

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX, INC.,
Petitioner,

v.

UCB BIOPHARMA SPRL,
Patent Owner.

IPR2019-00400
Patent 8,633,194 B2

Before ROBERT A. POLLOCK, RYAN H. FLAX, and
KRISTI L. R. SAWERT, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

ORDER

*Granting Patent Owner's Unopposed Renewed Motion to Seal
37 C.F.R. §§ 42.14 and 42.54*

In our Final Written Decision, we denied the Parties' Joint Motion to Seal (Paper 35) confidential, non-public versions of Exhibits 1039, 1042, 1043, and Paper 33 without prejudice, because Patent Owner failed to identify precisely what information is considered confidential and did not demonstrate good cause to grant the request. Paper 57, 43, 45. We invited Patent Owner to renew its request, accompanied by "a statement that the information sought to be redacted is not cited, directly or indirectly, in this Decision," or "[t]o the extent such statement cannot be made, Patent Owner shall propose a substitute version of the affected Exhibit(s) and provide an explanation of any differences." *Id.* at 43.

Patent Owner filed an Unopposed Renewed Motion to Seal the confidential, non-public version of Exhibit 1042 (filed January 16, 2020 and marked as "Parties and Board Only"). Paper 58 ("Motion" or "Mot."). Patent Owner also submitted a revised redacted, public version of Exhibit 1042 that "removed a number of proposed redactions" compared to the previous public version.¹ Mot. 1. Patent Owner has withdrawn its request to seal Exhibit 1043 and Paper 33. *Id.* Patent Owner indicates that Petitioner does not oppose the Motion. *Id.* For the reasons stated below, Patent Owner's Motion is *granted*.

Relevant to this motion, the Office Patent Trial Practice Guide states:

3. A party intending a document or thing to be sealed may file a

¹ With our authorization (Ex. 3006), Patent Owner emailed the revised redacted Exhibit 1042 to the Board on June 22, 2020. Ex. 3007. We note that the footer of this exhibit bears Petitioner's initial destination: "Ex. 1042 Un-redacted Non Public Version."

motion to seal concurrent with the filing of the document or thing. § 42.14. The document or thing will be provisionally sealed on receipt of the motion and remain so pending the outcome of the decision on motion.

4. *Protective Orders*: A party may file a motion to seal where the motion contains a proposed protective order, such as the default protective order in Appendix B. 37 C.F.R § 42.54. Specifically, protective orders may be issued for good cause by the Board to protect a party from disclosing confidential information. 37 C. F. R. § 42.54. Guidelines on proposing a protective order in a motion to seal, including a Default Protective Order, are provided in Appendix B. The document or thing will be protected on receipt of the motion and remain so, pending the outcome of the decision on motion.

Consolidated Office Patent Trial Practice Guide November 2019 (“CTPG”) at 19–20.²

“There is a strong public policy for making all information filed in a quasi-judicial administrative proceeding open to the public, especially in an inter partes review which determines the patentability of claims in an issued patent and therefore affects the rights of the public.” *Garmin Int’l v. Cuozzo Speed Techs., LLC*, IPR2012–00001, Paper 34 at 1–2 (PTAB Mar. 14, 2013). For this reason, except as otherwise ordered, the record of an *inter partes* review trial shall be made available to the public. *See* 35 U.S.C. § 316(a)(1); 37 C.F.R. § 42.14. Motions to seal may be granted for good cause; until the motion is decided, documents filed with the motion shall be sealed provisionally. *See* 37 C.F.R. §§ 42.14, 42.54(a). The moving party bears the burden of showing that there is good cause to seal the record. *See*

² Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

37 C.F.R. § 42.20(c); *see Argentum Pharm. LLC v. Alcon Research, Ltd.*, Case IPR2017-01053, Paper 27 (Jan. 19, 2018) (informative) (factors for showing good cause to seal information).

As set forth in the CTPG, confidential information that is sealed subject to a protective order ordinarily will become public 45 days after final judgment in a trial. CTPG at 21–22. A party seeking to maintain confidentiality of information may file a motion to expunge the information before it becomes public (*see* 37 C.F.R. § 42.56); however, if the existence of the information is identified in a final written decision following trial, there is an expectation that the information will be made public. *Id.* at 22. This rule “balances the needs of the parties to submit confidential information with the public interest in maintaining a complete and understandable file history for public notice purposes.” *Id.*

Patent Owner states that “Exhibit 1042 is the Opening Expert Report of Sarfaraz K. Niazi, Ph.D, which was filed in a related district court action and designated therein by Patent Owner as ‘Restricted Confidential Information-Subject to Protective Order.’” Mot. 2. According to Patent Owner,

[the] proposed redactions of Exhibit 1042 are limited to confidential commercial information regarding the commercial products Xyzal® and Xyzal Allergy 24 HR®, specifically excerpts of New Drug Application (“NDA”) Nos. 22-157 and 20-9090 and statements that identify the composition of these drug products. . . . The information Patent Owner seeks to seal is highly sensitive product information, specifically information that would reveal the composition and formulation of the commercial products subject to NDA Nos. 22-157 and 20-9090. *See* EX2008 (explaining Patent Owner’s interest in NDAs held

by Sanofi Aventis US LLC); *see also* EX3005 (unsealed version of EX2008). This information has not been made public by either party or by the United States Food and Drug Administration, and is not otherwise available to the public to Patent Owner's knowledge.

Mot. 2–3.³

Patent Owner contends disclosure of this information would be harmful to its business interests, while public interest in the redacted information is minimal because the Board does not rely on the material, directly or indirectly, in the Final Written Decision. Mot. 3.

Upon reviewing the Motion and Exhibit 1042, we agree with Patent Owner that the information at issue is confidential information. *See* Mot. 2–3; *see also* 37 C.F.R. § 42.2 (“Confidential information means trade secret or other confidential research, development, or commercial information.”). Considering the sensitivity of the information and the potential competitive harm were the information disclosed publicly at this time, and that we do not rely on this information in our Final Written Decision, we determine good cause has been shown for granting this request. Further, the revised redacted, public version of Exhibit 1042 appears to be tailored narrowly to redact only confidential information. We find Patent Owner's desire to keep this information confidential is not outweighed by the public interest in

³ Although we expressly stated that Patent Owner should “provide an explanation of any differences” between two versions of a substituted document, given the limited differences between the two versions of Exhibit 1042 and Patent Owner's explanation of the remaining redactions, any non-compliance is de minimus. Paper 57, 43.

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