IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTICALS USA, INC., *Plaintiffs,* *v.* TORRENT PHARMACEUTICALS LTD. and TORRENT PHARMA INC., *Defendants.*	Civil Action No. 07-024-JJF

EXPEDITED MOTION FOR DISCOVERY OF PROCESS INFORMATION

1. Plaintiffs Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") hereby request that the Court issue an Order directing Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively, "Torrent") to disclose immediately the method by which it manufactures a drug substance known as sertraline hydrochloride ("sertraline").

2. As alleged in its Complaint, Teva believes that there is a substantial likelihood that Torrent intends to market sertraline bulk active pharmaceutical ingredient ("API") in the U.S. imminently, and that Torrent's manufacturing method for this API infringes one or more patents owned by Teva.

3. Teva has made every reasonable effort to obtain from Torrent a disclosure of its manufacturing process, so that Teva could ascertain in advance of Torrent entering the market whether the process infringes Teva's patents. Torrent has completely ignored these requests.

4. With no other option, Teva now seeks the Court's assistance in compelling disclosure of this information – in advance of Torrent entering the market – so that Teva may ascertain whether it has grounds to seek preliminary injunctive relief and/or to maintain this infringement action to protect its patent rights.

I. BACKGROUND

5. Teva currently manufactures and sells generic sertraline tablets in the U.S., as well as sertraline API for use in the manufacture of finished pharmaceutical products such as tablets. Teva sells tablets under an Abbreviated New Drug Application ("ANDA") filed with the U.S. Food & Drug Administration ("FDA") and API under a Drug Master File ("DMF") also filed with the FDA.

6. A number of other companies have filed ANDAs with the FDA seeking permission to market sertraline tablets in the U.S., and a number of companies have filed DMFs with the FDA in order to sell API to the ANDA holders. However, Teva was granted a six month period of generic exclusivity in the U.S. under the Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (1994), meaning that none of these other companies could legally market their sertraline products in the U.S. during that period. Teva's exclusivity will expire on February 6, 2007. On or shortly after February 7, Teva believes that a number of companies will enter the market with competing sertraline tablets and API.

7. Torrent is one such company. Torrent has filed a DMF for sertraline API with the FDA, indicating its intention to supply one or more ANDA holders poised to enter the market with sertraline tablets on or shortly after February 7, 2007. Teva believes that Torrent will indeed begin to supply sertraline API to such ANDA holder(s) on or shortly after that date.

8. As explained in the Complaint, D.I. #1, Teva owns four U.S. patents which claim methods of making sertraline. Teva believes there is a substantial likelihood that the sertraline API supplied by Torrent is, or will be, made by a method which infringes one or more claims of those patents. In seeking to protect its patent rights, Teva has faced a conundrum. After a reasonable inquiry, Teva has been unable to ascertain Torrent's manufacturing method from any public source. Teva's only remaining option has been to seek voluntary disclosure of the method from Torrent itself, which Teva did. Teva also offered to keep Torrent's manufacturing information strictly confidential. Torrent has ignored Teva's request.

9. With Torrent poised to enter the market and begin potentially infringing Teva's patents as soon as February 7, 2007, and with no other options left to it, Teva filed a Complaint against Torrent in this Court. Such a filing is entirely consistent with Federal Circuit law, which holds that a patentee may file a Complaint and seek the assistance of the Court in obtaining information to confirm or deny suspected infringement, when the potential infringer refuses to answer a reasonable request for the information and the patentee cannot otherwise discover it. *Hoffman-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1364-65 (Fed. Cir. 2000). Should the information so obtained reveal that a claim of infringement cannot be supported, the patentee is required to withdraw the Complaint. Teva stands ready to do so.

10. After Teva filed the Complaint and sent a courtesy copy to Torrent, it waited for a period of time to see whether Torrent would respond to its request for information. Torrent has continued to ignore Teva. Again, with the clock ticking and with no other option left to it, Teva has now formally served the Complaint on Torrent and brings the instant motion.

II. ARGUMENT

11. Rule 26, Fed. R. Civ. P., grants Courts broad discretion in the timing and sequence of discovery. *See, e.g.,* Rule 26(d) (stating that discovery may be had of a party prior to the parties' Rule 26(f) conference by "order"). Courts may use this discretion to order a defendant to divulge limited discovery before filing its response to the Complaint where good cause has been shown and it is reasonable in light of all the surrounding circumstances to do so. *See Ayyash v. Bank Al-Madina,* 233 F.R.D. 325, 326 (S.D.N.Y. 2005). Indeed, where such discovery is needed to more fully develop the record prior to a preliminary injunction hearing, it is routinely granted. *See, e.g., Merrill Lynch, Pierce, Fenner & Smith, Inc. v. O'Connor*, 194 F.R.D. 618, 624 (N.D. Ill. 2000).

