UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

Case IPR2021-00880
Patent No. 9,669,069 B2

Case IPR2021-00881
Patent No. 9,254,338 B2

PATENT OWNER REGENERON PHARMACEUTICALS, INC.'S CONSOLIDATED SUR-REPLY TO PETITIONER'S REPLY TO PATENT OWNER PRELIMINARY RESPONSE

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I. INTRODUCTION

Citing only pre-*Advanced Bionics* cases, Mylan argues that discretionary denial under §325(d) is inappropriate unless the same or substantially the same art was applied in a rejection by the Office. *Advanced Bionics* squarely rejected this argument and held that if the same or substantially the same art was previously presented to the Office (including in an IDS), then Petitioner must show that the Office materially erred. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, 2020 WL 740292, *3 (Feb. 13, 2020) (precedential). The Board adopted this framework as "a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown." *Id.*

In IPR2021-00881 (the '338 Patent), each of Mylan's Grounds relies on a dosing regimen that was disclosed in a September 28, 2008 press release presented to the Office during prosecution. Mylan's main response — that the Examiner thought the 2008 press release was from 2012 — is simply not credible.

In IPR2021-00880 (the '069 Patent), the same or substantially the same art was presented to the Office as well. Mylan raises for the first time the argument that only a single page of Dixon was disclosed to the Examiner. Yet, the face of the '069 Patent and the Examiner's signature suggest that the Examiner considered Dixon in full and, in any event, Dixon's relevant disclosures were cumulative of other disclosures before the Examiner during prosecution of the '069 Patent.

Again ignoring *Advanced Bionics*, Mylan relies on the absence of a rejection on the cited art to allege error. But because the same or substantially the same art was before the Office, and because Mylan fails to show material error by the Examiner, discretionary denial is appropriate.

II. IPR2021-00881 SHOULD BE DENIED UNDER §325(D)

A. The Examiner Considered Substantially the Same Art

Mylan argues that its asserted art is not the same or substantially the same as the Thomson Reuters press release because: (1) the Examiner would not have understood the Thomson Reuters press release to be prior art; and (2) Mylan's art contains additional disclosures that are not in the press release. Neither has merit.

1. The Examiner Would Have Recognized the Thomson Reuters Publication as a September 28, 2008 Press Release

Regeneron presented a press release titled "VEGF Trap-Eye final phase II results in age-related macular degeneration presented at 2008 Retina Society Meeting" to the Office in an IDS, which was marked considered by the Examiner. Ex. 1017, 60 and 114. The IDS clearly identifies the title of the press release, the source as Thomas [sic] Reuters Integrity, and the date as September 28, 2008:

	12	THOMAS REUTERS INTEGRITY "VEGF Trap-Eye final phase II results in age-related macular degeneration presented at 2008 Retina Society Meeting" (September 28, 2008)	☐

Ex. 1017, 60. Nothing on the IDS suggests a 2012 date. Rather, the IDS and the face of the '338 Patent report the document's date as September 28, 2008. Ex. 1001.

Mylan does not dispute this. Instead, it argues that a 2012 copyright date on the publication would have indicated to the Examiner that the press release was from 2012, not 2008, and as a consequence, he would have disregarded it. But the document itself refutes this suggestion. Ex. 2007 identifies the "Reference" as "Regeneron Pharmaceuticals Press Release 2008, September 28" and the "Title" as "VEGF Trap-Eye final phase II results in age-related macular degeneration presented at 2008 Retina Society Meeting." And the footer of Ex. 2007 shows that the printout was obtained from a Thomson website visited on "18-04-2012." Thomson Reuters was a well-known source for retrieving literature citations (Ex. 2043) and the 2012 copyright date would indicate to anyone familiar with the Internet the retrieval date of the publication, not the date of the press release itself. Furthermore, it defies common sense to assert that a press release reporting on a 2008 Retina Society Meeting did not issue until 2012.

Indeed, the international search report from EP-325 (European counterpart to the '338 Patent), on which Mylan relies ('338 Pet. 10-11), confirms that this document was retrieved using Thomson Reuters Integrity on 2012-04-18:

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Thomson Reuters Integrity: "VEGF Trap-Eye final phase II results in age-related macular degeneration presented at 2008 Retina Society Meeting", , 28 September 2008 (2008-09-28), pages 1-1, XP002674126, Retrieved from the Internet: URL:https://integrity.thomson-pharma.com/integrity/xmlxsl/pk_ref_list.xml_show_llist at_refs?p_session_id=1868065&p_orig=&p_count=354&p_num_dailys=42&p_qry_save=&p_subtitol=Biomedical%20Literature%20List&p_dailys=N&p_tsearch=A&p_text=N&p_whatToShow=REF&p_prousQuantity=5&p_page=10#link [retrieved on 2012-04-18] the whole document ----- -/--	1-37

It also confirms that exactly the same document that is marked "XP002674126" and cited as D13 in EP-325 was submitted during prosecution of the '338 Patent (Ex. 2007). Ex. 1063 at 62, 194, 196. Remarkably, in the context of EP-325, Mylan characterizes this same Thomson Reuters publication as a "September 28, 2008 Press Release,"[1] yet, Mylan incorrectly asserts that this same document was never provided to the Office during prosecution of the '338 Patent. '338 Pet. at 11.

