IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL PHARMACEUTICALS PLC, ET AL., Defendants.	Case No. 21-691-MN

OPENING BRIEF IN SUPPORT OF AVADEL'S MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS

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I. NATURE AND STAGE OF THE PROCEEDINGS AND SUMMARY OF ARGUMENT

Jazz brought this suit asserting five patents, only one of which—U.S. Patent No. 8,731,963 (the "'963 patent")—is listed in the Orange Book for Jazz's twice-nightly sodium oxybate product XYREM®. The '963 patent, however, is directed to a computer system for storing information concerning prescriptions of a prescription drug and thus fails to meet the statutory requirements for Orange Book listing. It contains no claims directed to a drug substance, a drug product, or an FDA-approved method of using a drug. Avadel[1] respectfully requests that the Court grant judgment on the pleadings pursuant to FED. R. CIV. P 12(c) with respect to its counterclaim seeking de-listing of Jazz's '963 patent from the Orange Book. D.I. 11 at ¶¶ 25-32. Judgment on the pleadings should be granted because "no material issue of fact remains to be resolved" and Avadel "is entitled to judgment as a matter of law." *See Minnesota Lawyers Mut. Ins. Co. v. Ahrens*, 432 Fed. App'x 143, 147 (3d Cir. 2011) (quoting *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008)).

II. LEGAL STANDARD

The FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") provides a list of patents that the holder of a New Drug Application ("NDA") believes covers the active ingredient, formulation, or method of using the drug product covered by the NDA. *Caraco Pharm. Labs. Ltd. v. Novo Nordisk AS*, 556 U.S. 399, 406 (2012).

The Hatch-Waxman Act recites two requirements for a patent to be eligible for listing in the Orange Book. ***First***, the patent must be one for which "infringement could reasonably be

[1] "Avadel" refers collectively to Defendants Avadel CNS Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, Avadel Pharmaceuticals PLC, Avadel Specialty Pharmaceuticals, LLC, and Avadel US Holdings, Inc.

asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(A)(viii). ***Second***, the patent must claim one of the following three categories of subject matter: "a drug substance (active ingredient)," "a drug product (formulation or composition)," or "a method of using such drug for which approval is sought or has been granted in the [patent holder's NDA]." 21 U.S.C. § 355(b)(1)(A)(viii)(I-II); *see also* 21 CFR 314.53(b) (explaining that an NDA holder must list "each patent that claims the drug or a method of using the drug that is the subject of the NDA or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product."). Because the FDA "does not independently assess the [listed] patent's scope," a party sued for infringement of a listed patent may "assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information" listed in the Orange Book. *Caraco*, 556 U.S. at 406, 408-09.

Under Third Circuit law, judgment on the pleadings is appropriate where "the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." *See Minnesota Lawyers Mut. Ins.*, 432 Fed. App'x at 147.

III. FACTUAL BACKGROUND

A. Avadel's Single-Dose Narcolepsy Treatment

Unlike the typical pharmaceutical patent infringement case involving a defendant seeking to market a generic version of a brand-name drug, this case involves an innovative new drug product developed by Avadel, the defendant. D.I. 11 at 1. Avadel's revolutionary new ***once***-nightly at bedtime formulation of sodium oxybate (currently designated FT218) is designed to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy. *Id.* In contrast, Jazz's ***twice***-nightly sodium oxybate formulation, XYREM®, which has been on the market for nearly two

decades, requires patients to wake up in the middle of the night to take a second dose in order to treat their sleep disorder. *Id.* at 1-2. Avadel's formulation thus fills a significant, unmet need for a sleep disorder treatment that allows the patient to have an uninterrupted night's sleep. *Id.* at 2. Moreover, in part because FT218 is a new drug, rather than a generic version of Jazz's XYREM® product, Avadel did not file paragraph IV certifications against any of Jazz's Orange Book listed patents for XYREM®, and the '963 patent is the only Orange Book Listed patent that Jazz has asserted in this case.

B. The '963 Patent Is Directed To "A Computer-Implemented System"

The PTAB previously invalidated claims 24, 26, and 27 of the '963 patent, along with all claims of the six other issued patents in the family. Exhibit A, *Amneal Pharm. LLC v. Jazz Pharm., Inc.*, IPR2015-01903, Paper 31, Final Written Decision at 3 (Mar. 22, 2017), *aff'd, Jazz Pharm., Inc. v. Amneal Pharm. LLC*, 895 F.3d 1347, 1363 (Fed. Cir. 2018). Thus, only claims 1-23, 25, and 28 of the '963 patent remain.

It is undisputed (and undisputable) that these remaining claims of the '963 patent do not recite a drug substance, a drug product, or a method of using a drug. Instead, they are plainly directed to a "***computer-implemented system*** for treatment of a narcoleptic patient with a prescription drug . . . ," comprising, *inter alia*, "a [] computer database," "computer memories," and "a data processor." D.I. 11 at ¶ 28; *see also* D.I. 1, Ex. A at claims 1, 23, and 24.[2] Claim 1, an exemplary independent claim, has been reproduced below:

> A ***computer-implemented system*** for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, comprising:

[2] All emphasis added unless otherwise noted.

