IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY, LTD., and TAP PHARMACEUTICAL PRODUCTS INC.,	)	
Plaintiffs and Counterclaim-Defendants,	)	
v.	)	C.A. No. 06-033 (SLR)
TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants and Counterclaim-Plaintiffs.	)	

FINAL PRETRIAL ORDER

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Dated: October 8, 2007

On October 15, 2007, at 4:30 p.m., counsel for Plaintiffs and Counterclaim-Defendants Takeda Pharmaceutical Company Limited ("Takeda") and TAP Pharmaceutical Products, Inc. ("TAP") (collectively, "Plaintiffs") and counsel for Defendant and Counterclaim-Plaintiffs Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Industries") (collectively, "Teva") will attend a final pretrial conference before this Court.

The following matters as to the trial, commencing on October 29, 2007, are hereby ordered by the Court. This Order shall control the subsequent course of the action unless modified by the Court to prevent manifest injustice.

I. NATURE OF THE ACTION AND PLEADINGS

1. This action arises under the Patent Laws of the United States of America, Title 35, United States Code and asserts infringement of two patents owned by Takeda and exclusively licensed to TAP: U.S. Patent Nos. 4,628,098 ("the '098 patent") and 5,045,321 ("the '321 patent").

2. Plaintiffs filed a Complaint for infringement on January 17, 2006, asserting that Teva USA's submission of Abbreviated New Drug Application ("ANDA") No. 77-255 with the United States Food and Drug Administration ("FDA") infringes the '098 patent and the '321 patent. (D.I. 1). Teva USA filed its answer and counterclaims on February 6, 2006, alleging that the products covered by ANDA No. 77-255 did not infringe the '098 and '321 patents and that the asserted patents were invalid. (D.I. 9). On June 13, 2006, Plaintiffs amended the Complaint to add Teva USA's parent company, Teva Industries, as a party. (D.I. 36).

3. Plaintiffs' Complaint, as well as subsequent pleadings, contain allegations regarding three additional patents: U.S. Patent Nos. 5,026,560, 5,093,132 and 5,433,959.

Allegations relating to these patents were dismissed with prejudice pursuant to a stipulation of the parties on January 23, 2007 and are not at issue. (D.I. 92)

4. On July 3, 2007, the Court granted in part and denied in part a motion by Teva seeking leave to file an Amended Answer to assert additional defenses and counterclaims of unenforceability of the '098 patent based on allegations of inequitable conduct. (D.I. 120). Specifically, the Court granted Teva's motion "to the extent that defendants are asserting that plaintiff Takeda committed inequitable conduct during the prosecution of the application that resulted in the '098 patent" and denied Teva's motion "with respect to the second ground, that is, that plaintiff Takeda's petition for a patent term extension for the '098 patent was improper." Pursuant to that order, Teva filed an Amended Answer and Counterclaim on July 10, 2007. (D.I. 121). Plaintiffs replied to Teva's Amended Counterclaims on July 24, 2007, denying the additional allegations. (D.I. 123).

II. FEDERAL JURISDICTION

1. This action is based upon the Patent Laws of the United States, Title 35 of the United States Code. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and 1400(b).

2. Teva has filed counterclaims for declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the counterclaims under 28 U.S.C. §§ 2201, 1331, 1337(a), 1338(a) and 1367 based on an actual case or controversy arising under the Patent Laws of the United States.

3. Plaintiffs and Teva do not contest personal jurisdiction over them in this Court.

4. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

III. STATEMENT OF ADMITTED FACTS

A. The Parties

1. Takeda is a Japanese corporation, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan.

2. TAP is a Delaware corporation, having a principal place of business at 675 North Field Drive, Lake Forest, Illinois 60045.

3. Teva Industries is an Israeli corporation, having a principal place of business located at 5 Basel St., Petach Tikva 49131, Israel. Teva USA is a Delaware corporation, having a principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania 19454.

4. Takeda manufactures Prevacid® (lansoprazole delayed-release capsules). TAP sells Prevacid® (lansoprazole delayed release capsules) in the United States.

B. The '098 Patent

5. On December 9, 1986, the United States Patent and Trademark Office ("PTO") issued the '098 patent, entitled "2-[2-Pryidylmethylthio-(Sulfinyl)-]Benzimidazoles."

