

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. FALK PHARMA GMBH,
Petitioner,

v.

ELLODI PHARMACEUTICALS, L.P.,
Patent Owner.

Case No. IPR2024-01197
Patent No. 8,771,729 B2

PATENT OWNER'S SURREPLY

Petitioner's Reply misquotes and misinterprets the disclosure of the prior art cited during prosecution, fails to distinguish the Petition prior art from the substantially same art cited during prosecution, and fails to explain why the Examiner erred during prosecution. The Board should deny institution.

I. *ADVANCED BIONICS* PRONG 1: THE ART PRESENTED IN THE PETITION IS SUBSTANTIALLY THE SAME AS THE ART PRESENTED DURING PROSECUTION

As explained in the POPR, Dohil is the same or substantially the same as Phillips, cited during prosecution. (POPR, 12-20.) Both references disclose, in passing, solid dosage forms and neither reference discloses disintegration within 60 seconds. Consequently, Petitioner's Reply is premised on misquoting Patent Owner's statements during prosecution. (Reply, 1.) Specifically, Petitioner omits the portion, in bold, where Patent Owner argued that "*Phillips* provides no reason to have a rapid disintegration time, **particularly one of about 60 seconds....**" (Ex. 1031, 31-32 (bold emphasis added).) Petitioner does not address the Examiner's reasons for allowance, finding disintegration time to be an important limitation and stating that Phillips "does not teach or suggest an orally disintegrating solid pharmaceutical composition (or an orally disintegrating tablet) ***that disintegrates within 60 seconds.***" (Ex. 1031, 19 (emphasis in original).) Dohil, cited by Petitioner, teaches a lozenge that would dissolve "rapidly in the mouth or esophagus[.]" (Ex. 1002, ¶[0032]) but does not teach a disintegration time of 60 seconds. Dohil,

therefore, does **not** “contain[] the precise disclosure that Patent Owner asserted was missing from Phillips[,]” and instead contains the same disclosure. (Reply, 1.)

Petitioner attempts to fill this gap with a POSA’s knowledge of the FDA’s Guidance using the USP <701> Disintegration Test. (Reply, 2.) During prosecution, however, the Examiner rejected the claims over Phillips in view of Venkatesh 2009, which *expressly discloses* the USP <701> Disintegration Test. (Ex. 2002, ¶[0082].) Thus, Petitioner relies on substantially the same art and identical arguments that were previously presented and overcome.

Like its Petition, Petitioner again fails to explain the relevance of the EPO decision, which involves different claims and different legal standards. Contrary to Petitioner’s conclusion (Reply, 2), finding a reference “not prima facie more relevant” does not weigh on whether the reference is cumulative. In fact, a reference that is cumulative cannot be “prima facie more relevant.” Further, as pointed out in POPR, the EPO decision is neither binding on the Board nor considered prior art and thus irrelevant. (POPR, 30-31.) Petitioner gives no reason why it should apply here.

Petitioner also does not explain why Venkatesh 2009 is materially different from the FDA Guidance. Instead, Petitioner alleges, without declaration support, that because the FDA Guidance is allegedly more widespread, it cannot be cumulative to the allegedly lesser-known Venkatesh 2009. (Reply, 2.) Petitioner cites no legal authority establishing a more “widespread” reference cannot, per se, be non-

cumulative to another allegedly “lesser known” reference. Because Petitioner does not dispute that both the FDA Guidance and Venkatesh 2009 specifically disclose the ODT compositions that disintegrate within 60 seconds using the USP <701> Disintegration Test, the FDA Guidance is cumulative to art already considered during prosecution. (Ex. 1005; Ex. 2002, ¶[0085].)

Regarding Grother, Petitioner misunderstands Patent Owner’s argument. Petitioner argues that because Grother lists budesonide or fluticasone in its list of corticosteroids, it is not substantially the same as Venkatesh 2009 because a POSA would recognize those as topical steroids. Like Grother, Venkatesh 2009 lists at least one topical corticosteroid in its long list of corticosteroids (*see e.g.*, Ex. 2002, ¶[0029] (listing beclomethasone).) As Patent Owner argued during prosecution, Venkatesh 2009 does not suggest a preference for corticosteroids with topical, rather than systemic activity. (Ex. 1031, 72.) Similarly, Grother does not comment on any *preference* for a topical corticosteroid from its laundry list of drugs. (Ex. 1008, 15:19-20, 18:15-18.) Thus, Grother is substantially the same as Venkatesh 2009 that has already been considered by the Office. (POPR, 44.)

