APPENDICES

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 2020-1933

BIOGEN INTERNATIONAL GMBH,
BIOGEN MA, INC.,
Plaintiffs-Appellants,
v.

MYLAN PHARMACEUTICALS INC.,
Defendant-Appellee.

Appeal from the United States District Court for the Northern District of West Virginia in No. 1:17-cv-00116-IMK-JPM, Judge Irene M. Keeley.

Decided: November 30, 2021

Before O'MALLEY, REYNA, and HUGHES,
Circuit Judges.

Opinion for the Court filed by
Circuit Judge REYNA.

Dissenting Opinion filed by
Circuit Judge O'MALLEY.

REYNA, *Circuit Judge*.

This appeal from the United States District Court for the Northern District of West Virginia concerns a

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patent-infringement dispute between Biogen International GmbH, Biogen MA, Inc., and Mylan Pharmaceuticals, Inc. Biogen owns United States Patent 8,399,514 (the '514 Patent), which claims a method of treating multiple sclerosis with a drug called dimethyl fumarate. In 2017, Biogen filed a lawsuit against Mylan alleging patent infringement. Mylan counterclaimed for declaratory judgment that the patent was invalid and not infringed. Following a bench trial, the district court determined that the asserted claims of the '514 Patent were invalid for lack of written description. Biogen challenges the district court's decision on appeal.

For the reasons set forth in this opinion, we hold that the district court did not clearly err in determining that Mylan has established its burden of showing, by clear and convincing evidence, that the asserted '514 Patent claims are invalid for lack of written description under 35 U.S.C. § 112. Accordingly, we affirm the judgment of the district court.

I. BACKGROUND

Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), a manufacturer of a new generic drug that is bioequivalent[1] to a previously approved drug may seek

[1] For purposes of Hatch-Waxman litigation, a generic drug is considered bioequivalent to a brand-name drug if:

> (i) the rate and extent of absorption of the [generic] drug do not show a significant difference from the rate and extent of absorption of the listed [brandname] drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or
>
> (ii) the extent of absorption of the [generic] drug does not show a significant difference from the extent of ab-

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approval from the US Food and Drug Administration (FDA) to market the generic product by filing an Abbreviated New Drug Application (ANDA). *See* Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585–86 (1984) (codified as amended at 21 U.S.C. § 355(j)(2)(A)). The statute requires the generic-drug manufacturer to submit a certification regarding the status of any patent that purportedly protects the brand-name drug, including information as to whether no such patent exists or the patent already expired, and if the patent has not expired the manufacturer must indicate the date on which the patent will expire. 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(III).

If a patent that covers the brand-name drug has not expired, the generic-drug manufacturer may file what is known as a paragraph IV certification, attesting that the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(j)(2)(A)(vii)(IV). The manufacturer filing the ANDA and paragraph IV certification must promptly notify the owner of any patent subject to the certification. *Id.* § 355(j)(2)(B)(iii). And the FDA must approve the ANDA, unless the patent owner objects by filing an action for patent infringement against the generic-drug manufacturer

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> sorption of the listed [brand-name] drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

21 U.S.C. § 355(j)(8)(B)(i)–(ii).

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within forty-five days of receiving notice of the paragraph IV certification. *Id.* § 355(j)(5)(B)(iii). If the patent owner brings the infringement suit under the Hatch-Waxman Act within the statutory period, the law triggers an automatic, thirty-month stay in the FDA approval process of the generic drug, pending the outcome of the litigation. *See id.* § 355(j)(5)(B)(iii).

Mylan Pharmaceuticals, Inc. (Mylan) filed an ANDA seeking to manufacture, use, and market a generic dimethyl fumarate (DMF) product for the treatment of multiple sclerosis (MS) before the expiration date of the '514 Patent. J.A. 6001–02. On June 30, 2017, Biogen International GmbH and Biogen MA, Inc. (collectively Biogen) sued Mylan for patent infringement in the Northern District of West Virginia pursuant to the Hatch-Waxman Act. *Id.* In its original complaint, Biogen asserted six patents[1] purportedly covering Tecfidera®, Biogen's trademarked DMF-capsule formulation for the treatment of patients suffering from relapsing-remitting forms of MS. *Id.* Only the '514 Patent is at issue in this appeal. *See* J.A. 2–3.

A. The '514 Patent

The '514 Patent claims priority to United States Provisional Application 60/888,921 (the '921 Application), which Biogen filed on February 8, 2007. U.S. Patent No. 8,399,514, at [60] (filed Feb. 13, 2012) (issued Mar. 19, 2013). As issued, the patent is entitled "Treatment for Multiple Sclerosis." '514 Patent, at [54].

MS is a disabling autoimmune disease that affects the central nervous system (CNS) and involves an abnormal inflammatory response, which leads to damage

[1] In addition to the '514 Patent, Biogen asserted US Patents 6,509,376; 7,320,999; 7,619,001; 7,803,840; and 8,759,393. J.A. 6002.

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