6. The '098 patent lists Akira Nohara and Yoshitaka Maki as the inventors thereof, and identifies Takeda Chemical Industries, Ltd. as the assignee.

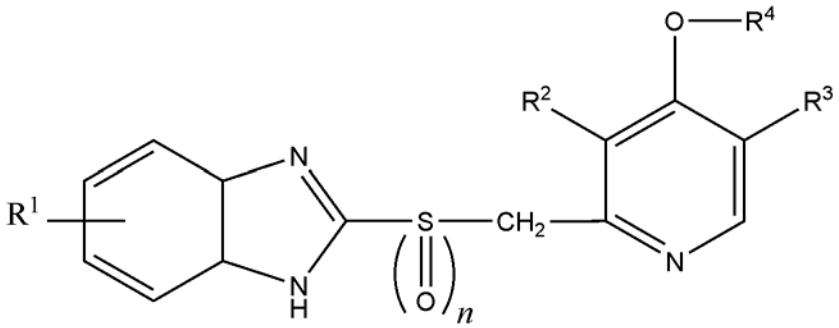
7. TAP is the exclusive licensee of the '098 patent.

8. The '098 patent issued from United States Patent Application 760,568, filed July 29, 1985 and claims priority to Japanese Patent Application No. 59-171069, filed August 16, 1984.

9. The '098 patent expires May 10, 2009 inclusive of a term extension under 35 U.S.C. § 156 granted by the PTO on January 6, 1997.

10. Plaintiffs are asserting infringement of claim 10 of the '098 patent in this action. Claim 10 of the '098 patent is dependent on claim 1 of the '098 patent. Claim 1 of the '098 patent reads:

A compound of the formula



wherein R^1 is hydrogen, methoxy or trifluoromethyl, R^2 and R^3 are independently hydrogen or methyl, R^4 is a C_{2-5} fluorinated alkyl and n denotes 0 or 1, and a pharmacologically acceptable salt thereof.

11. Claim 10 of the '098 patent reads:

A compound according to claim 1, wherein the compound is 2-[3-methyl-4-(2,2,2-trifluoroethoxy)-pyrid-2yl]methylsulfinylbenzimidazole.

12. The compound described in claim 10 of the '098 patent is lansoprazole.

13. The lansoprazole compound described in claim 10 of the '098 patent is manufactured and sold by Takeda and TAP under the trade name "Prevacid®."

14. The United States Food & Drug Administration ("FDA") approved TAP's New Drug Application ("NDA"), NDA No. 20-406, for 15 and 30 mg Prevacid® (lansoprazole) delayed-release capsules on May 10, 1995.

15. The '098 is listed in a publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") as covering Prevacid®(lansoprazole) 15 and 30 mg delayed release capsules.

C. The '321 Patent

16. On September 3, 1991, the PTO issued the '321 patent, entitled "Stabilized Pharmaceutical Composition and Its Production."

17. The '321 patent lists Tadashi Makino, Tetsuro Tabata and Shin-ichiro Hirai as the inventors thereof, and identifies Takeda Chemical Industries, Ltd. as the assignee.

18. TAP is the exclusive licensee of the '321 patent.

19. The '321 patent issued from United States Patent Application 14,303, filed February 13, 1987 and claims priority to Japanese Patent Application No. 61-29567, filed February 13, 1986 and Japanese Patent Application No. 61-38059, filed February 21, 1986.

20. The '321 patent expires September 3, 2008.

21. Plaintiffs are asserting infringement of claim 2 of the '321 patent in this action.

22. Claim 2 of the '321 patent depends from claim 1 of the '321 patent. Claim 1 of the '321 patent reads:

> A pharmaceutical composition, wherein the composition is made up into tablets or granules and then coated by a coating agent, which comprises an effective amount of the anti-ulcer compound 2-[[3-methyl-4-(2,2,2-trifluoroethoxy-2-pyridyl]methylsulfinyl] benzimidazole, and at least one of the basic inorganic salts of magnesium and calcium selected from heavy magnesium carbonate, magnesium carbonate, magnesium oxide, magnesium hydroxide, magnesium metasilicate aluminate, magnesium silicate aluminate, magnesium silicate, magnesium aluminate, synthetic hydrotalcite, aluminum magnesium hydroxide, precipitated calcium carbonate and calcium hydroxide; the amount of the basic inorganic salt relative to parts by weight of the benzimidazole

> compound being about 0.3-20 parts by weight; the benzimidazole compound being in contact with the basic inorganic salt evenly.

