

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE OFFICE OF THE UNDER SECRETARY OF COMMERCE
FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE
UNITED STATES PATENT AND TRADEMARK OFFICE

CSPC PHARMACEUTICAL GROUP LIMITED,
CSPC OUYI PHARMACEUTICAL CO., LTD., and
CONJUPRO BIOTHERAPEUTICS, INC.,
Petitioner,

v.

IPSEN BIOPHARM LTD.,
Patent Owner.

IPR2025-00505
Patent 11,344,552 B2

Before COKE MORGAN STEWART, *Acting Under Secretary of
Commerce for Intellectual Property and Acting Director of the United States
Patent and Trademark Office.*

DECISION
Referring the Petition to the Board

Ipsen Biopharm Ltd. (“Patent Owner”) filed a request for discretionary denial (Paper 8, “DD Req.”) in the above-captioned case, and CSPC Pharmaceutical Group Limited, CSPC Ouyi Pharmaceutical Co., Ltd., and Conjupro Biotherapeutics, Inc. (collectively “Petitioner”) filed an opposition (Paper 10, “DD Opp.”).

After considering the parties’ arguments and the record, and in view of all relevant considerations, discretionary denial of institution is not appropriate in this proceeding. This determination is based on the totality of the evidence and arguments the parties have presented.

In particular, Patent Owner and Petitioner are not engaged in a parallel litigation. Additionally, the challenged patent has not been in force for a significant period of time (issued in 2022). Accordingly, Patent Owner has not developed strong settled expectations that favor discretionary denial as to the challenged patent.

Furthermore, Petitioner provides persuasive reasoning, supported by evidence, that discretionary denial under 35 U.S.C. § 325(d) is not appropriate because the Office materially erred during prosecution of the challenged patent. In determining whether to discretionarily deny a petition under § 325(d), Office policy requires a determination of “(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*”).

Petitioner's arguments that the Office materially erred are persuasive. In particular, during prosecution, the patent examiner rejected all pending claims of the application that matured into the challenged patent over the combination of Bayever,¹ Conroy,² and one or more additional references. *See, e.g.*, Ex. 1119, 10–21. Although the patent examiner eventually allowed the claims over these references, Petitioner provides persuasive evidence that the Office erred in a manner material to the patentability of the challenged claims by not considering or overlooking specific teachings in Conroy's appendix and Conroy's associated protocol, both identified in Conroy itself, that disclose critical limitations in the claims.³ DD Opp. 9–12, 22–25; *see* Pet. 16; *see* Ex. 1003, 1, 3. On balance, discretionary denial is not appropriate.

Although certain arguments are highlighted above, the determination not to exercise discretion to deny institution is based on a holistic assessment of all of the evidence and arguments presented. Accordingly, the Petition is referred to the Board to handle the case in the normal course, including by issuing a decision on institution addressing the merits and other non-discretionary considerations, as appropriate.

In consideration of the foregoing, it is:

ORDERED that Patent Owner's request for discretionary denial is *denied*;

¹ WO2013/188583 A1 (Ex. 1006).

² Thierry Conroy, et al., *FOLFIRINOX versus Gemcitabine for Metastatic Pancreatic Cancer*, N. Engl. J. Med., 364(19):1817–25 (May 2011) (Ex. 1003).

³ According to Petitioner, Conroy's associated protocol was identified on an IDS, but no translation was provided, and Conroy's appendix was not of record during prosecution. DD Opp. 11–12 (citing Ex. 1119, 308–395).

FURTHER ORDERED that the Petition is referred to the Board; and

FURTHER ORDERED that neither party shall file a request for rehearing or Director Review of this decision until the Board issues a decision on institution.

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