12. Here, Teva has good cause for bringing this motion. Teva has been unable to obtain the requested discovery from a public source, and Torrent has refused to provide it voluntarily to Teva. Torrent should not be permitted to defeat Teva's efforts to enforce its patent rights against potential infringers poised to enter the market simply by ignoring Teva's request.

13. Teva's request is also reasonable. Instead of filing an expensive, time-consuming and potentially unnecessary preliminary injunction motion, Teva has filed a motion seeking only the discovery needed to determine whether such a motion is appropriate.[1] Teva has taken this approach to conserve the parties' and the Court's resources and yet position itself to fully protect its patent rights should Torrent decide to enter the market.

---

[1] Teva has filed civil actions in other District Courts against holders of ANDAs and/or DMFs relating to sertraline. *See, e.g.,* Civil Action Nos. 2:07-cv-196, -240, -241, -242, -243, -244, 245, -246, -247 and -248 (WHW) (D. N.J.) Of these actions, Teva has effected formal service on – and brought motions seeking discovery from – only the defendants named in this action and in 2:07-cv-242 and -247 (WHW) (D. N.J.). Other defendants have demonstrated at least some willingness to cooperate with Teva's requests for disclosure of their manufacturing processes. Teva is continuing to work with these other defendants to obtain such disclosures.

14. In addition, the discovery Teva seeks is extremely limited and cannot reasonably be construed as being burdensome to Torrent. Teva seeks only the handful of pages from Torrent's DMF which set forth the steps and materials employed in Torrent's manufacturing process. Producing this information would require five minutes and a fax machine. Further, to safeguard its confidentiality, Teva is willing to accept this information on an "outside counsel's eyes only" basis pending the entry of a more comprehensive Protective Order in the litigation.

15. Accordingly, Teva respectfully requests that its Proposed Order be GRANTED and that Torrent be required to disclose to Teva within one business day the portion of its DMF which discloses its manufacturing method for sertraline API.

16. In addition, in light of the imminence of Torrent's entry into the market, Teva respectfully requests that the Court grant an expedited hearing on the matter at the Court's earliest convenience.

Dated: January 29, 2007

YOUNG CONAWAY STARGATT & TAYLOR, LLP



Josy W. Ingersoll (No. 1088)
John W. Shaw (No. 3362)
The Brandywine Building
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, DE 19899-0391
Phone (302) 571-6600
Fax (302) 571-1253
jingersoll@ycst.com

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

OF COUNSEL:

KENYON & KENYON LLP
Steven J. Lee, Esq.
Robert V. Cerwinski, Esq.
One Broadway
New York, NY 10004-1050
Phone (212) 425-7200
Fax (212) 425-5288

CERTIFICATE OF SERVICE

I, Josy W. Ingersoll, hereby certify that on January 29, 2007, copies of the foregoing document were caused to be served on the following in the manner indicated:

BY HAND DELIVERY

Torrent Pharmaceuticals Ltd.
c/o Secretary of State
Division of Corporations
John G. Townsend Building
401 Federal Street, Suite 4
Dover, DE 19901

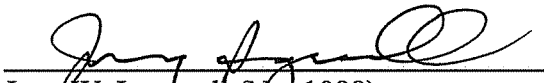
Torrent Pharmaceuticals Ltd.
c/o Torrent Pharma, Inc.
Corporation Service Company
2711 Centerville Road, Suite 400
Wilmington, DE 19808

Torrent Pharma, Inc.
c/o Corporation Service Company
2711 Centerville Road, Suite 400
Wilmington, DE 19808

BY FIRST CLASS MAIL

Torrent Pharmceuticals Ltd.
Off. Ashram Road
Ahmedabad – 380 009
Gujarat, India

YOUNG CONAWAY STARGATT & TAYLOR, LLP



Josy W. Ingersoll (No. 1088)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
jingersoll@ycst.com

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

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTICALS USA, INC., *Plaintiffs,* *v.* TORRENT PHARMACEUTICALS LTD. and TORRENT PHARMA INC., *Defendants.*	Civil Action No. 07-024-JJF

ORDER FOR DISCOVERY

THIS MATTER having come before the Court upon application of Young Conaway Stargatt & Taylor, LLP and Kenyon & Kenyon LLP, counsel for Plaintiffs, for an Order granting Plaintiffs certain discovery of Defendants, and the Court having reviewed the moving papers and any opposition thereto, and for good cause shown,

IT IS ON THIS ____ DAY OF _____, 2007

ORDERED that within one (1) day of the entry of this Order, Defendants shall produce to Plaintiffs' counsel at the offices of Kenyon & Kenyon LLP, the portion of Torrent Pharmaceuticals Ltd.'s Drug Master File ("DMF") No. 18311, and any other applicable DMF, which discloses the method by which the sertraline hydrochloride API contained in Defendants' products for the U.S. market is made.

_____
Joseph J. Farnan, Jr.
United States District Court Judge