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Papel No. 76
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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 IPR2015-01103
Patent 6,315,720 B1

Before MICHAEL P. TIERNEY, GRACE KARAFFA OBERMANN, and TINA E. HULSE, *Administrative Patent Judges*.

TIERNEY, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Inter Partes Review
35 U.S.C. §318(a) and 37 C.F.R. § 42.73

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." with redacted version Paper 12). We determined that there was a reasonable likelihood that Petitioner would prevail in challenging those claims as unpatentable. Pursuant to 35 U.S.C. § 314, we authorized an *inter partes* review to be instituted, on October 27, 2015. Paper 22 ("Dec. on Inst.").

After institution, Patent Owner filed a redacted Patent Owner Response. Paper 42 ("PO Resp." with redacted version Paper 43). Petitioner filed a Reply. Paper 55 ("Reply" with a redacted version Paper 54). Additionally, Petitioner filed Motions to Submit Supplemental Information (Papers 37 and 38), a Motion to Exclude Evidence (Paper 63) and a Motion to Seal (Paper 56). Further, Patent Owner filed a Motion to Exclude Evidence (Paper 63) and Motions to Seal and for Entry of Protective Order (Papers 9 and 41).

An oral hearing was held on July 21, 2016. A transcript of the hearing has been entered into the record of the proceeding as Paper 75 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–32 are unpatentable.

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.*, DNJ-2-15-00697 (filed Jan. 30, 2015); *Celgene Corp. v. Natco Pharma Ltd.*, DNJ-2-10-cv-05197 (filed Oct. 8, 2010); *Celgene Corp. v. Barr Laboratories, Inc.*, DNJ-2-08-cv-03357 (filed July 3, 2008); *Celgene Corp. v. Barr Laboratories, Inc.*, DNJ-2-07-cv-05485 (filed Nov. 14, 2007); *Celgene Corp. v. Barr Laboratories, Inc.*, DNJ-2-07-cv-04050 (filed Aug. 23, 2007); *Celgene Corp. v. Barr Laboratories, Inc.*, DNJ-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 IPR2015-01102.

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 specification states that this method may minimize and simplify demands on the pharmacy and reduce the risk that the drug will be dispensed to a contraindicated individual. *Id*. at 2:8–12.

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 6:33–37. 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 11:62–12:8.

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, claims 1 and 28, 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.

Claims 2–27 depend, directly or through other dependent claims, upon claim 1. Dependent claims 2–4 and require that a prescription is filled only following verified full disclosure and consent of the patient. Dependent claims 5–6 require that the informed consent is verified by the prescriber at the time the patient is registered in a computer, and consent is transmitted via facsimile and interpreted by optical character recognition software. Dependent claims 7–10 require information be obtained from the patient prior to treatment, including the results of diagnostic testing, which can comprise genetic testing. Dependent claims 11–14 and 20–25 further require additional features, such as a teratogenic effect being otherwise likely to arise in the patient, arise in a fetus carried by the patient, and that the drug is thalidomide. Dependent claims 15–19 and 26–27 require defining a second set of information to be collected from the patient on a periodic basis, which can comprise a telephonic survey regarding the results of pregnancy testing, and where the adverse side effect of the drug can be a teratogenic effect.

Dependent claims 29–32 each depend, directly or through other dependent claims, from independent claim 28. Dependent claims 29–32

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