

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TARO PHARMACEUTICALS U.S.A., INC.,
Petitioner,

v.

APOTEX TECHNOLOGIES, INC.,
Patent Owner.

Case IPR2017-01446
U.S. Patent No. 7,049,328

Title: USE FOR DEFERIPRONE

PATENT OWNER'S MOTION TO EXPUNGE

I. STATEMENT OF PRECISE RELIEF REQUESTED

Pursuant to 37 C.F.R. § 42.56, Patent Owner, Apotex Technologies, Inc. (“Apotex”), hereby requests that certain confidential information in the record be expunged. Specifically, Apotex requests expungement of Exhibits 1037-1043 and 1047-1049 from the record in this proceeding.¹

II. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. Procedural Background

Petitioner, Taro Pharmaceuticals U.S.A., Inc. (“Taro”), filed a petition for *Inter Partes* Review of U.S. Patent No. 7,049,328 (“the ’328 patent”) on May 16, 2017. (Paper 1.) On September 11, 2017, Apotex filed its Preliminary Response under 37 C.F.R. § 42.107. (Paper 6.) On September 28, 2017, the Board instituted an *inter partes* review of certain claims of the ’328 patent. (Paper 7.)

On April 16, 2018, Taro filed a redacted Motion to Compel Routine Discovery or, in the Alternative, for Additional Discovery relating to Exhibits 1037-1045 and 1047-1049 (Paper 22) along with a Motion to Seal (Paper 21). In response, Apotex filed a redacted paper opposing Taro’s Motion to Compel Routine Discovery or, in the Alternative, for Additional Discovery (Paper 30), and also filed a Motion to Seal (Paper 31). On May 11, 2018, the Board denied

¹ Petitioner, Taro Pharmaceuticals U.S.A., Inc., does not oppose this Motion.

without prejudice both Apotex's and Taro's Motion to Seal. (Paper 34 at 3.) The Board, however, authorized each party to file a Second Motion to Seal for the purpose of requesting to seal Exhibits 1037-1045 and 1047-1049. (*Id.* at 4.) On May 25, 2018, Apotex filed an unopposed Second Motion to Seal (Paper 35), which requested that Exhibits 1038-1043 and 1047-1049 be sealed, that certain portions of Exhibit 1037 be sealed. Concurrently, Apotex filed a non-confidential, redacted public version of Exhibit 1037, as Exhibit 2039. (*Id.*) On June 5, 2018, the Board granted Apotex's Second Motion to Seal in light of the "stated confidentiality" of Exhibits 1037-1043 and 1047-1049. (Paper 37 at 4-5.)

On August 6, 2018, pursuant to 35 U.S.C. § 317(a) (and 37 CFR § 42.72), the parties filed a Joint Motion to Terminate *Inter Partes* Review. (Paper 61.) And, on August 7, 2018, the Board granted that Motion. (Paper 65.)

B. Applicable Legal Standards

Section 6 of the Office Trial and Practice Guide provides in pertinent part:

There is an expectation that information will be made public where the existence of the information is referred to in a decision to grant or deny a request to institute a review or is identified in a final written decision following a trial. A party seeking to maintain the confidentiality of information, however, may file a motion to expunge the

information from the record prior to the information becoming public.

37 C.F.R. § 42.56 provides that, “[a]fter denial of a petition to institute a trial or after final judgment in a trial, a party may file a motion to expunge confidential information in the record.”

C. Good Cause Exists to Expunge Exhibits 1037-1043 and 1047-1049 from the Record in this Proceeding

There is good cause to expunge Exhibits 1037-1043 and 1047-1049 from the record in this proceeding. While the public’s interest is served by maintaining a complete and understandable file history, Exhibits 1037-1043 and 1047-1049 refer to and include Apotex’s confidential research, development, and commercial information. Such information is of the exact type that the Board has acknowledged that it has an “interest in protecting” Office Trial and Practice Guide at 48760 (stating that the “rules aim to strike a balance between the public’s interest in maintaining a complete and understandable file history and the parties’ interest in protecting truly sensitive information” where confidential information is identified as “confidential research, development, or commercial information.”) (77 Fed. Reg. 48756, 48760 (Aug. 14, 2012)).

Provided below is a concise explanation of the confidential nature of Exhibits 1038-1043 and 1047-1049, and portions of Exhibit 1037:

- **Ex. 1037:** The redacted portions of Exhibit 1037 concern Apotex’s

confidential business information related to NDA No. 21-825 for Ferriprox[®], including information related to the research and development of Ferriprox[®], and the clinical testing of Ferriprox[®]. Additional redacted portions of Ex. 1037 concern sensitive information related to a scientific dispute between, *inter alia*, Dr. Nancy Olivieri and Apotex concerning allegations made by Dr. Olivieri about the clinical efficacy of deferiprone, as well as the ownership, interpretation, and use of patient records and related data concerning the compassionate use of deferiprone at Toronto's Hospital for Sick Children. This dispute between Dr. Olivieri and Apotex resulted in lawsuits filed by both Dr. Olivieri and Apotex, including a libel suit filed by Dr. Olivieri against Apotex for defamation. These lawsuits were resolved pursuant to a settlement agreement, the terms of which are confidential. Therefore, in addition to the fact that these documents themselves are highly confidential, Apotex has significant concerns that public disclosure of certain portions of Ex. 1037 may be in violation of the terms of the confidential settlement agreement.

- **Exs. 1038-1041:** These documents are confidential internal email communications between Apotex employees that relate to the scientific dispute between Apotex and Dr. Nancy Olivieri concerning the long-term efficacy and possible side-effects of deferiprone. These emails and attachments concern the contemporaneous thoughts and mental impressions

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