

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MYLAN LABORATORIES LIMITED,  
Petitioner,

v.

AVENTIS PHARMA S.A.,  
Patent Owner.

---

Case IPR2016-00627  
Patent 5,847,170

---

Before: BRIAN P. MURPHY, TINA E. HULSE, and CHRISTOPHER M.  
KAISER, *Administrative Patent Judges*.

MURPHY, *Administrative Patent Judge*.

DECISION  
Denying Institution of *Inter Partes* Review  
*37 C.F.R. § 42.108*

## I. INTRODUCTION

Mylan Laboratories Limited (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1 and 2 of U.S. Patent No. 5,847,170 (Ex. 1001, “the ’170 patent”). Paper 3 (“Pet.”). Aventis Pharma S.A. (“Patent Owner”), filed a Preliminary Response to the Petition. Paper 8 (“Prelim. Resp.”). We have statutory authority under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Petitioner challenges claims 1 and 2 of the ’170 patent as unpatentable under 35 U.S.C. § 103(a). Pet. 13–14. Based on the arguments and evidence presented in the Petition and Preliminary Response, we are not persuaded there is a reasonable likelihood Petitioner would prevail with respect to at least one of the claims challenged in the Petition. Therefore, we decline to institute *inter partes* review.

### A. *Related Proceedings*

Petitioner identifies the following as related district court proceedings in the District of New Jersey regarding the ’170 patent: *Sanofi-Aventis U.S. LLC, Aventis Pharma S.A. and Sanofi v. Mylan Laboratories Ltd.*, C. A. No. 3:15-cv-00290 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC*, C. A. No. 14-07869 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Accord Healthcare, Inc.*, C. A. No. 14-08079 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. BPI Labs, LLC et al.*, C. A. No. 14-08081 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC*, C. A. No. 14-08082 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Apotex Corp. et al.*, C. A. No. 15-0287 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et*

*al. v. Breckenridge Pharmaceutical, Inc.*, C. A. No. 15-0289 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Mylan Laboratories Limited*, C. A. No. 15-0290 (MAS)(LHG); and *Sanofi-Aventis U.S. LLC et al. v. Actavis LLC et al.*, C. A. No. 15-0776 (MAS)(LHG). Pet. 12–13.

*B. Proposed Grounds of Unpatentability*

Petitioner advances two grounds of unpatentability under 35 U.S.C. § 103(a) in relation to the challenged claims in the '170 patent:

Reference[s]	Statutory Basis	Challenged Claims
Kant (Ex. 1005) <sup>1</sup> in view of Klein (Ex. 1006) <sup>2</sup>	§ 103	1 and 2
Colin (Ex. 1007) <sup>3</sup> in view of Klein and Kant	§ 103	1 and 2

Pet. 13–14. Petitioner supports its challenge with a Declaration by Eric N. Jacobsen, Ph.D. (“Jacobsen Decl.”). Ex. 1002.

*C. The '170 Patent*

The '170 patent, titled “Taxoids, Their Preparation and Pharmaceutical Compositions Containing Them,” issued December 8, 1998,

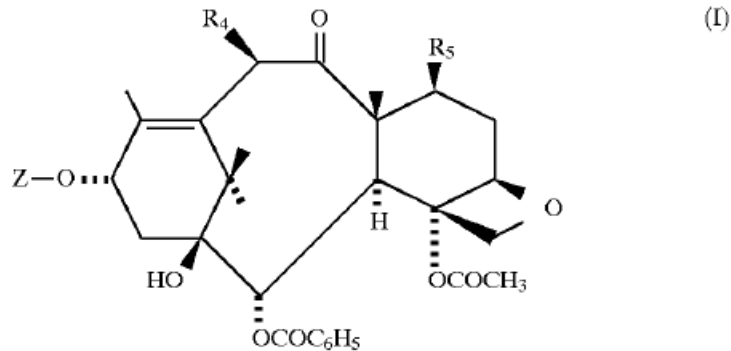
---

<sup>1</sup> Kant et al., *A Chemoselective Approach to Functionalize the C-10 Position of 10-Deacetylbaecatin III Synthesis and Biological Properties of Novel C-10 Taxol® Analogues*, *Tetrahedron Letters*, 35 (31), 5543–46 (1994) (“Kant”). Ex. 1005.

<sup>2</sup> Klein et al., Ch. 20 *Chemistry and Antitumor Activity of 9(R)-Dihydrotaxanes in Taxane Cancer Agents*, ACS Symposium Series Vol. 58, 276–287 (Georg et al., eds., 1994). Ex. 1006.

