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Paper 10
Date: July 12, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PROGENITY, INC.,
Petitioner,

v.

NATERA, INC.,
Patent Owner.

IPR2021-00282
Patent 10,266,893 B2

Before GRACE KARAFFA OBERMANN, ZHENYU YANG, and RYAN H. FLAX, *Administrative Patent Judges.*

YANG, *Administrative Patent Judge*.

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

I. INTRODUCTION

Progenity, Inc. ("Petitioner") filed a Petition, seeking an *inter partes* review of claims 1–11 and 13 of U.S. Patent No. 10,266,893 B2 (Ex. 1001, "the '893 patent"). Paper 2 ("Pet."). Natera, Inc. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp."). With our authorization (Paper 7), Petitioner filed a Reply (Paper 8) and Patent Owner filed a Sur-reply (Paper 9).

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).

For the reasons provided below, we determine Petitioner has not demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition. Accordingly, we deny institution of an *inter partes* review.

A. Related Matters

According to the parties, the '893 patent is the subject of *Natera, Inc. v. Progenity, Inc.*, No. 6:20-cv-00532 (W.D. Tex.); *Natera, Inc. v. Progenity, Inc.*, No. 3:20-cv-1634 (N.D. Tex.); *Progenity, Inc. v. Natera, Inc.*, No. 3:20-cv-01252 (S.D. Cal.). Pet. 4–5; Paper 5, 1.

Petitioner also filed IPR2021-00266, IPR2021-00267, IPR2021-00279, IPR2021-00280, and IPR2021-00281, challenging the claims of other patents of Patent Owner. Paper 5, 1–2.

B. The '893 Patent

The '893 patent issued from an application that claims priority to a series of earlier applications, including certain provisional applications filed in 2005. Ex. 1001, code 60. Petitioner, however, asserts that the challenged claims are not entitled to a priority date earlier than March 17, 2008. Pet. 14 (citing Ex. 1002, 337–38, 415–16). Patent Owner does not dispute this argument. Prelim. Resp. 1, 9. Thus, for purposes of this Decision, we analyze the patentability of the challenged claims, accepting March 17, 2008 as the priority date.

The '893 patent discloses a system and method for cleaning "incomplete or noisy genetic data using secondary genetic data as a source of information," and for determining "chromosome copy number using said genetic data." Ex. 1001, 11:37–40.

The '893 patent explains that a human being normally has "two sets of 23 chromosomes in every diploid cell, with one copy coming from each parent. Aneuploidy, the state of a cell with extra or missing chromosome(s)," is responsible for "a large percentage of failed implantations and miscarriages, and some genetic diseases." *Id.* at 2:53–60. For example, a child with Down syndrome has three copies of chromosome 21, i.e., trisomy 21. *Id.* at 5:41–42.

"[P]renatal diagnosis can alert physicians and parents to abnormalities in growing fetuses." *Id.* at 4:33–34. "Unfortunately, standard methods require invasive testing and carry a roughly 1 percent risk of miscarriage." *Id.* at 4:37–39. According to the '893 patent, "[a] need exists for a method of

prenatal diagnosis that mitigates these risks." *Id.* at 4:51–52. The '893 patent explains:

> It has recently been discovered that cell-free fetal DNA and intact fetal cells can enter maternal blood circulation. Consequently, analysis of these cells can allow early Non-Invasive Prenatal Genetic Diagnosis (NIPGD). A key challenge in using NIPGD is the task of identifying and extracting fetal cells or nucleic acids from the mother's blood.

Id. at 4:53–58, *see also id.* at 11:27–29 ("In the case of prenatal or pre-implantation genetic diagnoses a complicating factor is the relative paucity of genetic material available.").

The '893 patent states that "[g]iven the inherently noisy nature of the measured genetic data in cases where limited genetic material is used for genotyping, there is a great need for a method which can increase the fidelity of, or clean, the primary data." *Id.* at 11:29–33. According to the '893 patent, the techniques disclosed therein are "for cleaning genetic data," relevant in, among others, "non-invasive prenatal diagnosis, where a small quantity of fetal genetic material is isolated from maternal blood." *Id.* at 11:45–51.

C. Illustrative Claim

Claim 1, the only independent claim of the '893 patent, is illustrative of the claimed subject matter. The parties label the four steps recited in claim 1 as steps (a) through (d). For consistency, we do the same. Claim 1, with the labels added in brackets, is reproduced below.

> 1. A method for measuring the amounts of fetal chromosome segments in a maternal blood sample, comprising:

[a] obtaining cell-free DNA comprising fetal and maternal chromosome segments from the maternal blood sample;

[b] performing universal amplification on the chromosome segments to generate amplified chromosome segments;

[c] performing clonal amplification on the amplified chromosome segments to generate clonally amplified chromosome segments; and

[d] measuring the amounts of clonally amplified fetal chromosome segments by performing next-generation sequencing.

Id. at 79:47–60.

D. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claims Challenged	35 U.S.C. §[1]	References
1–11, 13	103(a)	Lo,[2] Robertson[3]

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the '893 patent has an effective filing date prior to March 16, 2013, we apply the pre-AIA version of § 103.
[2] U.S. Patent Publication No. 2009/0029377 A1, published Jan. 29, 2009 (Ex. 1007).
[3] Robertson et al., Genome-Wide Profiles of STAT1 DNA Association Using Chromatin Immunoprecipitation and Massively Parallel Sequencing, 4 NATURE METHODS 651–57 (2007) (Ex. 1009).

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