

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., DR. REDDY'S LABORATORIES,
INC., DR. REDDY'S LABORATORIES, LTD., SUN
PHARMACEUTICAL INDUSTRIES LTD.,
SUN PHARMACEUTICAL INDUSTRIES, INC., and APOTEX INC.,
Petitioner,

v.

NOVO NORDISK A/S,
Patent Owner.

IPR2023-00724¹
Patent 10,335,462 B2

Before JOHN G. NEW, SUSAN L. C. MITCHELL, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

DECISION

Unopposed Motion for Entry of the Default Protective Order and
Motions to Seal

37 C.F.R. §§ 42.1 and 42.54

¹ IPR2024-00009 (Dr. Reddy's Laboratories), IPR2024-00107 (Sun Pharmaceutical Industries), and IPR2024-00631 (Apotex Inc.) have been joined with this proceeding.

Novo Nordisk A/S (“Patent Owner”) filed four motions to seal and for entry of the default protective order, *see* Ex. 2079. *See* Papers 28, 72, 96, 101. Mylan Pharmaceuticals Inc. (“Petitioner”) filed two motions to seal. *See* Papers 51, 97. None of the motions is opposed. *See* Paper 28, 1 (stating Mylan does not oppose the motion, and [t]he parties agreed to the Board’s default protective order”); Paper 51, 1; Paper 72, 1; Paper 96, 1; Paper 97, 1.

We grant the parties’ request to enter the default protective order. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,771 (2012) (Appendix B: Standing Protective Order); Ex. 2079.

Discussion

The Board’s standards for granting motions to seal are discussed in *Garmin International v. Cuozzo Speed Technologies, LLC*, IPR2012-00001 (PTAB Mar. 14, 2013) (Paper 34). In summary, there is a strong public policy for making all information filed in *inter partes* review proceedings open to the public, especially because the proceeding determines the patentability of claims in an issued patent and, therefore, affects the rights of the public. *Id.* at slip op. 1–2. Under 35 U.S.C. § 316(a)(1) and 37 C.F.R. § 42.14, the default rule is that all papers filed in an *inter partes* review are open and available for access by the public; a party, however, may file a concurrent motion to seal and the information at issue is sealed pending the outcome of the motion. It is only “confidential information” that is protected from disclosure. 35 U.S.C. § 316(a)(7); *see* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,760 (Aug. 14, 2012). The standard for granting a motion to seal is “for good cause.” 37 C.F.R. § 42.54(a). The party moving to seal bears the burden of proof in showing entitlement to the requested relief, and must explain why the information sought to be sealed

constitutes confidential information. 37 C.F.R. § 42.20(c).

1. Patent Owner's Motions to Seal (Papers 28, 72, 96, 101)

a. Paper 28 – Patent Owner Response and Certain Exhibits

Patent Owner moves to seal its Patent Owner Response and Exhibits 2021–2036, 2038–2041, 2046–2048, 2050, 2051, 2056, 2300–2318, 2320–2334, submitted in support of its Patent Owner Response. *See* Paper 26, 1–5. Patent Owner states that it has also filed redacted versions of its Patent Owner Response (*see* Paper 30, and Exhibits 2050, 2051, 2056, and 2300), but has redacted the remaining Exhibits filed under seal in their entirety (Paper 26, 5).

Patent Owner represents that good cause exists for sealing its Patent Owner Response and accompanying Exhibits because these documents contain “non-public research and development information in the form of proprietary clinical and scientific data concerning semaglutide, confidential information about drug development and regulatory approval strategies, and confidential business information, including relating to financial information and proprietary marketing strategies,” that would cause competitive business harm to Patent Owner if publicly disclosed. Paper 28, 5–6 (citing Ex. 2052 ¶¶ 3–4). Patent Owner also notes that Exhibit 2301 contains third-party proprietary business and financial information provided such information is sealed in this proceeding. *Id.* at 6.

We have considered the Patent Owner’s arguments to seal portions of its Patent Owner Response and Exhibits 2050, 2051, 2056, and 2300, as well as its reasoning for requesting that the entirety of Exhibits 2021–2036, 2038–2041, 2046–2048, 2301–2318, and 2320–2334 be sealed. We determine that Patent Owner has demonstrated good cause for sealing these exhibits as requested.

b. Paper 72 – Patent Owner Sur-Reply and Certain Exhibits

Patent Owner moves to seal its Patent Owner Sur-Reply and Exhibits 2555 and 2558 submitted in support of its Sur-Reply. *See* paper 72, 1. Patent Owner states that it has also filed redacted versions of its Patent Owner Sur-Reply (*see* Paper 74, and Exhibit 2555), but has redacted Exhibit 2558 in its entirety (Paper 72, 1).

