

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

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

Case No.: IPR2017-01446

**PETITIONER'S MOTION TO COMPEL ROUTINE
DISCOVERY OR, IN THE ALTERNATIVE, FOR
ADDITIONAL DISCOVERY**

I. Introduction

Patent Owner Apotex Technologies, Inc. (“Apotex”) made statements in its Patent Owner Response (Paper 17, “POR”) that are inconsistent with facts discovered by Petitioner Taro Pharmaceuticals USA, Inc. (“Taro”) during the parallel district court case concerning the ’328 patent. These inconsistencies are central to the issues here, including (1) whether the prior art teaches away from the claimed method, as Apotex now contends; (2) whether the patients in the instituted prior art references necessarily had iron induced heart disease, as Taro contends and Apotex denies; and (3) whether the dosage disclosed in the prior art was inherently an effective dose, as Taro contends and Apotex denies.

The relevant documents, attached as Exhibits 1037-1045 and 1047-1049, were either served or generated during discovery in the ongoing litigation, and therefore, Taro is aware of their contents. However, because Apotex has designated the documents Highly Confidential, the protective order entered in the district court case prevents Taro from relying on them in this proceeding. Therefore, pursuant to the Board’s Order (Paper 18), Taro moves the Board to compel Apotex to produce the documents and a stipulation attesting to their authenticity in line with Apotex’s routine discovery obligations (37 CFR § 42.51(b)(1)), or, in the alternative, as additional discovery under 37 CFR § 42.51(b)(2).

II. The Requested Documents Are Relevant to and Inconsistent with Positions Advanced by Apotex in the POR and Should Have Been Produced as Routine Discovery

The rule on routine discovery obligates Patent Owner to produce the documents listed below because they contain statements inconsistent with those made in this proceeding. 37 CFR § 42.51(b)(1); *see also Becton, Dickinson and Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 20 at 4 (PTAB Feb. 28, 2018) (“Statements made by a party or by the party’s expert that are inconsistent with a position taken during this trial should be produced and become part of the record.”) (discussing *Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267, 1275 (Fed. Cir. 2017)).

A. Documents Inconsistent with Apotex’s Position on the Olivieri Publications

Here, Apotex describes publications by Dr. Olivieri that questioned the safety and efficacy of deferiprone as causing “significant disagreement in the scientific community” (POR at 5) and “teaching away” from the use of deferiprone (*id.* at 44-45, 53-54). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

B. Documents Inconsistent with Apotex’s Position Regarding the Cardiac Disease of Patients Treated with Deferiprone in the Prior Art

Apotex now contends that the Primary References “do not explicitly or inherently disclose administering deferiprone to blood-transfusion dependent patients having iron-induced cardiac disease” (POR at 26) because those patients’ cardiac disease may have had a different cause. (*Id.* at 26, 30.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Specifically with respect to Hoffbrand 1998, Apotex contends that it does not disclose patients with iron induced cardiac disease (POR at 26), [REDACTED]

[REDACTED]

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