

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NEPTUNE GENERICS, LLC,  
Petitioner,

v.

AVENTIS PHARMA S.A.,  
Patent Owner.

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Case IPR2019-00136  
Patent 5,847,170

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Before TINA E. HULSE, CHRISTOPHER M. KAISER, and  
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

DECISION  
Denying Institution of *Inter Partes* Review  
*35 U.S.C. § 314*

## I. INTRODUCTION

Neptune Generics, LLC (“Petitioner”),<sup>1</sup> on October 31, 2018, filed a Petition to institute *inter partes* review of claims 1 and 2 of U.S. Patent No. 5,847,170 (Ex. 1001, “the ’170 patent”). Paper 1 (“Pet.”). Aventis Pharma S.A. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 9 (“Prelim. Resp.”). We granted (Paper 11) Petitioner’s request to file a pre-institution Reply to Patent Owner’s Preliminary Response to address arguments related to discretionary denial of the Petition. Paper 13.

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the Petition “shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Upon considering the arguments and evidence, we determine that it is appropriate to exercise the Board’s discretion to deny institution under 35 U.S.C. § 325(d). Thus, as explained further below, we do not institute an *inter partes* review of claims 1 and 2 of the ’170 patent.

## II. BACKGROUND

### A. *Related Matters*

Petitioner identifies litigation related to the ’170 patent including *Sanofi-Aventis US LLC v. Fresenius Kabi USA, LLC*, No. 14-7869 (D.N.J. filed Dec. 17, 2014).<sup>2</sup> Pet. 8. According to Petitioner, “[a]pproximately one year ago the District of New Jersey held a bench trial on validity and infringement relating to the ’170 patent and certain Abbreviated New Drug

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<sup>1</sup> Petitioner lists several entities as the real parties-in-interest. Pet. 7–8. We do not repeat that listing here.

<sup>2</sup> This case was consolidated for trial with several other pending cases. Ex. 1049, 1 n.1.

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Applications.” *Id.* at 34–36; *see also* Prelim. Resp. 11–13 (stating that the ’170 patent was the subject of “a Hatch-Waxman action before the District of New Jersey involving, at its peak, 10 defendants,” and ending in “an 8-day bench trial”). Petitioner further notes that the district court, at the trial’s conclusion, held that the ’170 patent’s claims had not been shown to be obvious. Pet. 34; Ex. 1049, 29, 83.

Patent Owner states that “the district court defendants [from the litigation noted above] appealed and that appeal is now pending at the Federal Circuit.” Prelim. Resp. 14. According to Patent Owner, “the district court case has been completed, and the appeal of the district court’s decision upholding the ’170 patent is ready for oral argument at the Federal Circuit.” *Id.* at 28; *see Sanofi-Aventis U.S., LLC v. Dr. Reddy’s Labs., Inc.*, No. 2018-1804 (Fed. Cir.).<sup>3</sup>

As for related matters before the Board, Petitioner identifies an earlier challenge to claims 1 and 2 of the ’170 patent in *Mylan Laboratories Limited v. Aventis Pharma S.A.*, IPR2016-00627 (filed Feb. 17, 2016). Pet. 9; *see also* Ex. 2011 (“Mylan Petition”). Petitioner notes the Board’s denial of institution of *inter partes* review in this earlier matter. Pet. 77–78; Ex. 2020 (Aug. 23, 2016, Decision Denying Institution); *see also* Ex. 2021 (Jan. 26, 2017, Decision Denying Petitioner’s Rehearing Request).

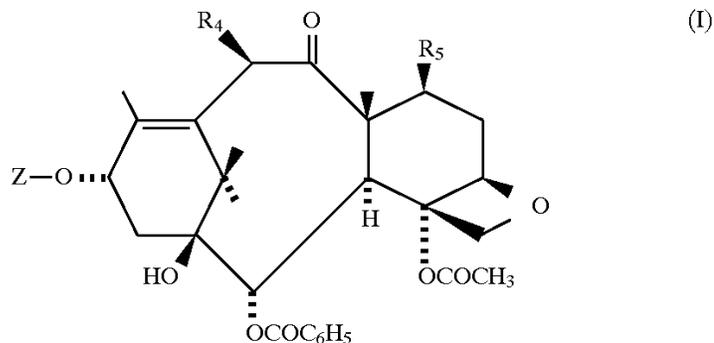
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<sup>3</sup> Case Number 2018-1804 at the Federal Circuit is the lead case for other related appeals (Nos. 2018-1808 and 2018-1809), and involves the appeal of several district court cases that were consolidated for discovery and/or trial. *See, e.g., Sanofi-Aventis U.S., LLC v. Dr. Reddy’s Laboratories, Inc.*, No. 2018-1804, Document 68, 1–2 (Fed. Cir. filed Aug. 20, 2018). Oral argument before the Federal Circuit is scheduled for June 5, 2019. *Sanofi-Aventis*, No. 2018-1804, Document 116 (Notice of Oral Argument).