23. Claim 2 of the '321 patent reads:

> A pharmaceutical composition as claimed in claim 1, wherein the basic inorganic salt of magnesium is magnesium carbonate.

24. The formulation described in claim 2 of the '321 patent is used in the product sold and marketed by Takeda and TAP under the trade name "Prevacid®."

25. The '321 patent is listed in the Orange Book as covering Prevacid® (lansoprazole) 15 and 30 mg delayed-release capsules.

D. Teva's ANDA

26. On August 27, 2004, Teva USA submitted Abbreviated New Drug Application ("ANDA") No. 77-255 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act seeking FDA approval to engage in the commercial manufacture, use, offer for sale and sale of a generic version of 15 and 30 mg dosages of lansoprazole delayed release capsules.

27. Teva submitted to the FDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii) ("the Paragraph IV certification"). Plaintiffs have received a letter dated December 5, 2005 from Teva USA notifying them of the Paragraph IV certification in ANDA No. 77-255.

28. Plaintiffs commenced this action on January 17, 2006, within 45 days of the date they received Teva USA's notice of ANDA No. 77-255 containing the Paragraph IV certification, as required by 21 U.S.C. § 355(j)(5)(B)(iii).

29. Teva continues to seek approval of ANDA No. 77-255 from the FDA.

30. Teva USA and Teva Industries admit that the proposed lansoprazole delayed release capsule products described in ANDA No. 77-255 contain 2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl]methyl]sulfinyl] benzimidazole.

31. Teva has agreed that Teva's proposed lansoprazole delayed-release capsule products described in ANDA No. 77-255 would infringe Claim 10 of the '098 patent if sold in the United States prior to the expiration of the '098 patent if Claim 10 is found to be valid and enforceable by the Court.

IV. ISSUES OF FACT REMAINING TO BE LITIGATED

A. Plaintiffs

Plaintiffs' statement of issues of fact that remain to be litigated is attached as Exhibit 1.

B. Defendants

Teva's statement of issues of fact that remain to be litigated is attached as Exhibit 2.

V. ISSUES OF LAW REMAINING TO BE LITIGATED

A. Plaintiffs

Plaintiffs' statement of issues of law that remain to be litigated is attached as Exhibit 3.

B. Defendants

Teva's statement of issues of law that remain to be litigated is attached as Exhibit 4.

VI. EXHIBITS

A. Plaintiffs

Plaintiffs' trial exhibit list is attached as Exhibit 5.

B. Defendants

Teva's trial exhibit list is attached as Exhibit 6.

C. Stipulations Regarding Exhibits

1. Plaintiffs provided their exhibit list to Teva on October 1, 2007, and Teva provided their exhibit list to Plaintiffs on October 4, 2007. The parties will exchange electronic versions of exhibits and one hard copy of the listed exhibits by October 12, 2007.

2. The parties agree to promptly disclose any supplemental exhibits within a reasonable period after identification. Reasonable supplementation of exhibit lists will be allowed until 9:30 am on October 26, 2007. Electronic and one hard copy set of supplemental exhibits shall be provided by no later than the following day.

3. The parties will disclose the exhibits they intend to use in direct testimony of their witnesses by no later than 7 p.m. two calendar days before the witness is to testify. Objections to any of the exhibits disclosed for a witness shall by made by no later than 7 p.m. the following calendar day. Objections to the exhibits need not be disclosed any earlier.

4. The parties agree that they will each disclose to the other any demonstrative exhibits and the names of the witnesses who will discuss the exhibits no later than 7 p.m. one calendar day before the demonstrative exhibits are used at trial unless raised earlier with the Court. Any objections to demonstratives will be made no later than 11 p.m. the same day.

5. The listing of an exhibit by one party does not constitute a waiver by that party of any objection to that exhibit if it is offered by the other party.

6. Each party reserves the right to offer an exhibit designated by the other party, even if not introduced by the designating party.

