

## 23ANDME, INC. V. ANCESTRY.COM DNA, LLC

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### U.S. IP Litigation and IP Procurement and Portfolio Management Alert

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In 2003, for the first time in history, mankind sequenced an entire human genome. [1] The endeavor – known as The Human Genome Project – took 13 years to complete. Today such an endeavor takes about 48 hours [2] and has been shaped into a multi-billion dollar industry. [3] Two front-runners in the genetic testing industry, 23andMe, Inc. ("23andMe ") and Ancestry.com DNA, LLC ("Ancestry"), got into a dispute in the United States District Court for the Northern District of California when 23andMe sued Ancestry for infringing U.S. Patent No. 8,463,554 [4] ("the '554 patent") titled "FINDING RELATIVES IN A DATABASE." [5]

On August 23, 2018, the court granted Ancestry's Rule 12(b)(6) motion to dismiss for failure to state a claim on which relief can be granted and held that the asserted claims were invalid under 35 U.S.C. § 101 ("§ 101") because they are directed to patent ineligible subject matter.

### THE '554 PATENT

The '554 patent is directed to a "relative finder technique," which entails using DNA to determine a "relative relationship" between people who share a common ancestor within a threshold number of generations. The technique relies upon "recombinable DNA," which the '554 patent describes as autosomal DNA and X-chromosome DNA. As the specification explains, the recombinable DNA is "shuffled" at the next generation with small mutations, and therefore only relatives will share long stretches of genome regions where their recombinable DNA is completely or nearly identical. These regions are known as Identical by Descent ("IBD") regions and the "relative finder" technique is based at least in part on locating IBD regions in the recombinable chromosomes of individuals. [6]

According to the '554 patent, prior genetic testing techniques used Y-chromosome DNA and mitochondrial DNA, which are passed down largely unchanged and are therefore useful for tracing patrilineal ancestry from father to son (Y-chromosome DNA) or matrilineal ancestry. Those techniques are helpful for identifying individuals that are related many generations ago but are not as effective for identifying closer relationships or relationships, which are not strictly patrilineal or matrilineal. [7] As the '554 patent states, the claimed invention (i.e., using recombinable DNA or portions thereof for comparison) represents an improvement over these techniques. [8]

The '554 patent technique essentially involves three steps: 1) receiving or obtaining recombinable DNA information; 2) determining a predicted degree of relative relationship based at least in part on a comparison of recombinable DNA information; and 3) notifying a person about the relative relationship. These steps, along with the involvement of a computer processor, make up claim 1 of the '554 patent. Claim 26 is similar to claim 1, and each asserted claim depends from claim 1 or claim 26.

The court analyzed asserted claim 7 as representative of the other asserted claims. [9] Claim 7 reads:

The method of claim 1, wherein: determining the predicted degree of relationship between the first user and the second user includes identifying one or more Inheritance By Descent (IBD) regions in which a portion of recombinable DNA sequence of the first user and a portion of recombinable DNA sequence of the second user arose from same DNA sequence of an ancestor; the predicted degree of relationship depends at least in part on an amount of DNA sequence information of the IBD regions; the amount of DNA sequence information of the IBD regions includes a sum of the lengths of IBD regions, percentage of DNA shared in the IBD regions, or both; and a greater amount of DNA sequence information of the IBD regions indicates a closer predicted degree of relationship. [10]

## § 101 ANALYSIS

The Supreme Court has held that § 101 contains implicit exceptions to the subject matter that may be patented: laws of nature, natural phenomena, and abstract ideas are not patentable. "Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." [11] The test for subject matter eligibility is twofold: First, the court determines whether the claims are directed to a patent-ineligible concept. [12] If so, the court asks whether the remainder of the claims transform that unpatentable law of nature into a patent-eligible application of that law. [13] The application of the law of nature must provide something inventive beyond what is "well-understood, routine, conventional activity." [14]

Regarding step one of the analysis, Ancestry argued that the claims of the '554 patent align with *Mayo* and a series of Federal Circuit opinions that hold methods observing natural phenomena unpatentable. [15] 23andMe cited to Federal Circuit cases in which the court found the patent claims to be patent-eligible subject matter. [16] Most of the cases involved life sciences and related subject matter. Interestingly, 23andMe relied heavily on a Federal Circuit opinion, *Thales*, which did not involve life-science but instead was directed toward an "inertial tracking system for tracking the motion of an object relative to a moving reference frame." [17] In essence, the patent claims in *Thales* used basic physics and strategically placed sensors to track the motion of two objects. 23andMe cited this case to demonstrate the proposition that natural phenomena may become patentable upon the creation of an "improved technique" by using a "particular configuration" and a "particular method of using the raw data" such that the claims protect only the "application" of the natural phenomenon to an "unconventional configuration[.]" [18]

However, the court found that the present claims were more in line with Ancestry's cited cases and therefore failed step one of the analysis. The court held that the claims of the '554 patent are directed to a law of nature because the "focus of the claims is a correlation that exists in nature – i.e., the more recombinable DNA information that is shared between two people, the closer the degree of a relationship." [19] For instance, the court stated that "[c]laim 5 is in all material respects indistinguishable from the patent claims at issue in *Genetic Technologies*, which focused on the observation and comparison of DNA sequences – occurrences in nature." [20] Similarly, according to the court, claim 7 simply compares certain regions of the users' DNA and observes that a greater amount of congruent information indicates a greater degree of relative relation. [21]

