UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

IPR2021-00880 (Patent 9,669,069 B2)
IPR2021-00881 (Patent 9,254,338 B2)

PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

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As authorized by the Board (Paper 13), Petitioner submits this Reply.

I. INTRODUCTION.

Discretionary denial is not warranted here. "The Board has consistently declined exercising its discretion under Section 325(d) when the only fact a Patent Owner can point to is that a reference was disclosed to the Examiner during the prosecution." *Amgen Inc. v. Alexion Pharms., Inc.*, IPR2019-00739, Paper 15 at 62 (P.T.A.B. Aug. 30, 2019) (citing *Amneal Pharms. LLC v. Alkermes Pharma Ireland Ltd.*, IPR2018-00943, Paper 8 at 40 (P.T.A.B. Nov. 7, 2018); *Amazon.com, Inc. v. M2M Solutions LLC*, IPR2019-01205, Paper 14 at 16 (P.T.A.B. Jan. 27, 2020) ("[A] reference that 'was neither applied against the claims nor discussed by the Examiner' does not weigh in favor of exercising the Board's discretion under § 325(d) to deny a petition."). In neither prosecution did the Examiner consider art or arguments the same or substantially the same as Petitioner's. Thus, there was no need for Petitioner to address *Becton, Dickinson* factors or allege Examiner error.[1]

[IPR2021-00880] The '069 Patent File History Does Not Pass *Advanced Bionics*' Threshold Inquiry. Neither "the same [nor] substantially the same" art or arguments were "previously . . . presented to the Office" for U.S. 9,669,069 ("the

[1] PO raised the Chengdu PGR2021-00035, which is inapposite. The '345 patent contains *eight pages* of "References Cited." PGR2021-00035, Ex.1001, 1-8.

'069 patent"). Petitioner asserts, among several other references, Dixon (Ex.1006), as anticipatory art. Patent Owner ("PO") argues that "Dixon was submitted to the Office . . . and was marked 'considered' by the Examiner." The intrinsic record confirms otherwise. *First*, like in *Amazon,* Dixon was "neither applied against the claims nor discussed by the Examiner." (*See also* Petition, 32 ("Dixon was not cited by the Examiner.")). *Second*, while *a* "Dixon" citation appears in an IDS submitted at the end of prosecution, Dixon—in the form asserted by Petitioner (Ex.1006)—was in fact neither presented nor considered. Instead, PO intentionally submitted only *the first page* of Dixon to the Examiner, misdirecting him from the critical disclosures that anticipate and invalidate the claims. PO never "'disclose[d]' to the PTO all information [it] kn[ew] 'to be material to patentability.'" *Minerva Surgical, Inc. v. Hologic, Inc.*, 141 S. Ct. 2298, 2309 n.3 (2021) (quoting 37 C.F.R. § 1.56(a)). The Examiner therefore never considered Dixon—in its entirety, as Petitioner asserts—or the dosing regimens disclosed therein.

[IPR2021-00881] The '338 Patent File History Does Not Pass *Advanced Bionics*' Threshold Inquiry. Similarly, neither "the same [nor] substantially the same" art or arguments were "previously . . . presented to the Office" for U.S. 9,254,338 ("the '338 patent"). PO distorts the intrinsic record, misrepresenting a 2012 (*post*-art) paper as a 2008 publication to argue cumulativeness. That argument fails for its deliberate contradiction of the facts, which confirm the Examiner never

considered Petitioner's asserted art or any other VIEW *prior* art.

In sum, the answer to *Advanced Bionics*' first inquiry—whether the same or substantially the same art or arguments were previously presented to the Office—for both challenged patents is a definitive "no." Petitioner thus had no reason to allege Examiner error or provide *Becton, Dickinson* analysis.