7. Legible copies of United States and foreign patents, and the contents of associated file histories, may be offered and received in evidence in lieu of certified copies thereof, subject to all other objections which might be made to admissibility of certified copies. The dates of filing and issuance and the identity of the inventors of record shall be deemed to be shown on the face of the patent or in the associated file history, subject to the right of the party against whom it is offered to adduce evidence to the contrary.

8. Legible copies of printed publications may be offered and received in evidence in lieu of certified copies thereof, subject to all other objections which might be made to admissibility of certified copies.

VII. WITNESSES

A. Plaintiffs' Witnesses

Plaintiffs' list of witnesses they may call to testify in person at the trial is attached as Exhibit 7. The deposition testimony that Plaintiffs may offer into evidence is listed in Exhibit 8.

As detailed in Exhibit 8, Plaintiffs also object to Teva's designation of the depositions of Paul Fackler because he is a current employee of Teva, within Defendants' control, and moreover within the 100 mile subpoena power of the Court. Plaintiffs requested that these witnesses be treated as "unavailable" and that Plaintiffs be allowed to designate testimony from them instead of issuing trial subpoenas.

As detailed in Exhibit 8, Plaintiffs also object to Teva's designation of the depositions of Jamie Boulet, Henry Jacoby and Gao Dong. These witnesses are within Teva's control. Moreover, these "experts" were not identified as required under Fed. R. Civ. P.

26(a)(2)(C) and did not submit expert reports. In addition, all three witnesses are within 100 miles of this Court and, thus, should instead be brought to trial as live witnesses.

B. Defendants' Witnesses

Teva's list of witnesses they may call to testify in person at the trial is attached as Exhibit 9. The deposition testimony that Teva may offer into evidence is listed in Exhibit 10.

Teva disputes Plaintiffs' objection to Teva's designation of deposition testimony from four witnesses – Paul Fackler, Jamie Boulet, Henry Jacoby and Gao Dong. With respect to Mr. Fackler, Teva allowed Plaintiffs to treat Mr. Fackler as "unavailable" for purposes of trial and to designate testimony from his deposition transcript instead of issuing a trial subpoena if they so chose. Teva maintains that the treatment of Mr. Fackler as "unavailable" should apply equally to Teva and allow Teva to designate from his deposition transcript.

With respect to Mssrs. Boulet, Jacoby and Dong , they are all employees of Product Safety Laboratories ("PSL"), a third party that was contracted to perform testing of various compounds for Teva. These fact witnesses are not under Teva's control, and Teva cannot require PSL's employees to attend trial.

C. Stipulations Regarding Witnesses

1. The parties will disclose the anticipated order of the witnesses they intend to call at trial no later than October 26, 2007. The identification of witnesses shall include both live witnesses and witnesses whose testimony will be read in from a deposition. A party shall promptly notify the opposing party of any change to the identity of witnesses or the anticipated order of witnesses.

2. During trial, the parties will disclose that a witness is expected to testify and the approximate amount of time that the witness is expected to testify by no later than 7 p.m. two calendar days before the witness is to testify. The identification of witnesses shall include

both live witnesses and witnesses who testimony will be read in from a deposition. For deposition testimony, the party shall identify the specific testimony that is anticipated to be read into the record. The opposing party will then have one business day to identify the specific counter-designated testimony that is anticipated to be read into the record.

3. In the event a party determines that a witness previously identified as a testifying witness is no longer anticipated to testify, that party shall give prompt notice and the opposing party shall have 48 hours to designate testimony from the witnesses deposition. Counter-designations shall be provided 24 hours from receipt of the initial designations.

4. In the event a party determines that a witness previously identified as a non-testifying witness will testify at trial, that party shall give notice of that witness prior to the completion of the Pre-Trial Conference. Once such notice is given, any designations or counter-designations of deposition testimony for that witness identified in the Pre-Trial Order shall be stricken. Absent good cause found by the Court, there shall be no additional testifying witnesses identified after completion of the Pre-Trial Conference.

VIII. INTENDED PROOF

A. Plaintiffs' Statement

Plaintiffs' statement of intended proof in support of Plaintiffs' claims is attached as Exhibit 11.

B. Defendants' Statement

Teva's statement of intended proof in support of Defendants' claims is attached as Exhibit 12.

