

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner

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

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

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**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)	<input type="checkbox"/>
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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:

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