Patent Owner represents that good cause exists for sealing its Patent Owner Sur-Reply and accompanying Exhibits because these documents contain Patent Owner’s “non-public business information.” Paper 72, 1. Specifically, Patent Owner represents that Exhibit 2555 contains

discussions of exhibits containing confidential information containing confidential research and development information of in the form of proprietary clinical and scientific data concerning semaglutide and confidential business information, including proprietary financial information and marketing strategies, as well as confidential information in the form of third-party proprietary business and financial information provided to Novo Nordisk

Paper 72, 2. Patent Owner also avers that Exhibit 2558 “contains non-public research and development information in the form of proprietary clinical and scientific data concerning semaglutide, and confidential information about drug development and regulatory approval strategies” Paper 72, 2.

We have considered Patent Owner's assertions to seal portions of its Patent Owner Sur-Reply and Exhibit 2555, as well as its reasoning for requesting that the entirety of Exhibit 2558 be sealed. We determine that Patent Owner has demonstrated good cause for sealing these exhibits as requested.

c. *Paper 96 – Patent Owner Oral Hearing Demonstratives and Patent Owner's Submission of Unresolved Objections to Petitioner's Demonstratives*

Patent Owner moves to seal its Patent Owner Oral Hearing Demonstratives and its Submission of Unresolved Objections to Petitioner's Demonstratives. Paper 96, 1. Patent Owner states that it has filed redacted versions of each of these filings. *Id.*

Patent Owner represents that good cause exists to seal these two filings because they include Patent Owner's non-public business information. *See* Paper 96, 1–2.

We have considered Patent Owner's assertions to seal portions of its Oral Hearing Demonstratives and its Submission of Unresolved Objections to Petitioner's Demonstratives. We determine that Patent Owner has demonstrated good cause for sealing these filings as requested.

d. *Paper 101 – Patent Owner*

Patent Owner moves to seal its Request for Director Review because it includes material Petitioner Apotex identifies as non-public business information. *See* Paper 101, 1. We determine that Patent Owner has demonstrated good cause for sealing this filing as requested.

e. *Conclusion*

Patent Owner's motions to seal are granted, *see* Papers 28, 72, 96, 101, and we note that the sponsoring party may file a motion to expunge these sealed documents from the official record. *See* 37 C.F.R. § 42.56.

2. *Petitioner's Motions to Seal (Papers 51, 97)*

Petitioner moves to seal its Reply and Exhibits 1308, 1311, 1312, 1314, and 1323 because the Reply and these Exhibits "address information filed under seal by Patent Owner." Paper 51, 1. Petitioner filed redacted versions of its Reply (*see* Paper 53), and Exhibits (*see* Exs. 1308, 1311, 1312, 1314, 1323 (redacted versions)).

Petitioner also moves to seal its Oral Hearing Demonstratives, Exhibit 1334, and its Objections to Patent Owner's Demonstrative Exhibits (Paper 94). *See* Paper 97, 1. Again, Petitioner states that it so moves because these papers and exhibits contain Patent Owner's non-public business information. *Id.* at 1–2.

For the same reasons set forth above involving Patent Owner's Motions to Seal, we also grant Petitioner's Motions to Seal and note that the sponsoring party may file a motion to expunge that document from the official record. *See* 37 C.F.R. § 42.56.

ORDER

In consideration of the foregoing, it is

ORDERED that the Default Protective Order, *see* 77 Fed. Reg. at 48,771 (Appendix B: Standing Protective Order), is hereby entered and shall govern the conduct of this proceeding unless otherwise modified;

FURTHER ORDERED that Patent Owner's Motions to Seal (Papers 28, 72, 96, 101) are *granted*;

FURTHER ORDERED that Petitioner's Motions to Seal (Papers 51, 97) are *granted*; and

FURTHER ORDERED that the following documents shall be sealed as "Board and Parties Only," and will be kept under seal unless and until we refer to material in the papers or exhibits in a final written decision:

Paper Number	Description
Paper 29	Patent Owner's Response
Paper 53	Petitioner's Reply
Paper 73	Patent Owner's Sur-Reply
Paper 89	Patent Owner's Oral Hearing Demonstratives
Paper 90	Patent Owner's Submission of Unresolved Objections to Petitioner's Demonstratives
Paper 94	Petitioner's Objections to Patent Owner's Demonstrative Exhibits
Paper 100	Patent Owner's Request for Director Review

FURTHER ORDERED that the following exhibits shall be sealed as "Board and Parties Only," and will be kept under seal unless and until we refer to material in the papers or exhibits in a final written decision:
Exhibits 1308, 1311, 1312, 1314, 1323, 1334, 2021–2036, 2038–2041, 2046–2048, 2050, 2051, 2056, 2300–2318, 2320–2334, 2555, 2558.

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