> one or more computer memories for storing a single computer database having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields;
>
> said prescription fields, contained within the database schema, storing prescriptions for the prescription drug with the potential for abuse, misuse or diversion, wherein the prescription drug is sold or distributed by a company that obtained approval for distribution of the prescription drug;
>
> said patient fields, contained within the database schema, storing information sufficient to identify the narcoleptic patient for whom the company's prescription drug is prescribed;
>
> said prescriber fields, contained within the database schema, storing information sufficient to identify a physician or other prescriber of the company's prescription drug and information to show that the physician or other prescriber is authorized to prescribe the company's prescription drug;
>
> a data processor configured to:
>
> process a database query that operates over all data related to the prescription fields, prescriber fields, and patient fields for the prescription drug; and
>
> reconcile inventory of the prescription drug before the shipments for a day or other time period are sent by using said database query to identify information in the prescription fields and patient fields;
>
> wherein the data processor is configured to process a second database query that identifies that the narcoleptic patient is a cash payer and a physician that is interrelated with the narcoleptic patient through the schema of the single computer database;
>
> said identifying that the narcoleptic patient is a cash payer by said second database query being an indicator of a potential misuse, abuse or diversion by the narcoleptic patient and being used to notify the physician that is interrelated with the narcoleptic patient through the schema of the single computer database.

Despite the fact that the ’963 patent is unmistakably directed to “a computer-implemented system” rather than a drug or a method of using a drug, Jazz nevertheless listed it in the Orange Book in connection with Jazz’s XYREM® product. D.I. 1 at ¶ 28.

IV. THE '963 PATENT IS NOT PROPERLY ORANGE BOOK LISTED BECAUSE IT DOES NOT CLAIM "A DRUG SUBSTANCE" "A DRUG PRODUCT," OR "A METHOD OF USING [A] DRUG"

The '963 patent is not properly Orange Book listed because it claims a "system," not a drug substance, drug product, or method of using a drug, as required by statute. As Congress has legislated, a patentee can obtain patent coverage for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. As explained by the Supreme Court, a process is "a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing." *Gottschalk v. Benson*, 409 U.S. 63, 70, 175 USPQ 673, 676 (1972) (quoting *Cochrane v. Deener*, 94 U.S. 780, 788, 24 L. Ed. 139, 141 (1876)). *See also In re Nuijten*, 500 F.3d 1346, 1355, 84 USPQ2d 1495, 1501 (Fed. Cir. 2007) ("The Supreme Court and this court have consistently interpreted the statutory term 'process' to require action."); *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1316, 75 USPQ2d 1763, 1791 (Fed. Cir. 2005) ("[A] process is a series of acts.") (quoting *Minton v. Natl. Ass'n. of Securities Dealers*, 336 F.3d 1373, 1378, 67 USPQ2d 1614, 1681 (Fed. Cir. 2003)). As defined in 35 U.S.C. § 100(b), the term "process" is synonymous with "method."

The '963 patent contains no method or process claim. This is evident from the plain language of the '963 patent's remaining claims, which all explicitly recite a "system" rather than a "process" or "method," as Jazz has incorrectly asserted. D.I. 11 at ¶ 29. Consistent with this "system" language, the recited elements are those of a computer system, not a method, such as "one or more computer memories," "a single computer database having a database schema," "prescription fields, contained within the database schema," and "a data processor," among others. *See, e.g.*, D.I. 1, Ex. A at claims 1, 23, and 24. Moreover, neither "process" or "method" appears in any of the remaining claims of the '963 patent, nor do any of those claims recite "an act, or a

series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing." *Gottschalk*, 409 U.S. at 70; *see* '963 patent at *passim*.

Lest there be any doubt that the '963 patent is directed to a "system," rather than "methods," Jazz itself has characterized the '963 patent claims as "system" claims in proceedings before the Patent Trial and Appeal Board. Exhibit B, *Amneal Pharm. LLC v. Jazz Pharm., Inc.*, IPR2015-01903, Paper 14, Patent Owner Response at 2 (Jun. 3, 2016) (characterizing the challenged claims as being directed to "computer-implemented systems").

The Federal Circuit has also made clear that system and method claims are "separate statutory classes of invention." *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005) (citing *Ex parte Lyell*, 17 USPQ2d 1548 (1990); *In re Kuehl*, 475 F.2d 658, 665 (1973); *and Rubber Co. v. Goodyear*, 76 U.S. 788, 796 (1869)). Thus, having conceded that the claims of the '963 patent are system claims, Jazz cannot also argue that those claims still qualify as "method" claims for purposes of the Orange Book listing.

Despite the unambiguous claim language of the '963 patent and Jazz's own admissions that the patent claims are directed to a "computer-implemented system," Jazz listed the '963 patent in the Orange Book. This was improper, and the '963 patent should be removed.

V. CONCLUSION

In light of the foregoing, Avadel respectfully requests that Jazz be ordered to remove the '963 patent from the Orange Book.

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