C. Issue Concerning Order of Presentation of Proof

1. Plaintiffs' Statement

There are two patents-in-suit: the '098 compound patent and the '321 formulation patent. Defendants concede infringement of the '098 patent, but challenge infringement of the '321 patent. Thus, Plaintiffs will be proceeding first at the trial to present their case on infringement, on which they have the burden of proof.

Plaintiffs request the ability to present their validity and enforceability witnesses in their case-in-chief on infringement. The reason for this is two fold. First, a number of the witnesses who will testify on validity and enforceability will also be providing context and background testimony on the inventions and products as part of Plaintiffs' direct case on infringement. It will be disjointed for the presentation and burdensome on the witnesses to have to bring them back to testify in Plaintiffs' rebuttal case. Second, some of these witnesses have scheduling issues that will make it very difficult to call them in the second week of the trial.

This is a bench trial, so there will be no confusion concerning which side has the burden of proof. Hence, Plaintiffs gain no advantage. The proceedings will be streamlined by proceeding as Plaintiffs propose. Moreover, Plaintiffs recognize that by presenting their validity and enforceability witnesses in their case-in-chief they will not have the opportunity to respond to Defendant's case on those issues absent the Court's permission.

2. Defendants' Statement

The issues to be tried relating to the '321 formulation patent and the '098 compound patent have little overlap. The '321 patent issues will focus on whether the lansoprazole in Teva's ANDA product is "in contact … evenly" with magnesium carbonate in that product, and whether prior art renders obvious the claimed formulation. In contrast, the '098 patent issues will focus on the obviousness of the claimed compound in light of prior art

compounds with the same structure, and whether Plaintiffs can enforce the patent in light of the selective presentation of data to the U.S. Patent and Trademark Office.

Teva submits that it would be most efficient for the Court to hear the entirety of the '321 patent issues first and then the '098 patent issues. However, if the Court prefers not to hear the issues for each patent separately, Teva requests that the parties present their witnesses at trial in the order of the burden of proof on the issues to be heard by the Court: (1) Plaintiffs' infringement case on the '321 patent, (2) Teva's response to Plaintiffs' infringement case, (3) Teva's invalidity case on the '321 and '098 patents and unenforceability case on the '098 patent, and (4) Plaintiffs' response to Teva's invalidity and unenforceability case.

Allowing the parties to present their case in order of burden of proof will not be burdensome to Plaintiffs' witnesses given the distinct nature of the issues relating to the '321 and '098 patents. Seven of the ten witnesses that Plaintiffs may call in this action are expert consultants. Plaintiffs' experts on the alleged infringement of the '321 patent have not provided opinions on the invalidity of the '321 patent or the invalidity and unenforceability of the '098 patent. Likewise, Plaintiffs' experts on the invalidity of the '321 patent and the invalidity and unenforceability of the '098 patent have not provided opinions on the alleged infringement of the '321 patent. Thus, Plaintiffs' will not have to call its expert witnesses twice if the issues are tried according to burden. Teva further submits that the remaining three fact witnesses likely would only be called to testify once if the issues were tried by burden. Finally, while Teva appreciates that Plaintiffs have scheduling issues, Teva has abundant scheduling challenges as well.

Moreover, proceeding according to burden has a number of advantages and would not lead to a disjointed presentation as Plaintiffs suggest. For example, the Court will have the opportunity to hear Teva's case-in-chief on invalidity and unenforceability of the '098 patent

before being presented with Plaintiffs' opposition on those issues. Second, Plaintiffs' will not have to assume what evidence will be presented in Teva's case-in-chief on invalidity and unenforceability of the '098 patent if Plaintiffs hear that case-in-chief first.

IX. SETTLEMENT EFFORTS

The parties hereby certify that two-way communication has occurred between persons having authority in a good faith effort to explore the resolution of the controversy by settlement, but the parties have not reached agreement to resolve this controversy by settlement.

X. ADDITIONAL STIPULATIONS

A. *Daubert* Motions

The parties agree to defer any *Daubert* challenges until post-trial briefing. However, the parties agree that before any witness for whom a party anticipates pursuing a *Daubert* challenge begins testimony, the party anticipating the later challenge will give notice that the challenge may be made in post-trial briefing and state the reasons for the potential challenge.

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Attorneys for Defendants, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.

Dated: October 8, 2007

SO ORDERED this _____ day of _____, 2007.

_____
UNITED STATES DISTRICT JUDGE