Petitioner also makes a conclusory assertion that because it is relying on Venkatesh as a secondary reference, and Venkatesh 2009 was relied on as a primary reference during prosecution, the Petition presents different combinations. (Reply, 3-4.) Petitioner cites no authority establishing that this alleged distinction is material.

Petitioner's combinations and arguments are the same as made during prosecution, and Petitioner's Reply does not explain otherwise. For Ground 3, Petitioner relies on substantially the same combination – Dohil in combination with Venkatesh – as the Examiner – Phillips in combination with Venkatesh 2009. (POPR, 18-20, 28-29.) For Grounds 2 and 4, Petitioner relies on combinations that are substantially similar to and/or cumulative of Venkatesh 2009. (POPR, 45.) None of the Petitioner's combinations or arguments are different from what the Office already considered.

II. *ADVANCED BIONICS* PRONG 2: PETITIONERS FAIL TO SHOW THAT THE OFFICE ERRED IN A MANNER MATERIAL TO PATENTABILITY

Petitioner's argument that the Office erred because it did not have the evidence cited in the Petition is unavailing. (Reply, 4-5.) First, as explained above and in the POPR, Dohil does not disclose the claimed disintegration time missing from Phillips. (POPR, 19.) Venkatesh 2009, considered by the Examiner, like the FDA Guidance, does disclose the claimed disintegration time, and the combination of Phillips and Venkatesh 2009 was overcome by Patent Owner during prosecution. (Ex. 1031, 47-52, 30-34, 19.) Thus, the teaching of the disintegration time was not overlooked by the Examiner as it was disclosed in Venkatesh 2009. Further, the EPO decision is not binding on the Board and the case Petitioner cites to is inapposite. In *Novartis Pharmaceuticals Corp. v. Shilpa Pharma, Inc.*, the Board found the EPO's decision "instructive" because Patent Owner made the same arguments in the

European prosecution as it did in response to the petition, which the EPO rejected. IPR2022-00886, Paper 13 at 28-29 (P.T.A.B. Oct. 26, 2022). Here, Patent Owner made the same argument during the EPO proceeding that Dohil does not disclose a disintegration time of 60 seconds, and the EPO conceded that this element is not described in Dohil. (Ex. 1004, ¶35.2.) Petitioner also inexplicably creates a new burden, arguing that Patent Owner must show the EPO erred in its decision, rather than addressing its own burden of showing how the Office erred in evaluating the asserted prior art. *See* factors (c), (e) and (f), *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 22-23, 24-28 (P.T.A.B. Dec. 15, 2017) (precedential as to § III.C.5, first paragraph).

Contrary to Petitioner's assertion (Reply, 4-5), the POPR details the arguments made in child applications, demonstrating that the Examiner accounted for the disclosures in Dohil 2009 of a tablet that dissolves "rapidly in the mouth or esophagus," which is identical to the disclosures in Dohil cited in the Petition. (POPR, 19-20.) Thus, Petitioner has failed to show any material error on the part of the Examiner regarding Dohil. The Examiner also did not overlook the lack of suggestion for a preference for topically administered corticosteroids in Venkatesh 2009 and Grother does not fill this gap. (Reply, 5.) The Examiner did not err in allowing the claims with respect to Grother. For the reasons set out in the POPR and here, denial under § 325(d) is warranted.

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**CERTIFICATION OF SERVICE
UNDER 37 C.F.R. §§ 42.6(e), 42.105(a)**

I, Sanya Sukduang, hereby certify that on December 4, 2024, the foregoing Patent Owner's Surreply pursuant to 37 C.F.R. § 42.8 were served electronically via email on the following counsel of record for Petitioner as follows:

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