Trials@uspto.gov
571-272-7822

Paper No. 10
Entered: May 4, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA, LLC,
Petitioner,

v.

CEPHALON, INC.,
Patent Owner.

Case IPR2016-00098
Patent 8,791,270 B2

Before JACQUELINE WRIGHT BONILLA, ZHENYU YANG, and TINA E. HULSE, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

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

INTRODUCTION

Fresenius Kabi USA, LLC ("Petitioner") filed a Petition for an *inter partes* review of claims 1–23 of U.S. Patent No. 8,791,270 B2 ("the '270 patent," Ex. 1001). Paper 2 ("Pet."). Cephalon, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 8 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314.

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of claims 7, 14, and 19–23, we institute an *inter partes* review of these claims. Petitioner, however, has not established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–6, 8–13, and 15–18. Therefore, we deny the Petition regarding the challenges to those claims.

Related Proceedings

According to the parties, the '270 patent is the subject of several cases in district courts. Pet. 7–8; Paper 5, 1–4. Even though Petitioner is not a party to any of those cases, its contractual partners, Hetero Labs, Ltd. and Hetero USA, Inc., are. Pet. 8.

The '270 patent is also the subject of IPR2016-00026, filed by Agila Specialties Inc. and Mylan Laboratories Limited. We previously denied the petition in that case. *Agila Specialties Inc. v. Cephalon, Inc.*, Case IPR2016-00026 (PTAB April 13, 2016) (Paper 14). Agila Specialties Inc. and Mylan Laboratories Limited also sought *inter partes* review of U.S. Patent No. 8,436,190 B2, a patent in the same family as the '270 patent. *Agila*

Specialties Inc. v. Cephalon, Inc., Case IPR2015-00503, Paper 4. There, we instituted trial to review the patentability of certain claims, but denied review of others. IPR2015-00503, Paper 10 (PTAB July 20, 2015). The parties subsequently settled, and we terminated the case. IPR2015-00503, Paper 21 (PTAB Nov. 16, 2015).

Petitioner also filed a petition seeking *inter partes* review of related U.S. Patent No. 8,895,756 B2. *Fresenius Kabi USA, LLC v. Cephalon, Inc.*, IPR2016-00111, Paper 2. A decision instituting *inter partes* review has issued concurrently with this decision. IPR2016-00111, Paper 9 (PTAB May 4, 2016).

The '270 Patent

The '270 patent is directed to stable pharmaceutical compositions of nitrogen mustards, in particular, lyophilized bendamustine, which can be used to treat various disease states, especially neoplastic diseases and autoimmune diseases. Ex. 1001, 3:20–24.

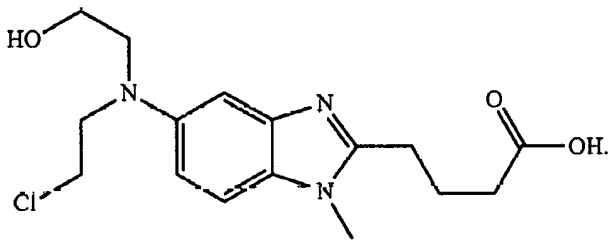
Bendamustine was first synthesized in East Germany in 1963. *Id.* at 2:1–2. At the time of the '270 patent invention, bendamustine was marketed in Germany under the name Ribomustin® to treat chronic lymphocytic leukemia, Hodgkin's disease, non-Hodgkin's lymphoma, multiple myeloma, and breast cancer. *Id.* at 2:5–9.

According to the '270 patent, "[b]endamustine degrades rapidly in water alone and forms predominantly the hydrolysis product, HP1 (monohydroxy bendamustine)." *Id.* at 21:3–5. Other degradants include the dimer of bendamustine (BM1 dimer), bendamustine ethylester (BM1EE), and BM1DCE. *Id.* at 21:30–50.

The '270 patent discloses stable pharmaceutical compositions prepared from bendamustine, in particular, "formulations for the lyophilization of bendamustine HCl." *Id.* at 12:27–30. According to the '270 patent, the lyophilized powder obtained from such formulations is more easily reconstituted and has a better impurity profile than Ribomustin®. *Id.* at 12:30–37.

Illustrative Claims

Among the challenged claims, claims 1 and 7 are independent. They read as follows:

> 1. A pharmaceutical composition that has been reconstituted from a lyophilized preparation of bendamustine or bendamustine hydrochloride, said composition containing not more than about 0.9% (area percent of bendamustine) of HP1:
>
> (HP1)
>
> 
>
>
> 7. A pharmaceutical composition of bendamustine hydrochloride, containing less than or equal to 4.0% (area percent of bendamustine) of bendamustine degradants.

Dependent claims 2–6 and 8–19 also are directed to pharmaceutical compositions. Claims 2–6 depend, directly or indirectly, from claim 1, while claims 8–19 depend, directly or indirectly, from claim 7.

Claim 20 is a method claim that depends from claim 7. It reads:

20. A method of treating cancer in a patient comprising administering to the patient a pharmaceutical composition of bendamustine hydrochloride according to claim 7.

Each of claims 21–23 is a method claim that depends directly from claim 20.

Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claims	Basis	Reference(s)
1–20	§ 103	Maas[1] and Teagarden[2]
13 and 19	§ 103	Maas, Teagarden, and Gust[3]
20–23	§ 102	Maas, Teagarden, and Ribomustin® Product Monograph[4]
1–23	§ 103	Admitted prior art in the '270 patent and Teagarden

In support of its patentability challenge, Petitioner relies on the Declarations of Drs. Michael J. Akers and Bernard Olsen. Exs. 1013, 1017.

---

[1] Maas et al., *Stability of Bendamustine Hydrochloride in Infusion Solutions*, 49 PHARMAZIE 775–77 (1994) (Ex. 1004, "Maas").
[2] Teagarden and Baker, *Practical Aspects of Lyophilization Using Non-Aqueous Co-Solvent Systems*, 15 EUR. J. PHARM. SCI. 115–33 (2002) (Ex. 1005, "Teagarden").
[3] Gust and Krauser, *Investigations on the Stability of Bendamustin, a Cytostatic Agent of the Nitrogen Mustard Type, I. Synthesis, Isolation, and Characterization of Reference Substances*, 128 CHEMICAL MONTHLY 291–99 (1997) (Ex. 1006, "Gust").
[4] Ribomustin® Product Monograph, 2002 (Ex. 1007).

DOCKET ALARM

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.