

Paper No. 116
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Filed on behalf of: Sanofi Mature IP
By:

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LIMITED
Petitioner,

v.

SANOFI MATURE IP
Patent Owner.

Case IPR2016-00712
U.S. Patent No. 8,927,592

PATENT OWNER'S MOTION TO EXPUNGE

I. STATEMENT OF RELIEF REQUESTED

Pursuant to the authorization granted by the Patent Trial and Appeal Board (“Board”) on April 7, 2021 and 37 C.F.R. § 42.56, Patent Owner Sanofi Mature IP (“Patent Owner” or “Sanofi”) submits this motion to expunge the previously sealed confidential versions of Exhibits 1042, 1043, 1044, 1054, 1065, 1068, 1069, 1070, 1071, 1072, 1074, 1079, 2149, 2170, 2171, 2176, 2179, 2182, 2211, and 2261, and Papers 43, 53, 64, 72, 77, 81, 89, and 92 (collectively, “the Identified Exhibits and Papers”). If the Board does not expunge any of these materials from the record, Sanofi requests that the sealed versions remain under seal.

For the reasons set forth below, good cause exists for expunging each of the Identified Exhibits and Papers. Sanofi has conferred with Petitioner concerning this motion and can represent that Petitioner does not plan to oppose the motion.

The original Final Written Decision (“FWD”) in this proceeding was issued on September 21, 2017. (Paper 99). On February 5, 2019, the Court of Appeals for the Federal Circuit vacated the Board’s denial of Sanofi’s contingent motion to amend and remanded for further proceedings. (Paper 113). The Final Written Decision on Remand (“FWD on Remand”) was issued on October 22, 2019. (Paper 112). The Federal Circuit issued a Rule 36 affirmance on January 15, 2021 and the mandate on February 23, 2021. The mandate was docketed on March 19, 2021. (Paper 115). Since the proceeding is now concluded, and the motion is timely,

Sanofi requests that the Board expunge the confidential Identified Exhibits and Papers from the record in this proceeding.

II. LEGAL STANDARD

“Confidential information that is subject to a protective order ordinarily would become public 45 days after denial of a petition to institute a trial or 45 days after final judgment in a trial.” Consolidated Trial Practice Guide 2019 at 21-22. “[A]fter final judgment in a trial, a party may file a motion to expunge confidential information from the record.” C.F.R. § 42.56. “[C]onfidential information” protected from disclosure includes “trade secret or other confidential research, development, or commercial information.” 37 C.F.R. § 42.54(a)(7). To determine whether to expunge confidential information, the Board must “balance 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.” Consolidated Trial Practice Guide 2019 at 22. Therefore, a party “seeking expungement of material from the record must show good cause by demonstrating that any information sought to be expunged constitutes confidential information, and that the party’s interest in expunging it outweighs the public’s interest in maintaining a complete and understandable history of this *inter partes* review.” *Cook Group Inc. v. Boston Sci. Scimed, Inc.*, IPR2017-00133, Paper 75 (P.T.A.B. Mar. 4, 2021) at 2-

3 (citing *Atlanta Gas Light Co. v. Bennett Regulator Guards, Inc.*, IPR2013-00453, Paper 97 (P.T.A.B. Apr. 15, 2015) at 2).

III. THE IDENTIFIED EXHIBITS AND PAPERS SHOULD BE EXPUNGED FROM THE RECORD

a. The Identified Exhibits and Papers Were Sealed Because They Contain Sanofi's Confidential Information that Could Subject Sanofi to Harm If It Was Disclosed

The Board granted Sanofi's unopposed motion for entry of a protective order on February 10, 2017 (Paper 35), and the Stipulated Protective Order was filed on February 15, 2017 (Paper 36). The parties filed various exhibits and papers under seal pursuant to the protective order and motions to seal those documents. (Paper 24; Paper 45; Paper 54; Paper 62; Paper 65; Paper 74; Paper 76; Paper 83; Paper 88; Paper 91; Paper 97). The Board granted the parties' motions to seal on February 10, 2017 (Paper 35) and September 26, 2017 (Paper 100).¹ Sanofi therefore previously demonstrated, and the Board agreed, that the Identified Exhibits and Papers contain confidential information, and there was good cause to seal the confidential information. (Paper 35; Paper 100). Sanofi seeks to maintain the confidentiality of the Identified Exhibits and Papers because they discuss Sanofi's sensitive, confidential information that could cause harm to Sanofi if it was made publicly available. There are two categories of confidential information that Sanofi seeks to

¹ The only exception is the Board's denial of Patent Owner's request to redact one sentence of Exhibit 2258. (Paper 100 at 7-10).

protect—clinical research information and business and financial information relating to sales and marketing of Sanofi’s Jevtana[®] (cabazitaxel) product.

Exhibits 1043, 1054, 2176, 2182, and 2211 and Papers 43 and 53 discuss Sanofi’s confidential clinical research information regarding cabazitaxel or larotaxel (a compound investigated by Sanofi but not covered by the claims of the patent-at-issue). If the highly sensitive clinical research information contained in these exhibits and papers is made public, it could give direct competitors knowledge of Sanofi’s clinical research strategy and operations and cause competitive harm to Sanofi. A description of these exhibits and papers is set forth in the table below.

Document	Redacted Version (No.)	Type of Confidential Information	Decision Granting Motion to Seal
Exhibit 1043 – March 14, 2017 Reply Declaration of Dr. Rahul Seth	Yes	Confidential clinical research information regarding cabazitaxel from Exhibit 2182	Paper 100
Exhibit 1054 – Briefing Document for EOP2 Meeting	No	Confidential regulatory submissions regarding clinical research of cabazitaxel	Paper 100
Exhibit 2176 – December 23, 2016 Declaration of Dr. Alton Oliver Sartor	Yes	Confidential clinical research information regarding cabazitaxel from Exhibits 2182 and 2211	Paper 35

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