# UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC., Petitioner,

v.

SENJU PHARMACEUTICAL CO., LTD., Patent Owner.

> Case IPR2015-01099 Patent 8,699,290 B2

Before FRANCISCO C. PRATS, ERICA A. FRANKLIN, and GRACE KARAFFA OBERMANN, *Administrative Patent Judges*.

OBERMANN, Administrative Patent Judge.

DOCKET

ORDER Granting Patent Owner's Renewed Motion to Seal 37 C.F.R. §§ 42.14

# IPR2015-01099 Patent 8,699,290 B2

On July 29, 2016, Patent Owner filed a Renewed Motion to Seal. Paper 67 ("Motion" or "Mot."). Concurrently herewith, we grant Petitioner's unopposed motion to enter the Board's Default Protective Order, which governs the disclosure of confidential information in this proceeding. Patent Owner states that "Petitioner Lupin does not oppose this motion." Mot. 1. No party has filed an opposition. This Order addresses the Motion.

Patent Owner requests sealing of the following documents: (1) excerpts of Patent Owner's New Drug Application ("NDA") (Exs. 2096, 2102, 2103, 2110, 2251, 2291-2293); (2) information related to alleged commercial success of Patent Owner's product from a related district court case (Ex. 2258, 2323); and (3) testing reports and materials that allegedly document proprietary testing methods of a non-party test company (Exs. 2267-2278, 2294). Mot. 1. Patent Owner also requests sealing of portions of its Patent Owner's Response (Paper 22) and witness declarations (Exs. 2126 (Myers), 2128 (Paulson), 2082 (Williams), 2116 (Trattler), and 2130 (Jarosz)) on the basis that they cite or substantially describe the above categories of documents. *Id*.

The Board previously denied requests to seal the same documents that are the subject of the instant Motion. Paper 57 (for Exhibit 2323); Paper 61 (for all other documents that are the subject of the Motion). On September 12, 2016, we entered a Final Written Decision. Paper 69.

### Motion to Seal Exhibit 2323

Among other documents, Patent Owner seeks to seal Exhibit 2323. Mot. 1. We previously denied Patent Owner's request to seal portions of Exhibit 2323. Paper 57. We determined that "Patent Owner has sufficiently established that the cited portions of Exhibit 2323 contain confidential information." *Id.* at 3. However, we denied the prior motion because we further determined that "a protective order has not been entered" in the proceeding, "and an acceptable proposed protective order has not been filed." *Id.* Given that a suitable protective order is entered concurrently herewith, and in light of our prior determination that Patent Owner has shown good cause for sealing Exhibit 2323, we *grant* Patent Owner's renewed request to seal that document.

# Motion to Seal NDA Documents and Filings Citing the NDA

We previously denied a request to seal Exhibits 2096, 2102, 2103, 2110, 2251, 2291–2293 as well as portions of Patent Owner's Response and witness declarations that cite or describe those exhibits. Paper 61, 6–7. We denied that request because it was accompanied by a proposed stipulated protective order that was "not in an adequate form for entry." *Id.* at 3. We further noted that Exhibit 2096 was sought to be sealed in its entirety without an adequate showing that all of the material reflected therein is confidential. *Id.* at 7. We also noted "that the entirety of Exhibit 2293 lacks any content. Every page of that exhibit is essentially blank, containing only a portion of an empty grid." *Id.* Our prior concerns have been addressed. Concurrently herewith, we issue an order granting the parties' joint request to enter the Board's Default Protective Order, which governs disclosure of confidential information in these proceedings. Patent Owner, moreover, has provided revised redacted versions of Exhibits 2096 and 2293 that address the issues noted in our prior decision—a public version of Exhibit 2096

containing appropriate redactions has been filed, and Exhibit 2293 has been refiled with content instead of a blank grid.

Patent Owner presents information sufficient to demonstrate that Exhibits 2096, 2102, 2103, 2110, 2251, 2291–2293 reflect Patent Owner's confidential information and that good cause exists for sealing those exhibits, as well as specific portions of the Patent Owner's Response and the Myers, Trattler, Jarosz, and Willaims declarations that cite or describe the confidential information contained in those exhibits. Mot. 8–11. No party opposes the request. Accordingly, we *grant* Patent Owner's request to seal the NDA and related portions of Patent Owner's Response and witness declarations that cite or describe the NDA.

### Motion to Seal Exhibit 2258

We previously denied a request to seal Exhibit 2258 (deposition testimony of Ms. Tracy Valorie, an officer of Patent Owner's parent company) because the exhibit contained "seven inconsecutive pages from a transcript of the deposition" and the first and second pages were not shown to reflect any confidential information. Paper 61, 8. Under those circumstances, we were not persuaded that Patent Owner had shown good cause for sealing Exhibit 2258 in its entirety. *Id.* Patent Owner has filed a revised public version of Exhibit 2258 that addresses our prior concerns, redacting no material on the first or second pages of the exhibit. No party opposes the Motion. According, we *grant* Patent Owner's request to seal Exhibit 2258.

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### Motion to Seal Exhibits of Non-Party BioScience

In addition, Patent Owner requests to seal exhibits alleged to reflect confidential information owned by non-party BioScience, specifically, Exhibits 2267–2278, 2294 and portions of the Declaration of Dr. Paulson (Ex. 2128) that cite or describe those exhibits. Mot. 11. Previously, we denied Patent Owner's prior request to seal those materials because Patent Owner had "neither demonstrated that the exhibits contain proprietary information nor established its standing to assert" any interest of BioScience in this proceeding. Paper 61, 8–9. The instant Motion, by contrast, is supported by a declaration of Deanna J. Field, Vice President of Finance and Administration of BioScience (Ex. 2347). That declaration establishes adequately BioScience's interest in shielding from public disclosure certain proprietary testing protocol and standard operating procedures, kept confidential by BioScience, as reflected in Exhibits 2249–2263. Mot. 11–12; Ex. 2347, 3–11.

Patent Owner shows sufficiently that public disclosure of the information sought to be sealed would cause financial damage to BioScience. Ex. 2347, 11. Patent Owner further shows sufficiently that "BioScience has authorized Patent Owner to request that Exs. 2267-2278 and 2294 be sealed." Mot. 11–12 (bridging sentence) (citing Ex. 2347, 2). Patent Owner submits an appropriately redacted public version of Exhibit 2267. Petitioner further shows sufficiently that the remaining exhibits in this category (Exhibits 2268–2278 and 2294) "contain confidential information on all but one page, thus redaction is not practical." Mot. 12 (citing Ex. 2347, 3–11). No party has filed an opposition. Accordingly, Patent Owner's request to seal Exhibits 2267–2278, 2294 is *granted*.

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