Trials@uspto.gov
571-272-7822

Paper 68
Entered: May 11, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INCYTE CORPORATION,
Petitioner,

v.

CONCERT PHARMACEUTICALS, INC.,
Patent Owner.

PGR2021-00006
Patent 10,561,659 B2

Before CHRISTOPHER G. PAULRAJ, ROBERT A. POLLOCK, and DEVON ZASTROW NEWMAN, *Administrative Patent Judges.*

NEWMAN, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 328(a)

Denying in Part and Dismissing in Part
Patent Owner's Motion to Exclude Evidence

Dismissing Petitioner's Motion to Exclude Evidence
37 C.F.R. § 42.64

I. INTRODUCTION

This is a Final Written Decision in a post-grant review challenging the patentability of claims 1–21 (the "challenged claims") of U.S. Patent No. 10,561,659 B2 (Ex. 1001, "the '659 patent"). We have jurisdiction under 35 U.S.C. § 6.

Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioner has not demonstrated by a preponderance of the evidence that each of the challenged claims is unpatentable.

A. Summary of Procedural History

Incyte Corporation ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting a post-grant review of claims 1–21 of the '659 patent. Concert Pharmaceuticals, Inc., ("Patent Owner") filed a Preliminary Response (Paper 11, "Prelim. Resp."). Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 17, "Prelim. Reply") and Patent Owner filed a Preliminary Sur-Reply (Paper 19, "Prelim. Sur-Reply"). Based on the record then before us, we instituted trial with respect to all challenged claims 1–7 and 9–21[1]. Paper 20, 49 ("Dec.").

After institution of trial, Patent Owner filed a Request for Rehearing (Paper 23), which was denied (Paper 25). Patent Owner filed a Response (Paper 37, "Resp."), Petitioner filed a Reply to Patent Owner's Response (Paper 44, "Reply"), and Patent Owner filed a Sur-reply to Petitioner's Reply (Paper 51, "Sur-reply").

[1] Patent Owner disclaimed claim 8 subsequent to filing. *See* Ex. 2020. Hence, claim 8 and the Petition's Ground 3 challenging only claim 8 are no longer at issue in this case.

Both parties filed motions to exclude evidence and replies in support of those motions (Patent Owner: Papers 55, 61; Petitioner: Papers 56, 62). Both parties opposed each other's motions to exclude (Patent Owner: Paper 59; Petitioner: Paper 60).

We heard oral argument on February 10, 2022. A transcript of that hearing is entered as Paper 67 ("Tr."). Petitioner bears the burden of proving unpatentability of each claim it has challenged by a preponderance of the evidence, and the burden of persuasion never shifts to Patent Owner. *See* 35 U.S.C. § 326(e) (2018); 37 C.F.R. § 42.1(d); *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). This Final Written Decision is issued pursuant to 35 U.S.C. § 328(a) and 37 C.F.R. § 42.73.

B. Real Parties in Interest

Petitioner identifies itself as the real party-in-interest for Petitioner. Pet. 91. Patent Owner identifies itself as the real party-in-interest for Patent Owner. Paper 50, 1.

C. Related Matters

As related matters, Petitioner identifies pending U.S. Application No. 16/704,402, which claims the benefit of priority to U.S. Application No. 16/098,338, and IPR2017-01256 against Patent Owner's U.S. Patent No. 9,249,149. Pet. 91. Patent Owner also identifies U.S. Patent Application No. 16/704,402 as a related matter. Paper 50, 1.

D. The '659 Patent

The '659 patent is entitled "Treatment of Hair Loss Disorders with Deuterated JAK Inhibitors" and issued on February 18, 2020. Ex. 1001, codes (54), (45). According to the '659 patent, many current medicines

suffer from poor adsorption, distribution, metabolism, and/or excretion ("ADME") properties that limit their use for certain indications. *Id*. at 1:20–23. For example, rapid metabolism can cause drugs to be cleared too rapidly from the body, decreasing the drugs' efficacy in treating a disease. *Id*. at 1:29–32. Another ADME limitation is the formation of toxic or biologically reactive metabolites. *Id*. at 1:40–41.

The cytochrome P450 enzyme ("CYP") is typically responsible for the metabolism of drugs. *Id*. at 1:52–54. As such, the '659 patent identifies deuterium modification as a "potentially attractive strategy for improving a drug's metabolic properties." *Id*. at 2:7–8. Deuterium modification involves replacing one or more hydrogen atoms of a drug with deuterium atoms in an attempt to slow the CYP-mediated metabolism of a drug or to reduce the formation of undesirable metabolites. *Id*. at 2:8–12. Because deuterium forms stronger bonds with carbon than hydrogen, in certain cases, that stronger bond strength can positively impact the ADME properties of a drug, resulting in the potential for improved drug efficacy, safety, and/or tolerability. *Id*. at 2:13–19.

Ruxolitinib phosphate, a heteroaryl-substituted pyrrolo [2,3-d]pyrimidine, is an FDA-approved drug for treating patients with intermediate or high-risk myelofibrosis. *Id*. at 2:51–66. Ruxolitinib also has other potential applications, including the treatment of essential thrombocytopenia and is currently in clinical trials for the treatment of additional conditions. *Id*. at 2:66–3:5. Thus, according to the Specification, "[d]espite the beneficial activities of ruxolitinib, there is a continuing need for new compounds to treat the aforementioned diseases and conditions." *Id*. at 3:3–5.

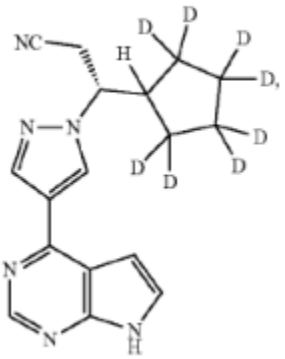
The '659 patent discloses "a method for treating hair loss disorders that can be treated by compounds that modulate the activity of Janus Associated Kinase 1 (JAKl) and/or Janus Associated Kinase 2 (JAK2)." *Id*. at 3:43–46. The method comprises administering an effective amount of a deuterated compound (Compound (I)), or its pharmaceutically acceptable salt, once or twice a day, in specific dose ranges. *Id*. at 3:46–66. The method is disclosed as for use in treating the hair loss disorder alopecia areata or for generally "inducing hair growth in a subject." *Id*. at 3:66–67, 4:18–20. The level of deuterium incorporation into the drug is disclosed as between 52.5% to upwards of 99.5%. *Id*. at 6:42–52.

E. Illustrative Claim

Petitioner challenges claims 1–7, 9–21 of the '659 patent. Claim 1 is illustrative and recites:

1. A method of treating a hair loss disorder in a mammalian subject, the method comprising administering to the subject 16 mg/day or 24 mg/day of a compound represented by the following structural formula:

Compound (I)



or a pharmaceutically acceptable salt thereof, wherein each position in Compound (I) designated specifically as deuterium has at least 95% incorporation of deuterium. Ex. 1001, 24:30–53.

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.