United States Court of Appeals for the Federal Circuit

JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV,
Plaintiffs-Appellees

v.

TEVA PHARMACEUTICALS USA, INC., MYLAN LABORATORIES LTD.,
Defendants-Appellants

2022-1258, 2022-1307

Appeals from the United States District Court for the District of New Jersey in Nos. 2:18-cv-00734-CCC-LDW, 2:19-cv-16484-CCC-LDW, Judge Claire C. Cecchi.

Decided: April 1, 2024

BARBARA MULLIN, Patterson Belknap Webb & Tyler LLP, New York, NY, argued for plaintiffs-appellees. Also represented by ANDREW D. COHEN, ARON RUSSELL FISCHER, MEGHAN LARYWON.

JOHN C. O'QUINN, Kirkland & Ellis LLP, Washington, DC, argued for all defendants-appellants. Defendant-appellant Teva Pharmaceuticals USA, Inc. also represented by WILLIAM H. BURGESS; CHRISTOPHER T. JAGOE, JEANNA WACKER, New York, NY.

DEEPRO MUKERJEE, Katten Muchin Rosenman LLP, for defendant-appellant Mylan Laboratories Ltd. Also represented by LANCE SODERSTROM; JITENDRA MALIK, Charlotte, NC; JILLIAN SCHURR, Chicago, IL; ERIC THOMAS WERLINGER, Washington, DC.

Before DYK, PROST, and HUGHES, *Circuit Judges*.

PROST, *Circuit Judge*.

Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (collectively, "Janssen") sued Teva Pharmaceuticals USA, Inc. ("Teva") for patent infringement in the United States District Court for the District of New Jersey. Janssen asserted U.S. Patent No. 9,439,906 ("the '906 patent"). Teva stipulated to infringement but challenged validity. Relevant here, Teva argued that all representative claims were invalid as obvious and that claims 19–21 were also invalid as indefinite. After a bench trial, the district court found that Teva had not proven invalidity on either basis. Teva appeals.[1] For the reasons below, we affirm the district court's indefiniteness determination but vacate and remand its nonobviousness determination.

BACKGROUND

Janssen markets and sells Invega Sustenna. Invega Sustenna is an extended-release intramuscular injectable of paliperidone palmitate, which is indicated for the treatment of schizophrenia in adults. J.A. 13118. After Teva

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[1] Janssen also sued Mylan Laboratories Ltd. ("Mylan") in a separate action. In that action, the parties stipulated to be bound by the final judgment in the Teva action with respect to infringement and validity. J.A. 49 (final judgment). Although we refer to Teva throughout, Mylan is also an Appellant here.

filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to sell a generic version of Invega Sustenna, Janssen sued and asserted various claims of the '906 patent. The '906 patent, which generally relates to dosing regimens of paliperidone palmitate, is the last remaining Orange Book patent for Invega Sustenna.

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The '906 patent is titled "dosing regimen associated with long acting injectable paliperidone esters." '906 patent col. 1 ll. 1–3 (capitalization normalized). It was filed in December 2008 and claims priority to a provisional application filed in December 2007. *Id.* at col. 1 ll. 8–10. For purposes of this appeal, Teva does not contest that the '906 patent is entitled to the December 2007 priority date. Appellants' Br. 19.

The parties agreed that claims 2, 10, 13, and 20–21 were representative. *Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.*, 571 F. Supp. 3d 281, 291 n.3 (D.N.J. 2021) ("*Opinion*"). All asserted claims relate to "[a] dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment for schizophrenia." '906 patent claims 1 and 8.

Claim 2 (non-renal-impairment claim), which depends from claim 1, relates to a normal or non-renal-impairment dosing regimen. Both claims are reproduced below.

> 1. A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder comprising
>
> > (1) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

> (2) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6th to about 10th day of treatment; and
>
> (3) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a first maintenance dose of about 25 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation a month (±7 days) after the second loading dose.
>
> 2. The dosing regimen of claim 1 wherein after administration of the first maintenance dose, subsequent maintenance doses of from about 25 mg-eq. to 150 mg-eq. are administered in the deltoid or gluteal muscle of the psychiatric patient in need of treatment at monthly (±7 days) intervals.

'906 patent claims 1 and 2.

Representative claims 10 and 13 (renal-impairment claims) claim dosing regimens for renally impaired patients. Claim 10 depends from claim 8. Both claims are reproduced below.

> 8. A dosing regimen for administering paliperidone palmitate to a renally impaired psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder comprising
>
> (a) administering intramuscularly in the deltoid of a renally impaired psychiatric patient in need of treatment a first loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated

> in a sustained release formulation on the first day of treatment;
>
> (b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6th to about 10th day of treatment; and
>
> (c) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a first maintenance dose of about 25 mg-eq. to about 75 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation a month (±7 days) after the second loading dose.
>
> 10. The dosing regimen of claim 8 wherein the sustained release formulation is an aqueous nanoparticle suspension.

'906 patent claims 8 and 10.

Claim 13 differs from claim 10 by requiring that the patient is in need of treatment for schizophrenia and reciting a range of 25 mg-eq. to about 50 mg-eq. for the maintenance dose.

Claims 20 and 21 (particle-size claims) are only representative as they depend from claims 1 and 8. They both further depend from claim 19. Because for our purposes the particle-size limitation of claim 19 is most pertinent, only claim 19 is reproduced below.

> 19. The dosing regimen of claims *1*, 4, *8* or 11 wherein the sustained release depot formulation is an aqueous nanoparticle suspension consists essentially of

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