the '912, '042, and '295 Patents, Purdue and its affiliates sued Mallinckrodt for infringement on November 9, 2006, based on Mallinckrodt's filing of ANDA #77-882 containing Paragraph IV Certifications against the listed Purdue patents. The November 9, 2006 Complaint is provided as Attachment C to this Petition. On December 9, 2006, Purdue also filed its Motion, seeking an Order from the District Court of a 30-month stay of approval of ANDA # 77-822 under 21 U.S.C. § 355(j)(5)(B)(iii), starting from the date Purdue received Mallinckrodt's patent notice on October 4, 2005.¹⁰ See Attachment A.

C. The Requested Stay Is Fully Justified

Section 10.35(e) of FDA's regulations provides that a stay shall be granted if all of the following criteria are met:

- (1) The petitioner will otherwise suffer irreparable injury;
- (2) The petitioner's case is not frivolous and is being pursued in good faith;
- (3) The petitioner has demonstrated sound public policy grounds supporting the stay; and
- (4) The delay resulting from the stay is not outweighed by public health or other public interests.

As described below, each of these criteria is met, and the requested stay should therefore be granted.

¹⁰ In light of the Federal Circuit's February 2006 Opinion and subsequent activity in the District Court, Mallinckrodt's original Paragraph IV Certification and notice relying solely on collateral estoppel are inaccurate. Moreover, for those same reasons, the notice provided in Mallinckrodt's September 30, 2005, letter does not provide a detailed statement of the factual and legal basis for Mallinckrodt's position that the '912, '042, and '295 Patents are not valid, unenforceable, or not infringed, as required by 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c)(6). Accordingly, had Mallinckrodt responded appropriately to these recent developments, it would have issued a new notice under 21 U.S.C. § 355(j)(2)(B), thus affording Purdue its statutory right to trigger a 30-month stay of approval from the date of the new notice, and obviating the need for the Motion and this Petition for Stay.

KLEINFELD, KAPLAN AND BECKER, LLP

Dockets Management Branch
December 11, 2006
Page 7 of 9

First, Purdue's case is strong and compelling, and denial of this Petition for Stay would cause Purdue irreparable harm. The District Court's erroneous decision and resulting Endo Unenforceability Order and Endo Injunction have already permitted generic versions of OxyContin® to enter the market prematurely, depriving Purdue of its rights under the patent laws and the Federal Food, Drug and Cosmetic Act ("FFDCA"). The District Court should be given the opportunity to address and remedy the remaining effects of its improvidently granted Order and Injunction by ruling on the Motion. Yet, if the Agency denies this Petition for Stay and grants effective approval for ANDA # 77-822, Purdue may be deprived of its statutory right to a 30-month stay. In addition, effective approval would permit Mallinckrodt to begin sales of its generic versions of OxyContin prematurely, before the District Court has completed its established procedures for ruling on Motions and before the District Court has evaluated the merits of Purdue's patent infringement claims against Mallinckrodt.¹¹

Moreover, sound public policy requires that the stay be granted. Granting of the stay will further the deliberative process by which issues of patent infringement for generic drugs are provided by law to be litigated and resolved before a potentially infringing product is approved for marketing in less than 30 months from the date of notice of the filing. Specifically, the provisions of the FFDCA providing for the 30 month stay of approval are intended to allow sufficient time for courts to evaluate the merits of a patent infringement action before generic copies of pioneer products are granted effective approval and introduced to the market. In this way, such patent disputes are resolved in an orderly and timely manner, thus reducing the likelihood that a generic manufacturer will be found to infringe a valid and enforceable patent *after* launching its generic product. As recognized by Congress when drafting the Hatch-Waxman amendments, such a situation would destroy market share and pricing structure for the pioneer product and create crippling damage claims for the generic manufacturer. In addition, such situations are disruptive to the marketplace and to physicians, pharmacists, and their patients. In the case of Schedule II drugs such as oxycodone, failure to follow an orderly process for resolving patent disputes also entails significant problems for manufacturers and for the Drug Enforcement Administration in assuring adequate supplies of API and finished product to meet patient needs, under the manufacturing and procurement quota restrictions imposed by the Controlled Substances Act. Accordingly, it is clearly in the public interest to stay effective approval of the Mallinckrodt ANDA until the District Court has had the opportunity to consider whether to grant Purdue's Motion.

Finally, any delay resulting from the stay is not outweighed by public health or other public interests. Granting the requested stay will not unduly delay approval of

¹¹ Purdue has already suffered significant and unrecompensed harm due to the previous effective approvals of ANDAs for generic versions of OxyContin, based on the now vacated Endo Unenforceability Order and Endo Injunction. Introduction to the market of the Mallinckrodt product will cause the same type of significant financial harm.

KLEINFELD, KAPLAN AND BECKER, LLP

Dockets Management Branch
December 11, 2006
Page 8 of 9

Mallinckrodt's ANDA. In light of the September 30, 2005 date of Mallinckrodt's letter to Purdue advising of its Paragraph IV certifications, we assume that the Agency accepted the Mallinckrodt application for filing in September 2005. The median approval time for an ANDA in 2005 was 16.4 months,¹² and the Mallinckrodt ANDA is ineligible for expedited treatment under the new OGD review policy. *See Review Order of Original ANDAs, Amendments, and Supplements*, MAPP 5240.3 (Oct. 18, 2006). A stay during the time the District Court considers Purdue's Motion would therefore not unduly delay approval of ANDA # 77-822 beyond the time period expected based on past OGD experience and OGD standard first-in, first-reviewed practices. Indeed, approval of Mallinckrodt's ANDA in the near term would reflect an unusually rapid review. In any event, any delay in final approval of Mallinckrodt's generic product that may result from a stay is fully justified in light of the significant harm to Purdue and public interest considerations discussed above.¹³

IV. Conclusion

For the reasons outlined above, the undersigned request that FDA stay any pending action to grant effective approval of ANDA # 77-822 until after the District Court has issued a ruling on the pending Motion for an Order of a 30-month stay of approval of ANDA # 77-822 under 21 U.S.C. § 355(j)(5)(B)(iii), starting from the date Purdue received Mallinckrodt's patent notice on October 4, 2005.

Respectfully submitted,



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¹² CDER Report to the Nation: 2005, *Improving Public Health Through Human Drugs*, available at: <http://www.fda.gov/cder/reports/rtn/2005/rtn2005.htm>.

¹³ In this regard, we also point out that approval of the Mallinckrodt ANDA would represent the fourth approval of a generic version of OxyContin. Thus, delaying the effective approval of the Mallinckrodt application is unlikely to have a significant impact on the availability of generic versions of OxyContin. As explained above, however, failure to grant the stay could substantially compromise Purdue's ability to effectively enforce its patent rights against Mallinckrodt as contemplated by the Hatch-Waxman compromise.

KLEINFELD, KAPLAN AND BECKER, LLP

Dockets Management Branch
December 11, 2006
Page 9 of 9

Attachments:

- A Plaintiff's Motion for Order of the Statutory 30-Month Stay Under the Hatch-Waxman Act, including Exhibit 1 thereto (September 30, 2005 Letter to H. Udell from J. Boone) and Declaration of Philip C. Strassburger
- B Excerpts from Orange Book, patent listings for NDA # 20-553
- C Complaint of Patent Infringement against Mallinckrodt, Inc., 06 CV 13095 (S.D.N.Y.)