II. ARGUMENT.

A. BACKGROUND: INTRINSIC RECORDS OF THE CHALLENGED PATENTS.

[IPR2021-00880] The '069 Patent Prosecution. *First*, Dixon (Ex.1006) was "neither applied against the claims nor discussed by the [E]xaminer." *Amazon.com*, Paper 14 at 16; (*see also* Petition, 32).[2] The Examiner issued one office action, asserting OTDP over several prior PO patents, none of which disclosed CLEAR-IT-2[3] (Ex.1017, 105-09), and further stating that while the OTDP patents "do[] not disclose the [claimed] dosing schedules," the element was "routine experimentation." The Examiner did not apply any prior art disclosing the dosing

[2] PO alleges Regeneron (30-April-2009) is cumulative of Regeneron (20-December-2010). Not so. The 2010 document is 102(a) art; Regeneron (30-April-2009) is 102(b) art, and, like Dixon, was never asserted or discussed by the Examiner. Further, Mitchell (ranibizumab) is not cumulative of one-page Dixon (aflibercept).

[3] PO notably does not allege Dixon is cumulative of the art or arguments the Examiner actually asserted (i.e., the OTDP patents) during prosecution.

regimens in Dixon. In response, PO asserted so-called "improved unexpected results," presenting Heier-2012 as support. (*Id.*, 136). PO never directed the Examiner to Dixon or any other prior art disclosing the dosing regimens in Dixon.

Second, Dixon was, in fact, *not* presented to the Examiner. The EFS Acknowledgment Receipt clearly states that the Examiner received only *one* page:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
	*	* *			
5	Non Patent Literature	Dixon_Expert_Opin_Investig_Drugs_2009.pdf	72933 c5cca12bc9e6f81d3fa8d4000c3bb8efcfa56b39	no	1

(Ex.1017, 126 (emphasis added)).[4] The certified file history confirms PO only submitted a one-page copy. (Ex.1087 [-880 IPR]). Under 37 C.F.R. § 1.98(a)(2), PO thus informed the Examiner that its one-page copy represented the "portion which caused [Dixon] to be listed," affirmatively excluding the rest. The submitted page, however, does not disclose (or even mention) the prior art regimens described

[4] PO argues the Examiner's initials signify he "considered" Dixon. (POPR, 10-11). The initialed IDS shows, *at best*, that he "considered" the single page—no more. *Coolpad Techs., Inc. v. Bell N. Rsch., LLC*, IPR2019-01319, Paper 19 at 9-12 (P.T.A.B. Jan. 29, 2020) (citing *Semiconductor Energy Lab'y Co. v. Samsung Electronics Co.*, 204 F.3d 1368, 1377-78 (Fed. Cir. 2000) (initials "extend[] only to the examiner's consideration of the brief translated portion")).

extensively in the complete Dixon (Ex.1006). (*Compare id.*, *with* Petition, 32-34).

[IPR2021-00881] The '338 Patent Prosecution. Petitioner's anticipatory art was not considered by the Examiner. (Petition, 27-36). PO contends that art is cumulative of an IDS-listed document which PO presents to the Board as a "September 28, 2008, Regeneron Press Release" (hereinafter, the "9/28/08 PR"). (POPR, 9). This is false and misleading. The paper on which PO hinges its argument is a ***2012*** (i.e., post-art)[5] printout of a "Thomson Reuters" website ("Reuters-2012")—i.e., not the 9/28/08 PR.[6] (Ex.2007). The *actual* 9/28/08 PR (accessible to PO but withheld from the Examiner[7]) contains information absent in Reuters-2012. (Ex.1098 [-881 IPR] (comparison, with text missing from Reuters-2012 in blue)).

Reuters-2012 was also never "applied against the claims []or discussed by the [E]xaminer"—nor was any VIEW dosing regimen prior art. *Amazon.com*, Paper 14 at 16. Instead, the Examiner made one round of OTDP rejections (based upon

[5] The '338 patent purports a Jan. 2011 priority date. Nothing in the record supports finding the Examiner accepted Reuters-2012 as prior art or a printed publication.

[6] In its POPR, PO short-cites Reuters-2012 (Ex.2007) as "9/28/2008 Press Release," repeatedly mispresenting it as a *2008* disclosure. (POPR, 9, 12-14, 58-59).

[7] Actual, complete press releases, e.g., 9/28/08 PR, were accessible to PO. (Ex.1012; Ex.1013; Ex.1028; Ex.1041; Ex.1053; Ex.1054; Ex.1056). None were presented.

