

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 No. IPR2017-01446

U.S. Patent No. 7,049,328 B2

Title: USE FOR DEFERIPRONE

PATENT OWNER'S SECOND MOTION TO SEAL

Pursuant to 37 C.F.R. §§ 42.14 and 42.54, Patent Owner, Apotex Technologies, Inc. (“Apotex”), respectfully submits this Second Motion to Seal Apotex’s sensitive and highly confidential business information contained and/or discussed in Exhibits 1038-1043 and 1047-1049, and certain portions of Exhibit 1037 pursuant to the terms of the Protective Order in this matter (Exhibit 1051). A non-confidential, redacted public version of Petitioner’s Exhibit 1037 is filed herewith as IPR2017-01446, Exhibit 2039.

If the Board is not inclined to grant this Second Motion to Seal with respect to Exhibits 1037-1043 and 1047-1049, then Apotex respectfully requests leave to file a third motion to seal or, in the alternative, a motion to expunge such exhibits from the record. Apotex agreed to Petitioner’s request to submit Exhibits 1037-1043 and 1047-1049 with its Motion to Compel Routine Discovery (Paper 22) solely to aid the Board in deciding Petitioner’s Motion and with the express understanding that such exhibits would be sealed. To the extent such protection is not available, Apotex would not have agreed to this Request and therefore would seek to remove Exhibits 1037-1043 and 1047-1049 from the record through expungement.

I. GOOD CAUSE EXISTS FOR SEALING CERTAIN CONFIDENTIAL AND/OR SENSITIVE INFORMATION

There is good cause to seal Exhibits 1038-1043 and 1047-1049, and portions of Exhibit 1037. While the public interest is served by maintaining a complete and

understandable file history in these proceedings, Exhibits 1038-1043 and 1047-1049 refer to and include Apotex's confidential research, development, and commercial information, which the Board has acknowledged that it has an "interest in protecting [such] truly sensitive information." Office Trial and Practice Guide at 48760 (77 Fed. Reg. 48756, 48760 (Aug. 14, 2012)). Further, such protection would be "in a manner consistent with Federal Rule of Civil Procedure 26(c)(1)(G), which provides for protective orders for trade secret or other confidential research, development, or commercial information." *Id.* (citing 37 C.F.R. § 42.54).

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 this exhibit 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 of Dr. Michael Spino, an inventor of the '328 patent, and his colleagues at Apotex as they attempted to rebut allegations by Dr. Olivieri concerning the safety and efficacy of deferiprone. As noted above, the 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 Exhibits 1038-1041 may be in violation of the terms of the confidential settlement agreement. What is more, Ex. 1041 contains personal information, including names and confidential phone numbers of individuals purported to be knowledgeable of deferiprone and its clinical use.

- **Exs. 1042-1043**: The Deposition Transcripts of Dr. Fernando Tricta (Nov. 7, 2017) and Dr. Michael Spino, the President of ApoPharma, Inc. (Nov. 8, 2017) include testimony regarding Apotex's confidential business information, including, *inter alia*, information related to the research and development of Ferriprox[®], Apotex's NDA No. 21-825, correspondence with FDA regarding NDA No. 21-825, and internal Apotex emails concerning the same. Further, these transcripts include testimony related to the above-described scientific dispute between Dr. Olivieri and Apotex and the subsequent lawsuits related thereto.
- **Exs. 1047-1049**: These documents are part of the closed portions of Apotex's confidential NDA No. 21-825 that was filed with FDA. Information in these documents concerns the design and execution of

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