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Paper 9
Entered: July 26, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC.,
Petitioner,

v.

EXACT SCIENCES CORPORATION,
Patent Owner.

IPR2024-00459
Patent 11,634,781 B2

Before TINA E. HULSE, DAVID COTTA, and JAMIE T. WISZ,
Administrative Patent Judges.

HULSE, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Geneoscopy, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–20 of U.S. Patent No. 11,634,781 B2 (Ex. 1001, "the '781 Patent"). Paper 1 ("Pet."). Exact Sciences Corporation ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). We authorized additional briefing for the parties to address (1) discretionary denial under 35 U.S.C. § 325(d); and (2) discretionary denial under *General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017) (precedential as to § II.B.4.i) ("*General Plastic*"). Ex. 3001. Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 7, "Pet. Reply") and Patent Owner filed a Sur-reply (Paper 8, "PO Sur-reply").

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the arguments and evidence presented in the papers, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition and we decline to exercise our discretion to deny institution under 35 U.S.C. §§ 314(a) and 325(d). Accordingly, we institute an *inter partes* review of the challenged claims of the '781 Patent.

A. Real Parties-in-Interest

Petitioner identifies itself as the real party-in-interest. Pet. 2.

Patent Owner identifies itself as the real party-in-interest. Paper 4, 2.

B. Related Matters

The parties identify *Exact Sciences Corporation v. Geneoscopy, Inc.*, No. 23-cv-1319-MN (D. Del.) as involving the '781 Patent. Pet. 2–3; Paper 4, 2.

C. The '781 Patent

The '781 Patent, entitled "Fecal Sample Processing and Analysis Comprising Detection of Blood," was filed as U.S. Application No. 17/936,335 on September 28, 2022, and claims priority to a series of continuation applications, including U.S. Application No. 16/634,607 ("the '607 Application"), and U.S. Provisional Application No. 61/149,581 ("the '581 Provisional"), which was filed on February 3, 2009. Ex. 1001, codes (54), (21), (22), (60), (63), 1:8–19. Thus, the earliest possible effective filing date of the '781 Patent is February 3, 2009, which we apply to our analysis in this Decision.

The '781 Patent relates to methods and kits for analysis of fecal samples. *Id.* at 1:30–31. According to the Specification, colorectal cancer ("CRC") is a leading cause of cancer-related deaths worldwide. *Id.* at 1:41–42. Most colon cancers arise from adenomatous polyps, which are usually asymptomatic. *Id.* at 1:46–52. Because of this, mass screening of asymptomatic patients is the cornerstone for detecting and eliminating these precursor lesions to reduce the risk of CRC. *Id.* at 1:52–55.

Colonoscopy is the primary screening test for CRC because of its high sensitivity and specificity and the ability to remove polyps if found. *Id.* at 1:65–2:1. The procedure, however, is invasive, costly, and has certain risks, such as infection and perforation of the bowel. *Id.* at 2:1–3. Fecal occult blood testing ("FOBT"), which tests for blood in the stool, is commonly used and less invasive and less expensive than colonoscopy. *Id.* at 2:4–12.

But because occult blood in stool can be indicative of different gastrointestinal disorders, further testing is necessary to detect CRC. *Id.* at 2:9–12. There are two types of FOBT: guaiac FOBT ("gFOBT"), which detects peroxidase activity of hemoglobin in fecal blood, and immunochemical FOBT ("iFOBT" or "FIT"), which uses anti-human hemoglobin antibodies to detect fecal blood. *Id.* at 2:13–34. Although the immunochemical procedure is more complicated and more expensive, iFOBT is more sensitive than gFOBT. *Id.* at 2:25–40.

The Specification also explains that recent developments in testing look specifically for mutations in DNA characteristic of colorectal neoplasia that are detectable in exfoliated epithelial cells in the stool. *Id.* at 2:44–47. The Specification explains that increased DNA methylation is an epigenetic alteration that is common in human cancers. *Id.* at 3:5–7. Aberrantly methylated DNA has also been proposed as a potential tumor marker for CRC detection. *Id.* at 3:7–9.

The '781 Patent further explains that, although combined assays for detecting CRC have been described, their approach targets either multiple protein markers or multiple DNA alterations. *Id.* at 3:41–43. According to the Specification, "[t]o date, immunochemical tests and DNA tests for CRC detection have been evaluated and compared on a separate basis only." *Id.* at 3:43–45.

The '781 Patent states that the invention "aims to improve the positive and negative predictive value and also the sensitivity and specificity of detection of colorectal cancer through non-invasive means." *Id.* at 6:42–45. Accordingly, the invention is based upon a combination of tests for detecting proteins and epigenetic modification markers in the same fecal sample. *Id.* at 6:49–53.

D. Illustrative Claim

Petitioner challenges claims 1–20 of the '781 Patent, of which claim 1 is the only independent claim. Claim 1 is illustrative and reproduced below:

> 1. A method of processing a freshly-collected fecal sample without freezing, the method comprising:
>
> a) collecting a fecal sample from a human subject, wherein the fecal sample is collected at home by the human subject by defecation directly into a sealable collection vessel;
>
> b) removing a portion of the fecal sample to a separate sealable container to produce a removed portion and a remaining portion of the fecal sample;
>
> c) combining the removed portion of the fecal sample in the separate sealable container with a buffer that prevents denaturation or degradation of blood proteins found in a fecal sample, and sealing the sealable container; and
>
> d) combining the remaining portion of the fecal sample in the sealable collection vessel with a stabilizing buffer, and sealing the sealable collection vessel.

Ex. 1001, 45:21–38.

E. The Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–20 would have been unpatentable on the following grounds:

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