<sup>3</sup> U.S. Patent No. 4,814,470 issued March 21, 1989 to Colin et al. (“Colin”). Ex. 1007.

from an application filed March 26, 1996. Ex. 1001.<sup>4</sup> The '170 patent is directed to new taxoids of general formula (I):



in which:

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

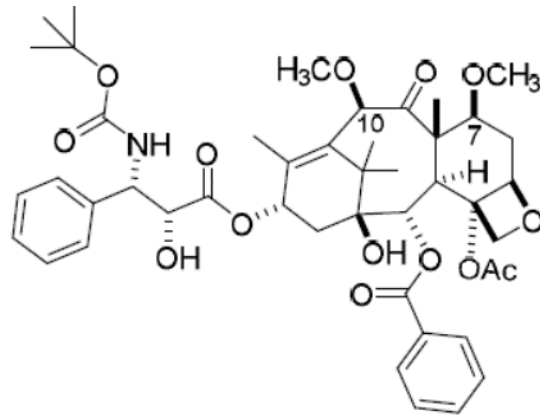


Ex. 1001, 1:7–28. The '170 patent discloses and claims, in particular, a compound known as cabazitaxel, pharmaceutical compositions containing cabazitaxel, and processes to prepare cabazitaxel. *Id.* at 12:52–13:33. The compounds of the '170 patent, including cabazitaxel, inhibit abnormal cell proliferation and have “antitumour properties, and more especially activity against tumours which are resistant to Taxol® or to Taxotere®.”<sup>5</sup> *Id.* at 11:59–61, 26:32–37. Cabazitaxel is indicated for treatment of certain types of prostate cancer. Ex. 2002.

<sup>4</sup> The '170 patent claims priority to a provisional application dated January 17, 1996 and to French applications 95 03545 and 95 15381, dated March 27, 1995 and December 22, 1995, respectively. Ex. 1001, [60], [30].

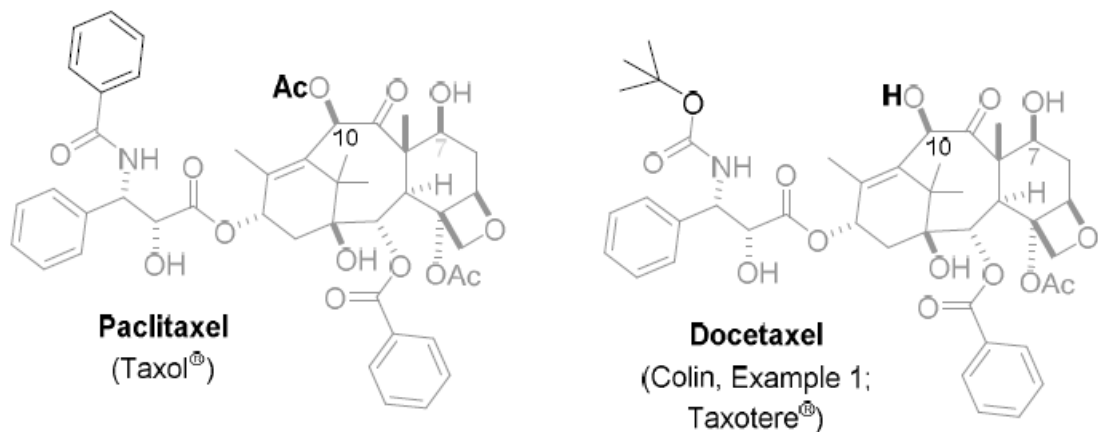
<sup>5</sup> Taxol® is the brand name for paclitaxel. Taxotere® is the brand name for docetaxel. We also refer to “Taxol” and “Taxotere” in this Decision.

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. *Id.* at 13:9–12, 28:57–60. The chemical structure of cabazitaxel is:



Pet. 3. Of particular interest in cabazitaxel are the presence of a methoxy group (OCH<sub>3</sub>) at both the C-7 position (R<sub>5</sub> in formula I) and C-10 position (R<sub>4</sub> in formula I), and a carbonyl (C=O) at the C-9 position. Ex. 1001, 2:40–42, 3:1–3.

The prior art paclitaxel and docetaxel compound structures are shown below.



Pet. 9; Ex. 1002 ¶¶ 36–38. Paclitaxel and docetaxel are synthesized from a key “advanced precursor” known as 10-deacetyl baccatin III (“10-DAB”).

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.