Regeneron's earlier sequence patents) before allowing the claims. No § 102 or § 103 rejections were lodged by the Examiner. (Ex.1017, 259-69).

B. DISCRETIONARY DENIAL UNDER § 325(d) IS NOT WARRANTED.

In light of *Advanced Bionics*, incorporating the *Becton, Dickinson* factors, the Board should not exercise its discretionary denial authority.

1. Petitioner's asserted art and arguments are not the same or cumulative. (*Becton, Dickinson* (a), (b), and (d)).

[IPR2021-00880]. PO classifies Petitioner's primary references (Exs.1006, 1012, 1020) as cumulative of the one-page "Dixon" the Examiner received at the end of prosecution.[8] As set forth above, neither Dixon (Ex.1006) nor any cumulative art or substantially the same arguments were presented to or considered by the Examiner. Indeed, PO's one-page "Dixon" excludes every invalidating disclosure of the prior art dosing regimens—all of which are expressly *included* in Petitioner's art. Accordingly, the first *Advanced Bionics* factor is not, and cannot be, satisfied.[9]

[8] As stated above (*see* n.2 *supra*), Regeneron (30-April-2009) (Ex.1028) is also not the same or substantially the same art as Regeneron (20-Dec-2010).

[9] Petitioner further submits that the one-page "Dixon" fails to comply with PO's Rule 56 duties of candor, good faith, and disclosure. Instead, PO's "misleadingly incomplete" one-page copy "misdirect[ed] the examiner's attention from [Dixon's] relevant teaching." *See Semiconductor*, 204 F.3d at 1377-78.

[IPR2021-00881]. It is undisputed that Petitioner's anticipatory references were never presented, considered, or asserted during prosecution. Petitioner's art—all predating the '338 patent—also is not substantially the same as Reuters-2012. *First*, Reuters-2012 is post-art and thus is not, and cannot be, the "same or substantially the same *prior art.*" 35 U.S.C. § 325(d) (emphasis added); *Dish Network L.L.C. v. Broadband iTV, Inc.*, IPR2020-01332, Paper 14 at 15 (P.T.A.B. Jan. 27, 2021) (the cited reference "was not 'prior art,' as provided in § 325(d) . . . [thus] does not present 'the same or substantially the same *prior art*'")).[10]

Second, Petitioner's art contains additional disclosures not in Reuters-2012. For example, Dixon discusses Lucentis extended dosing regimens and the problems with monthly intravitreal injections. (Ex.1006, 1574, 1577; Petition, 28-29). Adis and Dixon disclose that VEGF Trap-Eye is aflibercept. (Ex.1006, 1573; Ex.1007, 261; Petition, 23-24). Regeneron (8-May-2008) includes efficacy endpoints for the VIEW trials and PO/inventor statements about the claimed regimens. (Ex.1013).[11]

[Both IPRs] PO concedes Petitioner's secondary references ('758 patent and Dix) were not presented to the Examiner. Instead, PO argues the '234 application is substantially the same, but, in doing so, PO ignores the additional, non-cumulative

[10] Reuters-2012 is the only dosing reference PO bases its § 325(d) arguments on.

[11] Such disclosures will rebut PO's efficacy and expectation of success arguments.

disclosures in Petitioner's art. For example, the '758 patent contains Fig. 24, the aflibercept sequence and domain annotations not found in the '234 application or the OTDP references. (Ex.1010, Fig.24A-C; Petition, 36, 63). Dix incorporates Holash, the original publication detailing the creation and structure of aflibercept. (Ex.1033, [0005]; Petition, 37, 63). The '758 patent file history contains an EYLEA® PTE application with PO admissions confirming Fig. 24A-C is the aflibercept sequence and tying aflibercept to Holash. (Ex.1024, 2, 6-7; Petition, 36).[12]

2. Petitioner presents additional, new art and arguments. (*Becton, Dickinson* (a), (b), (d)).

[IPR2021-00880]. Beyond the complete version of Dixon and other § 102(b) references, Petitioner relies on new art and arguments. For example, the Examiner never rejected claims under §§ 102/103, whereas Petitioner asserts four anticipation and two obviousness grounds—all involving art the Examiner never considered.

