

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LIMITED,
Petitioner,

v.

AVENTIS PHARMA S.A.,
Patent Owner.

Case IPR2016-00712
Patent 8,927,592 B2

Before ZHENYU YANG, TINA E. HULSE, and
CHRISTOPHER M. KAISER, *Administrative Patent Judges.*

KAISER, *Administrative Patent Judge.*

FINAL WRITTEN DECISION ON REMAND
35 U.S.C. § 318(a); 37 C.F.R. § 42.73(a)

INTRODUCTION

A. Background

Mylan Laboratories Limited (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–5 and 7–30 of U.S. Patent No. 8,927,592 (Ex. 1001, “the ’592 patent”). Paper 3 (“Petition” or “Pet.”). Petitioner supported its challenge with the Declaration of Dr. Rahul Seth. Ex. 1002. Aventis Pharma S.A. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”). On September 22, 2016, the Board instituted an *inter partes* review of claims 1–5 and 7–30 of the ’592 patent. Paper 9 (“Institution Decision”).

After institution, Patent Owner filed a Response (Paper 21, “PO Resp.”) and a Contingent Motion to Amend claims 27–30 of the ’592 patent (Paper 22, “MTA”). Patent Owner supported its Response and MTA with the Declaration of Dr. Alton Oliver Sartor (Ex. 2176), the Declaration of Mr. Michael Tate (Ex. 2149), and the Declaration of Mr. Art Lathers (Ex. 2231).

Petitioner filed a Reply (Paper 42, “Reply”) and Opposition to Patent Owner’s MTA (Paper 43, “MTA Opp.”¹). Petitioner supported its Reply and MTA Opposition with the Reply Declaration of Dr. Seth (Ex. 1043), and the Declaration of Mr. Robert McSorley (Ex. 1044).²

¹ Petitioner filed the MTA Opposition under seal, subject to the Board’s ruling on Petitioner’s Motion to Seal (Paper 45). Petitioner filed a redacted public version of the MTA Opposition as Paper 44.

² Petitioner filed Dr. Seth’s Reply Declaration and Mr. McSorley’s Declaration under seal, subject to the Board’s ruling on Petitioner’s Motion to Seal (Paper 45). Petitioner filed redacted public versions of the declarations using the same respective exhibit numbers.

Patent Owner filed a Reply to Petitioner's Opposition to Patent Owner's MTA. Paper 53 ("MTA Reply").³ Patent Owner supported its MTA Reply with the Reply Declaration of Dr. Sartor (Ex. 2259) and the Declaration of Patricia Matthews, RN, BSN (Ex. 2234).

Patent Owner filed Observations (Paper 80) on the cross-examination testimony of Dr. Seth (Ex. 2258) regarding Petitioner's Reply (Paper 42), and Petitioner filed a response to Patent Owner's Observations (Paper 93). Patent Owner also filed Observations (Paper 81 (under seal), Paper 82 (public version)) on the cross-examination testimony of Mr. McSorley (Ex. 2261) regarding Petitioner's Reply (Paper 42), and Petitioner filed a response to Patent Owner's Observations (Paper 92 (under seal), Paper 94 (public version)).

Petitioner filed Observations (Paper 84) on the cross-examination testimony of Dr. Sartor (Ex. 1098) with respect to Patent Owner's MTA, and Patent Owner filed a Response (Paper 90).

An oral hearing was held on June 13, 2017, and a transcript of the oral hearing is of record. Paper 98 ("Tr.").

On September 21, 2017, the Board issued a Final Written Decision (Paper 99, "Dec."), in which it concluded that Petitioner had shown by a preponderance of the evidence that claims 1–5 and 7–30 of the '592 patent were unpatentable and that Patent Owner had not shown by a preponderance of the evidence that proposed claims 31–34 were patentable. On November

³ Patent Owner filed the MTA Reply under seal, subject to the Board's ruling on Patent Owner's Motion to Seal (Paper 54). Patent Owner filed a redacted public version of the MTA Reply as Paper 52.

IPR2016-00712
Patent 8,927,592 B2

17, 2017, Patent Owner appealed to the Court of Appeals for the Federal Circuit. Paper 103.

On appeal, Patent Owner argued that the Board erred in denying its MTA. *Sanofi Mature IP v. Mylan Labs. Ltd.*, 757 F. App'x 988, 989 (Fed. Cir. 2019). The Federal Circuit agreed, vacating the denial of the MTA and remanding. *Id.*

On remand, Petitioner submitted a brief setting forth the issues for us to decide and its arguments on those issues. Paper 109 (“Pet. Remand Br.”). Patent Owner filed a responsive brief. Paper 110 (“PO Remand Br.”). Petitioner filed a reply. Paper 111 (“Pet. Remand Reply”).

We have jurisdiction under 35 U.S.C. § 6, and we issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons discussed below, we conclude that Petitioner has not established by a preponderance of the evidence that proposed claims 31–34 are unpatentable. Accordingly, we grant Patent Owner’s Motion to Amend claims 27–30 by replacing them with proposed claims 31–34.

B. The Issues on Remand

When Patent Owner appealed the earlier Final Written Decision, it noted that “the issues on appeal” included

the Board’s determination of unpatentability of claims 21 and 30 of U.S. Patent No. 8,927,592 (“the ’592 patent”) under 35 U.S.C. § 103, including the Board’s determination and application of its construction of terms in those claims; the Board’s denial of Patent Owner’s Contingent Motion to Amend claims 27-30 with proposed substitute claims 31-34, including the Board’s determination and application of its construction of terms in proposed substitute claims 31-34; the constitutionality of the inter partes review proceeding as raised in *Oil States Energy Services, LLC v. Greene’s Energy Group*, 639 F. App’x

IPR2016-00712
Patent 8,927,592 B2

639 (Fed. Cir. May 4, 2016), *cert. granted*, 85 U.S.L.W. 3578 (U.S. June 12, 2017) (No. 16-712) that the Board’s findings in this proceeding and this proceeding itself violate due process; and any finding or determination supporting or related to these issues, as well as all other issues decided adversely to Aventis in any orders, decisions, rulings and opinions, all of which, taken together or independently, caused prejudicial harm to Aventis related to these issues.

Paper 103, 1–2.

Despite this extensive list of “issues on appeal,” the Federal Circuit’s decision on appeal addressed only the denial of the MTA. *Sanofi*, 757 F. App’x at 994 (“[W]e *vacate* the Board’s denial of Sanofi’s contingent motion to amend and its construction of the proposed substitute claims and we *remand* for further consideration consistent with this opinion.”). Because the Federal Circuit did not otherwise disturb the Board’s findings and conclusions, we need only decide whether to grant Patent Owner’s MTA. Accordingly, except to the extent that they are contradicted by any statement herein, we maintain the analysis, findings, and conclusions reached in the earlier Final Written Decision, which we incorporate by reference. *See* Paper 99.

In opposing the MTA, Petitioner argues that the proposed claims are unpatentable on the following grounds:

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.