

**United States Court of Appeals
for the Federal Circuit**

CELGENE CORPORATION,
Appellant

v.

**LAURA A. PETER, DEPUTY UNDER SECRETARY
OF COMMERCE FOR INTELLECTUAL PROPERTY
AND DEPUTY DIRECTOR OF THE UNITED
STATES PATENT AND TRADEMARK OFFICE,**
Intervenor

2018-1167, 2018-1168, 2018-1169

Appeals from the United States Patent and Trademark
Office, Patent Trial and Appeal Board in Nos. IPR2015-
01096, IPR2015-01102, IPR2015-01103.

CELGENE CORPORATION,
Appellant

v.

**LAURA A. PETER, DEPUTY UNDER SECRETARY
OF COMMERCE FOR INTELLECTUAL PROPERTY
AND DEPUTY DIRECTOR OF THE UNITED
STATES PATENT AND TRADEMARK OFFICE,**
Intervenor

2018-1171

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2015-01092.

Decided: July 30, 2019

GREGORY A. CASTANIAS, Jones Day, Washington, DC, argued for appellant. Also represented by JIHONG LOU, JENNIFER LORAIN SWIZE; GASPER LAROSA, New York, NY; ANTHONY INSOGNA, San Diego, CA; FRANK CHARLES CALVOSA, F. DOMINIC CERRITO, ANDREW CHALSON, Quinn Emanuel Urquhart & Sullivan, LLP, New York, NY.

AMY J. NELSON, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by MEREDITH HOPE SCHOENFELD, THOMAS W. KRAUSE. Also argued by KATHERINE TWOMEY ALLEN, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC. Also represented by MARK R. FREEMAN, SCOTT R. MCINTOSH, JOSEPH H. HUNT.

Before PROST, *Chief Judge*, BRYSON and REYNA,
Circuit Judges.

PROST, *Chief Judge*.

The Coalition for Affordable Drugs VI LLC (“CFAD”) filed a petition for *inter partes* review (“IPR”) challenging the validity of all of the claims of U.S. Patent No. 6,045,501 (“the ’501 patent”) and three petitions for IPR challenging the validity of all of the claims of U.S. Patent No. 6,315,720 (“the ’720 patent”). The Patent Trial and Appeal Board

(“Board”) determined that all of the claims of the ’501 patent and claims 1–9 and 11–32 of the ’720 patent were obvious. Celgene Corporation (“Celgene”) appeals the Board’s decisions.

For the reasons explained below, we affirm the Board’s decisions finding the appealed claims obvious. We also hold that the retroactive application of IPR proceedings to pre-AIA patents is not an unconstitutional taking under the Fifth Amendment.

I

A

A teratogen is an agent known to disturb the development of an embryo or fetus. Teratogenic drugs can cause birth defects or other abnormalities following fetal exposure during pregnancy. One example of a teratogenic drug is thalidomide. Thalidomide, first synthesized in 1957, was originally marketed for use as a sedative in many countries, not including the United States. *See* ’501 patent col. 1 ll. 19–22. Following reports of serious birth defects, thalidomide was withdrawn from all markets by 1962. *Id.* at col. 1 ll. 22–24. Despite these teratogenic effects, thalidomide has proven to be effective in treating other conditions. *See id.* at col. 1 ll. 24–35. The ’501 patent and the ’720 patent are generally directed to methods for safely distributing teratogenic or other potentially hazardous drugs while avoiding exposure to a fetus to avoid adverse side effects of the drug.

B

In order to obtain FDA approval to sell and distribute thalidomide, Celgene developed a system to safely distribute thalidomide to patients, which it called the System for Thalidomide Education and Prescription Safety (“Original S.T.E.P.S.”). Appeal No. 18-1171, Appellant’s Br. 8–9. According to Celgene, the ’501 patent is directed to its Original S.T.E.P.S. program. *See id.* at 10.

Celgene's '501 patent relates to "methods for delivering a drug to a patient while preventing the exposure of a fetus or other contraindicated individual to the drug." '501 patent at Abstract. Claim 1 is representative and states:

1. A method for delivering a teratogenic drug to patients in need of the drug while avoiding the delivery of said drug to a fetus comprising:
 - a. registering in a computer readable storage medium prescribers who are qualified to prescribe said drug;
 - b. registering in said medium pharmacies to fill prescriptions for said drug;
 - c. registering said patients in said medium, including information concerning the ability of female patients to become pregnant and the ability of male patients to impregnate females;
 - d. retrieving from said medium information identifying a subpopulation of said female patients who are capable of becoming pregnant and male patients who are capable of impregnating females;
 - e. providing to the subpopulation, counseling information concerning the risks attendant to fetal exposure to said drug;
 - f. determining whether patients comprising said subpopulation are pregnant; and
 - g. in response to a determination of non-pregnancy for said patients, authorizing said registered pharmacies to fill prescriptions from said registered prescribers for said non-pregnant registered patients.

Id. at claim 1. Claim 2 recites “[t]he method of claim 1 wherein said drug is thalidomide.” The remaining claims depend from claim 1 and are not limited to thalidomide.

CFAD filed a petition for IPR challenging all ten claims of the ’501 patent. The Board instituted review of claims 1–10 on a single ground—obviousness based on Powell,¹ Mitchell,² and Dishman.³ *Coalition for Affordable Drugs VI LLC v. Celgene Corp.*, No. IPR2015-01092, Paper 20 (P.T.A.B. Oct. 27, 2015).

In its final written decision, the Board held that CFAD had shown by a preponderance of the evidence that claims 1–10 of the ’501 patent are unpatentable as obvious over the combination of Powell, Mitchell, and Dishman. *Coalition for Affordable Drugs VI LLC v. Celgene Corp.*, No. IPR2015-01092, Paper 73, at 33 (P.T.A.B. Oct. 26, 2016) (“*’501 Final Written Decision*”). The Board denied Celgene’s request for rehearing.

C

In the interim, Celgene “overhaul[ed]” its Original S.T.E.P.S. program to create what it called an “Enhanced S.T.E.P.S.” program. Appeal No. 18-1167, Appellant’s Br.

¹ R.J. Powell & J.M.M. Gardner-Medwin, *Guideline for the Clinical Use and Dispensing of Thalidomide*, 70 Postgrad Med. J. 901–904 (1994) (Appeal No. 18-1171, J.A. 324–25).

² Allen A. Mitchell et al., *A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin*, 333:2 New Eng. J. Med. 101–06 (July 13, 1995) (Appeal No. 18-1171, J.A. 328–33).

³ Benjamin R. Dishman et al., *Pharmacists’ Role in Clozapine Therapy at a Veterans Affairs Medical Center*, 51 Am. J. Hosp. Pharm. 899–901 (Apr. 1, 1994) (Appeal No. 18-1171, J.A. 334–36).

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