[IPR2021-00881]. As discussed above, Petitioner's asserted art was neither presented to the Examiner, nor is it "substantially the same" as Reuters-2012. In addition, Petitioner presents arguments never considered by the Examiner, who never rejected claims under §§ 102/103. Plus, there is no evidence the Examiner considered, evaluated, or asserted prior art based on the VIEW dosing regimen.

[12] US2005/0163798, not raised in the POPR, also does not include the incorporation by reference to Holash, or the EYLEA® PTE application disclosures.

In both IPRs, Petitioner also presents Dr. Albini's opinions and analyses, further weighing against § 325(d) denial. *See Guardian Indus. Corp. v. Pilkington Deutschland AG*, IPR2016-01635, Paper 9 at 9-10 (P.T.A.B. Feb. 15, 2017).

3. If the Board concludes step one of *Advanced Bionics* is satisfied, the Office erred. (*Becton, Dickinson* (c), (e), (f)).

As explained, the records do not reflect that Petitioner's art or arguments were presented to, or considered by, the Examiner. Petitioner submits that PO's documents (the one-page Dixon; Regeneron (20-December-2010); and Reuters-2012) are not Rule 56 disclosures of "the same or substantially the same art." Plus, the Examiner issued no analogous rejections. Accordingly, *Advanced Bionics'* first factor is not satisfied and Petitioner should not have been required to allege error.

[IPR2021-00880]. In the event the Board disagrees, Petitioner respectfully submits that the Examiner materially erred in (i) accepting PO's one-page submission, (ii) not obtaining a complete copy of Dixon, and (iii) not rejecting the claims over Dixon and/or any other § 102(b) reference disclosing the PRN regimens set forth therein. (*See* Petition, 1 ("These claims should have never issued.")).

[IPR2021-00881]. Likewise, Petitioner respectfully submits that the Examiner materially erred in not evaluating whether Reuters-2012 could be tied to earlier publications, and further erred in not locating and asserting any of the art that reads directly on the claims, including the VIEW prior art, during prosecution.

4. The cases cited in the POPR are not relevant to the facts here.

None of PO's cases support its attempt to shield the challenged claims from substantive review. *NXP USA, Inc. v. Impinj, Inc.* involved a reference that was prior art; cited as the lone reference in an IDS; with the same authors as the IPR-asserted art; involving numerous § 103 rejections wherein the Examiner extensively evaluated and compared the pending claims against art disclosing the same features as the IDS reference. IPR2020-00519, Paper 7 (P.T.A.B. Aug. 17, 2020); (*see, e.g.*, Ex.1088 [-880 IPR], 1, 4-18, 22-36, 44-46; Ex.1099 [-881 IPR] (same)).

In *ABS Global, Inc. v. Cytonome/ST, LLC*, an IDS listed three of the IPR-asserted references; one was evaluated and asserted by the Examiner during prosecution; and the petitioner had "multiple failed attempts" asserting the art in related IPRs and district court. IPR2021-00306, Paper 13 (P.T.A.B. June 7, 2021). In *Gardner Denver, Inc. v. Utex Indus., Inc.*, "nearly identical" disclosures were "thoroughly considered" "multiple times" in the Examiner's §§ 102/103 rejections. IPR2020-00333, Paper 12 (P.T.A.B. Aug. 5, 2020). *Boragen, Inc. v. Syngenta Participations AG*, involved IPR art "asserted by the Examiner in five separate office actions." IPR2020-00124, Paper 16 (P.T.A.B. May 5, 2020).

In short, PO cites no cases that deny institution based upon merely an IDS listing, where, as here, the claims were never subject to any §§102/103 challenges.

III. CONCLUSION.

Petitioner respectfully asks the Board reject PO's request for § 325(d) denial.

Dated: September 29, 2021

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE was served on September 29, 2021, via electronic mail by agreement of the parties, to the following counsel for record of Patent Owners:

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