23andMe countered by arguing that the focus of the claims is not just a law of nature but is a "new and useful way to identify a relative and the degree of relative relatedness, based on a specific selection and characterization of

recombinable DNA." [22] The court found this unpersuasive and commented that "as *Mayo*, *Genetic Technologies*, and *True Health* demonstrate, even if a patent claims discovery of a particular correlation – and even if that correlation is quantified – the patent still focuses on a naturally occurring phenomenon. Discovering some new fact about nature does not negate the patent's focus on a law of nature." [23] Rather, the court held that the law of nature found in the '554 patent is not merely a tool in a novel application of a law of nature but is instead the essence and end result of the '554 patent itself. [24]

In step two of the § 101 analysis, the court provided much less discussion than that surrounding the first step. The court held that the claims of the '554 patent failed this step because, although 23andMe asserted that the claims represent a new and useful technique of detecting a relative relationship, "the only means of detecting a relative relationship is comparing the recombinable DNA information[.]" [25] Such an instruction to perform a simple comparison does not represent an unconventional, inventive application sufficient to render an ineligible claim into an eligible one. 23andMe countered by pointing to claim 7 and arguing that the use of IBD information (i.e., summing DNA lengths shared in the IBD regions and total percentage of shared DNA in such regions) represents an inventive application of the natural phenomena. However, the court found that this simply reflected the basic principle that the more DNA information that is shared, the closer the degree of relationship. [26] According to the court, this technique was not novel and no aspect of the claims purport to claim a novel technique for comparing DNA. [27]

Finally, 23andMe argued that dismissing their patent infringement claim on a motion to dismiss for failure to state a claim is improper at this stage because there exists a factual dispute regarding what was wellunderstood, routine, and conventional activity in the realm of genetic testing. But the court was not persuaded and found nothing about the claimed technique to be "unconventional." The court added that "even if the '554 patent claims a new discovery of nature, it claims no inventive, unconventional technique in making that discovery or applying it." [28]

## CONCLUSION

In the present case, the applicant drafted the claims to be directed toward the result of the method and used language such as "The method of claim 1, wherein the predicted degree of relative relationship indicates that the first user and the second user share a common ancestor at least three generations out or beyond." This case continues a trend of courts invalidating claims under § 101 that are directed to observing a correlation that exists in nature and performing an "analyzing" or "comparing" step using that observation. This observed correlation happens to involve DNA, which is similar to *Myriad* [29] and *BRCA* before it. The court here followed the line of Supreme Court and Federal Circuit cases holding claims invalid under § 101, while distinguishing two cases 23andMe cited. It remains to be seen whether future decisions will determine precisely what transforms an "analyzing" or "comparing" step using an observed correlation from a patent-ineligible concept to a patentable invention.

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[1] (<https://www.genome.gov/10001772/all-about-the--human-genome-project-hgp/>).

[2] (<https://www.livescience.com/28708-human-genome-project-anniversary.html>).

[3] (<https://globenewswire.com/news-release/2018/06/05/1516735/0/en/Genetic-Testing-Market-worth-over-22-Billion-By-2024-Global-Market-Insights-Inc.html>).

[4] (<https://portal.uspto.gov/pair/PublicPair>).

[5] 23andMe, Inc. v. Ancestry.com DNA, LLC, No. 18-02791 (N.D. Cal. Aug. 23, 2018) (order granting in part and denying in part defendants' motion to dismiss).

[6] See U.S. Patent No. 8,463,554, col. 2, ln. 32-43.

[7] *Id.* at col. 1, ln. 21-34.

[8] The Abstract to the '554 patent reads:

Determining relative relationship includes receiving recombinable deoxyribonucleic acid (DNA) information of a first user and recombinable DNA information of a second user, determining, based at least in part on the recombinable DNA information of the first user and recombinable DNA information of the second user, a predicted degree of relationship between the first user and the second user, and in the event that the expected degree of relationship between the first user and the second user at least meets the threshold, notifying at least the first user about a relative relationship with the second user.

See *id.* at Abstract.

[9] The asserted claims are claims 5, 7-8, 12-14, 17, 22, 31-32, and 37-38.

[10] *Id.* at col. 11, ln. 1-19.

[11] *Genetic Techs. Ld. v. Merial L.L.C.*, 818 F.3d 1369, 1374 (Fed. Cir. 2016).

[12] *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014).

[13] *Mayo Collab. Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012) ("If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort to monopolize the law of nature itself.").

[14] *Genetic Techs.*, 818 F.3d at 1376.

[15] Ancestry cited *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015); *Genetic Techs.*; *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017); and *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation v. Ambry Genetics Corp.*, 774 F.3d 755 (Fed. Cir. 2014).

[16] The court only discussed two of the cases cited by 23andMe. Namely, the court discussed *Rapid Litigation Management v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016) and *Thales Visionix, Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017).

[17] *Thales*, 850 F.3d at 1344.

[18] *Thales*, 850 F.3d at 1348-49.

[19] 23ANDME, No. 18-02791 at 15–16; see BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation v. Ambry Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014).

[20] *Id.* at 16.

[21] *Id.*

[22] *Id.*

[23] *Id.* at 17.

[24] *Id.*

[25] *Id.* at 18.

[26] *Id.*

[27] *Id.* at 19.

[28] *Id.*

[29] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 579 (2013).

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