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Paper 10
Entered: September 22, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.,
Petitioner,

v.

MERCK SERONO S.A.,
Patent Owner.

IPR2023-00481
Patent 8,377,903 B2

Before ZHENYU YANG, ROBERT A. POLLOCK, and TIMOTHY G. MAJORS, *Administrative Patent Judges.*

MAJORS, *Administrative Patent Judge*.

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

I. INTRODUCTION

Hopewell Pharma Ventures, Inc. ("Petitioner" or "Hopewell") filed a Petition (Paper 2, "Pet") requesting *inter partes* review of claims 17, 19, 20, and 22–27 of U.S. Patent No. 8,377,903 B2 (Ex. 1001, "the '903 patent"). Pet. 1, 33. Merck Serono S.A. ("Patent Owner" or "Merck") filed a Preliminary Response (Paper 8, "Prelim. Resp.").

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless it is determined that there is a reasonable likelihood that the petitioner will prevail with respect to at least one of the claims challenged in the petition. Considering the parties' arguments and evidence, for the reasons set forth below, we conclude that Petitioner demonstrates a reasonable likelihood of prevailing with respect to at least one of the '903 patent's challenged claims. We decline to deny the Petition on the basis of discretion under 35 U.S.C. § 325(d) as sought by Patent Owner. We therefore institute an *inter partes* review on all challenged claims. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018).

Any findings and conclusions at this stage are preliminary and based on the current record. This is not a final decision on the patentability of the challenged claims. Any such final decision will be based on a complete record developed through trial.

II. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies itself and the following entities as real parties-in-interest: Hopewell Pharma Ventures LLC; Levy SPV, LLC; GLS Capital Partners Fund I, LP; GLS Capital Partners GP, LLC; and GLS Capital, LLC. Pet. 70–71. Merck identifies itself along with Merck KGaA and Ares Trading SA as the real parties-in-interest. Paper 3, 1.

B. Related Matters

The parties identify the following lawsuits involving assertions of the '903 patent: *Merck KGaA et al. v. Accord Healthcare, Inc. et al.*, 1-22-cv-00974 (D. Del.); *Merck KGaA et al. v. Hopewell Pharma Ventures, Inc.*, 1-22-cv-01365 (D. Del); *Merck KGaA et al v. Aurobindo Pharma USA, Inc. et al.*, 1-23-cv-00039 (D. Del.). Pet. 70; Paper 3, 1.

The parties also identify other related matters before the Board. Pet. 69–70; Paper 3, 1–2. Those matters include IPR2023-00480, filed by Hopewell, challenging U.S. Patent No. 7,713,947 ("the '947 patent"), in which we institute trial concurrent with this decision.[1] Paper 3, 1. Additionally, the parties identify IPR2023-00049 and IPR2023-00050, which were filed by a different petitioner (TWi Pharmaceuticals, Inc. ("TWi")), challenging the '947 and '903 patents.[2] *Id.* at 1–2; Pet. 70.

C. The '903 Patent & Technology Background

The '903 patent, titled "Cladribine Regimen for Treating Multiple Sclerosis," issued on February 19, 2013. Ex. 1001, codes (45), (54). The application that matured into the '903 patent was filed April 23, 2010, and claims the priority benefit of Application No. 11/722,018, filed as PCT/EP2005/056954 on December 20, 2005 (issued as the '947 patent), as well as a provisional patent application filed December 22, 2004. *Id.* at codes (22), (60), (63).[3]

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[1] IPR2023-00482 involved the same parties (or their RPIs) and a patent on related subject matter, but that case terminated on August 16, 2023, before institution due to settlement. IPR2023-00482, Paper 12.

[2] The Board denied institution on the TWi-filed petitions. *See* IPR2023-00049, Paper 10; IPR2023-00050, Paper 8.

[3] Although not conceding that the '903 patent is entitled to claim priority to the date this provisional application was filed (Pet. 7–8 n.3), Petitioner

According to the '903 patent, the "invention relates to the use of multiple doses of Cladribine for the treatment of multiple sclerosis, especially relapsing-remitting multiple sclerosis or early secondary progressive multiple sclerosis." Ex. 1001, 1:19–22.

Cladribine is a chlorinated purine analogue, 2-chloro-2′deoxyadenosine (also known as 2-CdA). *Id.* at 2:24–27. Cladribine was known in the prior art, as were oral, i.v., and subcutaneous formulations including it. *See, e.g.*, *id.* at 6:19–25 (noting oral formulations described in, for example, WO 2004/087101, which is the Bodor reference asserted in this proceeding). As background, the '903 patent also notes that cladribine has been suggested previously as useful for treating multiple sclerosis. *Id.* at 2:24–3:21 (discussing prior studies on cladribine's use, in various forms including delivery via oral and subcutaneous routes, in patients with multiple sclerosis); *see also* Pet. 18–20; Ex. 1002 ¶¶ 33–52 (testimony of Dr. Aaron Miller on studies by Beutler, Stelmasiak, Rice, and others).

As described in the '903 patent, "[m]ultiple sclerosis (MS) is the most known chronic inflammatory demyelinating disease of the central nervous system in humans." Ex. 1001, 1:26–28. "Over time, MS may result in the accumulation of various neurological disabilities" and "[c]linical disability in MS is presumed to be a result of repeated inflammatory injury with subsequent loss of myelin and axons, leading to tissue atrophy." *Id.* at 1:31–35. The patent states that "MS is manifested in physical symptoms (relapses

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applies that date (December 22, 2004) in explaining the state of the art at that time and for its obviousness analysis. *Id.* at 2–4, 13–28. In determining whether Petitioner has shown a reasonable likelihood that it would prevail herein, we will likewise apply that date.

and disability progression), Central Nervous System (CNS) inflammation, brain atrophy and cognitive impairment." *Id.* at 1:36–38.

Before December 2004, it was known that lymphocytes (or T cells), which cells are part of the body's acquired immune system, play a role in the pathophysiology of MS. Ex. 1002 ¶¶ 28–29. According to Dr. Miller, "[p]atients with MS 'harbor T cells that react with CNS autoantigens'" and, "[a]lthough these T cells (a type of lymphocyte) may 'remain dormant for decades, at some point they are activated in the periphery,'" allowing the cells to "'migrate through the blood-brain barrier to the brain and spinal cord.'" *Id.* (citing Ex. 1044, 1–3; Ex. 1007, 131). "Once these T cells are reactivated in the CNS . . . they 'release pro-inflammatory Th1 cytokines and orchestrate the destruction of the myelin sheath by various types of immune cells.'" *Id.* (citing Ex. 1007, 131). As Dr. Miller further explains, inflammation and resulting demyelination creates "lesions" in the affected tissues that can be detected and monitored. Ex. 1002 ¶¶ 15, 24, 27 (discussing detection of active/enhancing lesions using MRI).

According to the '903 patent, MS is "considered to be a multi-phasic disease and periods of clinical quiescence (remissions) occur between exacerbations. Remissions vary in length and may last several years but are infrequently permanent." Ex. 1001, 1:44–47. Moreover, the patent states, "[f]our courses of the disease are individualized: relapsing-remitting (RR), secondary progressive (SP), primary progressive (PP) and progressive relapsing (PR) multiple sclerosis." *Id.* at 1:48–50. "More than 80% of patients with MS will initially display a RR course with clinical exacerbation of neurological symptoms, followed by recovery that may or may not be complete." *Id.* at 1:51–56 (noting that disability arises from incomplete recovery from relapses). "Approximately, half of the patients with RRMS

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