[1] Mylan asserts the EPO Examiner rejected EP-325 over "prior art VEGF Trap-Eye dosing regimens (*e.g.*, Regeneron Sept. 28, 2008 Press Release (Ex. 1056). See Ex. 1063, EP-325-FH, 8/21/2014 Communication, 3-8.)." '338 Pet. at 11. Yet, D13 (Ex. 2007), ***and not Ex. 1056***, was the only VEGF Trap-Eye dosing regimen art cited in the 8/21/2014 Communication. Ex. 1063, 190-200.

2. Mylan's Relied-Upon Disclosures Are Substantially the Same as the 2008 Regeneron Press Release

Each of Mylan's Grounds relies on the same dosing regimen disclosure that is set forth in Ex. 2007. POPR at 12-14. Mylan nevertheless argues that its references contain disclosures not present in Ex. 2007. Reply at 7.

As an initial matter, Mylan's argument that different press releases, or different versions of press releases, contain different disclosures is a red herring. *Id*. at 5. Mylan does not dispute that Ex. 2007 was of record; thus, the relevant issue is whether Ex. 2007 contains substantially the same disclosures as Mylan's cited art, not whether other press releases may contain more or different disclosures.

Mylan says that Dixon discusses problems with monthly dosing of Lucentis in the prior art. But Mylan does not rely on this disclosure for its anticipation Grounds and, as to obviousness, it was known in the art that Lucentis® was dosed on a monthly basis and that there was a need in the art for less frequent dosing, as set forth in the "Background" section of the '338 Patent. Ex. 1001, Col. 1:50-61. Mylan next argues that Regeneron (8-May-2008) includes efficacy endpoints and an inventor statement, but Mylan relies on neither of these passages in its Grounds. Finally, Mylan asserts that Adis and Dixon disclose that VEGF Trap-Eye is aflibercept,[2] but, as the POPR explained, Mylan's argument rests on the flawed

[2] Dixon never identifies aflibercept as the agent in Regeneron's Phase III trials.

premise that these terms are synonymous. See POPR at 12, fn. 2.

3. Mylan's Secondary References Are Substantially the Same as the '234 Application

Mylan relies on the '758 Patent and Dix as secondary references for obviousness ('338 Pet., Ground 6; '069 Pet., Ground 5). Mylan argues that the '758 Patent is not substantially the same as the '234 Application, a CIP child that was considered by the Office in prosecution of both patents, because it lacks sequence information. Reply at 7-8; Ex. 1017 at 66 and 112. Mylan ignores that the '234 Application specifically incorporates by reference the entirety of the '758 Patent. Ex. 2009 at [0001] ("This application is a continuation-in-part of application Ser. No. 11/016,097 . . . which applications are herein specifically incorporated by reference in their entireties.").[3] Mylan also argues Dix is not cumulative of the '234 Application because it incorporates Holash. Reply at 8. But Holash (Ex. 1033), which lacks any sequence information, is not relied upon in Mylan's Grounds.

Also, Mylan's contention that it presents arguments not previously considered by the Office ignores this Board's consistent holding that "the first part of the 325(d)

[3] Mylan also points to the EYLEA PTE application in the file history as a difference (Reply at 8), but the '758 file history is a different document (Ex. 1024) than the '758 patent (Ex. 1010), is not prior art, and is not relied upon in Mylan's Grounds.

framework may be met when relied-upon art is presented in an IDS but never discussed or cited in a rejection by the Examiner…." *Mylan Pharms. Inc. v. Merck Sharp & Dohme Corp.*, 2020 WL 2478503, *6 (May 12, 2020); *Philip Morris Prods., S.A. v. Rai Strategic Holdings, Inc.*, 2020 WL 6750120, *5 (Nov. 16, 2020); *see also BMW of North Am., LLC v. Stragent, LLC*, 2021 WL 3074671, *5 (Jul. 19, 2021).[4]

B. Mylan Fails to Show Examiner Error

Mylan argues that the Examiner erred by not rejecting claims based on prior art disclosures of Regeneron's prospective Phase 3 dosing regimen. Reply at 9. However, the Board has consistently held that the absence of a rejection or a difference of opinion over treatment of art does not demonstrate Examiner error. *See, e.g.*, *Google LLC v. Kewazinga Corp.*, 2021 WL 3746361, *8 (Aug. 24, 2021) ("But whether a reference was a basis for a rejection is not dispositive… ."); *Sony Interactive Entm't LLC v. Terminal Realty, Inc.*, 2020 WL 6065188, *5 (Oct. 13,

[4] Mylan asserts that it "presents Dr. Albini's opinions and analyses, further weighing against § 325(d) denial" in both Petitions. Reply at 9. But Mylan "does not explain how this testimony serves to show, if at all, that the Examiner erred." *Google*, 2021 WL 3746361, *8. Thus, Dr. Albini's declaration is an insufficient basis to deny institution under §325(d). *Id*.; *Medtronic CoreValve LLC v. Speyside Medical, LLC*, 2021 WL 3137302, *13 (Jul. 23, 2021).