Notwithstanding the related matters above, Petitioner states that it “has never been accused of infringing the ’170 patent, nor has [Petitioner] previously filed IPR petitions against any related patents.” Pet. 78 n.3.

*B. The ’170 Patent and Background on Taxoids*

The ’170 patent, which issued December 8, 1998, relates to compounds known as “taxoids.” Ex. 1001, Abstract, 1:7. The ’170 patent’s taxoids have the following general formula (I):



in which:

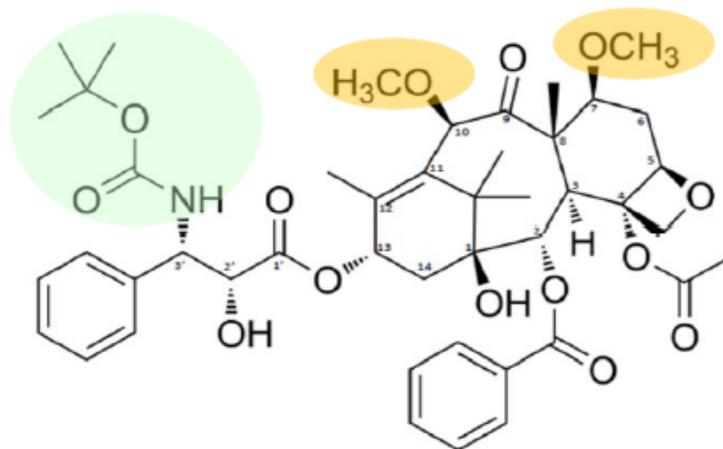
Z represents a hydrogen atom or a radical of general formula (II):



Ex. 1001, 1:7–28. The ’170 patent discloses that “radicals R<sub>4</sub> and R<sub>5</sub>, which may be identical or different, represent unbranched or branched alkoxy radicals containing 1 to 6 carbon atoms.” *Id.* at 3:62–64. According to the ’170 patent, “[t]he new [taxoid] products have antitumour properties, and more especially activity against tumours which are resistant to Taxol® or to Taxotere®.” *Id.* at 11:59–63 (“Such tumours comprise colon tumours which have high expression of the *mdr* 1 gene (multiple drug resistance gene).”). Taxol® is the trade name for the compound paclitaxel, a taxoid known in the

prior art. Ex. 1002 ¶ 71; Ex. 1009, 2; Ex. 1010, 1.<sup>4</sup> Taxotere® is the trade name for another known taxoid, docetaxel, a semi-synthetic analog of paclitaxel. Ex. 1009, 2; Ex. 1011, 2.

The claims of the '170 patent challenged here are directed to a specific compound known as cabazitaxel and to compositions comprising the compound. Ex. 1001, 28:57–65 (claims 1 and 2); Pet. 1; Ex. 1002 ¶ 37. The chemical name for cabazitaxel is 4 $\alpha$ -Acetoxy-2 $\alpha$ -benzoyloxy-5 $\beta$ ,20-epoxy-1 $\beta$ -hydroxy-7 $\beta$ ,10 $\beta$ -dimethoxy-9-oxo-11-taxen-13 $\alpha$ -yl(2R,3S)-3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate. Ex. 1001, 28:56–60; Ex. 1002 ¶¶ 36–37. Cabazitaxel's chemical structure is shown below:



Ex. 1002 ¶ 37 (annotations added). Relevant to the challenge in this Petition, we highlight in orange the two methoxy (OCH<sub>3</sub>) groups at the C-7 and C-10 positions (R<sub>5</sub> and R<sub>4</sub>, respectively in Formula I of the '170 patent). We highlight in green the 3-tert-butoxycarbonylamino group (3'-NHBOC, which we refer to herein as a “BOC” group) at the C-3' position of the

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<sup>4</sup> For purposes of the citations to the prior art (e.g., Exs. 1009, 1010, etc.), we refer to the page numbers provided on the exhibit copies, rather than the references' original page numbering.

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