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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI, LLC,
Petitioner,

v.

CELGENE CORPORATION,
Patent Owner.

Case IPR2015-01102
Patent 6,315,720 B1

Before MICHAEL P. TIERNEY, MICHAEL W. KIM, and TINA E. HULSE, *Administrative Patent Judges*.

TIERNEY, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Coalition for Affordable Drugs VI, LLC ("Petitioner"), filed a Petition requesting an *inter partes* review of claims 1–32 of U.S. Patent 6,315,720 (Ex. 1001, "the '720 patent"). Paper 1 ("Pet."). Patent Owner, Celgene Corporation, ("Patent Owner") filed a Preliminary Response. Paper 11 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314. The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides:

> THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Upon consideration of the Petition and Preliminary Response, we conclude that the information presented in the Petition demonstrates that there is a reasonable likelihood that Petitioner would prevail in challenging claims 1–32 as unpatentable. Pursuant to 35 U.S.C. § 314, we hereby authorize an *inter partes* review to be instituted as to claims 1–32 of the '720 patent.

A. Related Proceedings

According to Petitioner, the '720 patent has been the subject of the following judicial matters: *Celgene Corp. et al. v. Lannett Holdings, Inc.*, NJD-2-15-00697 (filed Jan. 30, 2015); *Celgene Corp. v. Natco Pharma Ltd.*, NJD-2-10-cv-05197 (filed Oct. 8, 2010); *Celgene Corp. v. Barr Laboratories, Inc.*, NJD-2-08-cv-03357 (filed July 3, 2008); *Celgene Corp.*

v. Barr Laboratories, Inc., NJD-2-07-cv-05485 (filed Nov. 14, 2007); *Celgene Corp. v. Barr Laboratories, Inc.*, NJD-2-07-cv-04050 (filed Aug. 23, 2007); *Celgene Corp. v. Barr Laboratories, Inc.*, NJD-2-07-cv-00286 (filed Jan. 18, 2007). Pet. 2–3. Additionally, the claims of the '720 patent have been challenged in two related *inter partes* review proceedings, IPR2015-01096 and IPR2015-01103.

B. The '720 Patent

The '720 patent specification describes methods for delivering a drug to a patient. Ex. 1001, 1:8–9. For example, the method can be used to deliver a drug known to cause birth defects in pregnant women, while avoiding the occurrence of known or suspected side effects of the drug. *Id.* at 1:9–13, 19–30.

The patent describes prior-art methods that involved filling drug prescriptions, only after a computer readable storage medium was consulted, to assure that the prescriber is registered in the medium and qualified to prescribe the drug, and that the patient is registered in the medium and approved to receive the drug. *Id.* at 2:50–60. The '720 patent specification is said to describe an improvement over the acknowledged prior art, where the improvement involves assigning patients to risk groups based on the risk that the drug will cause adverse side effects. The improvement further requires entering the risk group assignment in the storage medium. After determining the acceptability of likely adverse effects, a prescription approval code is generated to the pharmacy before the prescription is filled. *Id.* at 2:60–3:4.

The ’720 patent specification states that it is preferable that information probative of the risk of a drug’s side effects is collected from the patient. *Id.* at 6:30–33. This information can then be compared with a defined set of risk parameters for the drug, allowing for assignment of the patient to a particular risk group. *Id.* at 6:33–36. If the risk of adverse side effects is deemed acceptable, the patient may receive the drug from a registered pharmacy, subject to conditions such as a negative pregnancy test, but may not receive refills without a renewal prescription from the prescriber. *Id.* at 11:63–12:8.

The ’720 patent specification states that its method can be used to deliver teratogenic drugs, and drugs that can cause severe birth defects when administered to a pregnant woman, such as thalidomide. *Id.* at 4:1–14, 8:39–45.

C. Illustrative Claims

The ’720 patent contains two independent claims and thirty dependent claims, all of which are challenged by Petitioner. Each of the independent claims is directed to a method of delivering a drug to a patient in need of the drug and is written in a Jepson claim format, where the preamble defines admitted prior art of prescribing drugs only after a computer readable storage medium has been consulted properly. The claimed improvement over the admitted prior art includes defining a plurality of patient risk groups, defining information to be obtained from a patient that is probative of risk of an adverse side effect, assigning the patient to a risk group, determining whether the risk of the side effect is acceptable and generating an approval code to be retrieved by a pharmacy before filling a prescription

for the drug. Independent claim 1 is illustrative of the challenged claims, and is recited below:

> 1. In a method for delivering a drug to a patient in need of the drug, while avoiding the occurrence of an adverse side effect known or suspected of being caused by said drug, wherein said method is of the type in which prescriptions for said drug are filled only after a computer readable storage medium has been consulted to assure that the prescriber is registered in said medium and qualified to prescribe said drug, that the pharmacy is registered in said medium and qualified to fill the prescription for said drug, and the patient is registered in said medium and approved to receive said drug, the improvement comprising:
>
> a. defining a plurality of patient risk groups based upon a predefined set of risk parameters for said drug;
>
> b. defining a set of information to be obtained from said patient, which information is probative of the risk that said adverse side effect is likely to occur if said drug is taken by said patient;
>
> c. in response to said information set, assigning said patient to at least one of said risk groups and entering said risk group assignment in said medium;
>
> d. based upon said information and said risk group assignment, determining whether the risk that said adverse side effect is likely to occur is acceptable; and
>
> e. upon a determination that said risk is acceptable, generating a prescription approval code to be retrieved by said pharmacy before said prescription is filled.

Claim 28, the only other independent claim, includes all the elements of claim 1 and adds a wherein clause that "said adverse side effect is likely to arise in patients who take the drug in combination with at least one other drug." Prelim. Resp. 15.

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