2020) (argument that the asserted references were not evaluated by the examiner failed to sufficiently identify Examiner error); *Universal Imaging v. Lexmark Int'l, Inc.*, 2020 WL 959375, *5 (the absence of a rejection based upon the petitioned grounds "is not the end of [the Board's] analysis" on material error); *Regeneron Pharms., Inc. v. Kymab Ltd.*, 2020 WL 2738613, *7 (May 26, 2020) (petitioner offered "a different interpretation" of prior art, which is not material error).

III. IPR2021-00880 SHOULD ALSO BE DENIED UNDER §325(D)

A. The Examiner Considered the Same or Substantially the Same Art

Mylan relies on Dixon for each of the five Grounds in the '069 Petition. Yet, Mylan argues for the first time in Reply that Dixon was not before the Office. Upon receipt of the Reply, Patent Owner promptly investigated Mylan's allegations and agrees that only one page of Dixon, instead of the whole paper, was filed due to a clerical error. Mylan insinuates that Patent Owner "misdirected [the Examiner] from critical disclosures that anticipate and invalidate the claims." Reply at 2. But Patent Owner was unaware that Dixon was submitted as a single page before Mylan's Reply.

Mylan also disregards that the full citation to the Dixon paper was presented in an IDS, the reference was publicly available, and was marked considered by the Examiner. Ex. 1017 at 121, 168. "The initials of the examiner placed adjacent to the citations . . . or its equivalent mean that the information has been considered by the examiner" in the same manner as other documents in Office search files are

considered. M.P.E.P. at § 609.05(b). The record does not suggest that the Examiner found Patent Owner's disclosure of Dixon to be defective or incomplete, as the Examiner has not drawn a line through the citation on the IDS. *Id.* Further, Mylan's reliance on *Coolpad Techs., Inc.* and *Semiconductor Energy Lab'y Co.* for its contention that the Examiner's initials extend to only a portion of Dixon is misplaced. Reply at 4. In both cases, the references at issue required translation for the Examiner's full consideration. Here, in contrast, Dixon is a publicly available, English-language reference that the Examiner could consider without translation.

In any event, the Dixon disclosures relied upon by Mylan — namely, the CLEAR-IT-2 dosing regimen and results ('069 Pet. at 3-4) — are also disclosed in the Thomson Reuters press release (Ex. 2007), which was presented to and considered by the Examiner, and cited on the face of the '069 Patent. Ex. 1017 at 68, 114; Ex. 1001. Mylan's secondary references, as discussed *infra*, are also cumulative of art that was considered by the Office. Thus, the same or substantially the same art was considered by the Examiner during prosecution of the '069 Patent.

B. Mylan Fails to Show Examiner Error

Mylan asserts that the Examiner "materially erred" in not obtaining a complete copy of Dixon. Reply at 9. But Mylan assumes without basis that the Examiner did not obtain a copy of Dixon based on the full citation provided to the Examiner on the IDS. Yet, it cannot know that and, notwithstanding the one-page

submission, the file history of the ’069 Patent in view of M.P.E.P. § 609.05(b) otherwise supports that the Examiner fully considered the Dixon reference. Mylan also argues that the Examiner erred in not rejecting the claims over Dixon and/or other §102(b) references cited in the Petition. But, as discussed above, the absence of a prior art rejection does not establish Examiner error.

IV. MYLAN’S BELATED §325(D) ARGUMENTS ARE PROCEDURALLY UNFAIR

Mylan does not dispute that Ex. 2007 was before the Examiner during prosecution but chose to cast its Petition as Patent Owner failing to disclose to the Office. *See, e.g.*, ’338 Pet. at 1, 11, 27-28, 31. Mylan should not be permitted to change its theory of its case on Reply to now parse the text of a 2008 Press Release, or worse yet, assert that it is not from 2008 at all. Likewise, Mylan knew that Dixon was cited in an IDS to the Examiner and listed on the face of the ’069 Patent. Yet, Mylan raised the argument that Dixon was not fully considered only on Reply.

Permitting Mylan to lie in the weeds in its Petition and raise new arguments on Reply circumvents the Board’s word count rules, runs counter to *General Plastics*’ admonition against road-mapping from the POPR, flouts the good cause standard required for Reply, and is unfairly prejudicial to Patent Owner.

V. CONCLUSION

For the foregoing reasons, discretionary denial of IPR2021-00880 and IPR2021-00881 under §325(d) is warranted.

Dated: October 6, 2021

Respectfully Submitted,

/s/ Deborah E. Fishman

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4)(i) *et seq*. and 42.105(b), the undersigned Certifies that on October 6, 2021, a true and entire copy of this **PATENT OWNER REGENERON PHARMACEUTICALS, INC.'S CONSOLIDATED SUR REPLY TO PETITIONER'S REPLY TO PATENT OWNER PRELIMINARY RESPONSE**, and all supporting exhibits, were served via e-mail to the Petitioner at the following email addresses:

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