UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: BRCA1- AND BRCA2-BASED HEREDITARY CANCER TEST PATENT LITIGATION MDL No. 2510

TRANSFER ORDER

Before the Panel:[*] Pursuant to 28 U.S.C. § 1407, patentholders University of Utah Research Foundation, Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership, Endorecherche, Inc., and Myriad Genetics, Inc. (Myriad; collectively, Movants) move for centralization of this patent infringement litigation in the District of Utah. This litigation currently consists of three actions pending in the District of Utah and two actions pending in the Central and Northern Districts of California, as listed on Schedule A.[1]

At issue in these five actions are fourteen patents related to diagnostic testing for hereditary breast or ovarian cancer risks caused by certain mutations in the BRCA1 and BRCA2 genes.[2] In the actions pending in the District of Utah, Movants assert that the defendants' diagnostic tests for the BRCA1 and BRCA2 genes infringe one or more claims of the patents. In the California actions,

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[*] Judges Paul J. Barbadoro, Marjorie O. Rendell, and Lewis A. Kaplan took no part in the decision of this matter.

[1] Originally, there were six actions on the motion to centralize, but an action by Movants against Gene by Gene, Ltd., in the District of Utah was subsequently dismissed. Additionally, the parties have notified the Panel of three related actions pending in the Northern District of California and the District of Utah. These and any other related actions are potential tag-along actions. *See* Panel Rule 7.1.

[2] The fourteen BRCA patents include: U.S. Patent No. 5,654,155, entitled "Consensus Sequence of the Human BRCA1 Gene"; U.S. Patent Nos. 5,693,473 and 5,709,999, entitled "Linked Breast and Ovarian Cancer Susceptibility Gene"; U.S. Patent Nos. 5,710,001 and 5,747,282 (the '282 patent), entitled "17Q-Linked Breast and Ovarian Cancer Susceptibility Gene"; U.S. Patent No. 5,750,400, entitled "Coding Sequences of the Human BRCA1 Gene"; U.S. Patent No. 5,753,441, entitled "170-Linked Breast and Ovarian Cancer Susceptibility Gene"; U.S. Patent Nos. 5,837,492 and 6,033,857, entitled "Chromosome 13-Linked Breast Cancer Susceptibility Gene"; U.S. Patent No. 6,051,379, entitled "Cancer Susceptibility Mutations of BRCA2"; U.S. Patent No. 6,083,698, entitled "Cancer Susceptibility Mutations of BRCA1"; U.S. Patent No. 6,492,109, entitled "Susceptibility Mutation 6495DELGC of BRCA2"; U.S. Patent No. 6,951,721, entitled "Method for Determining the Haplotype of a Human BRCA1 Gene"; and U.S. Patent No. 7,250,497, entitled "Large Deletions in Human BRCA1 Gene and Use Thereof."

plaintiffs Counsyl, Inc. (Counsyl), Quest Diagnostics Inc., and Quest Diagnostics Nichols Institute (collectively, Quest) seek declaratory judgments that diagnostic tests they offer or plan to offer for the BRCA1 and BRCA2 genes do not infringe the BRCA patents, and that those patents are invalid. Additionally, in two of the actions pending in the District of Utah, Movants assert five patents related to genetic testing to identify risks of colon cancer.[3]

Respondents Counsyl, Quest, and GeneDx, Inc. (a defendant in one of the actions pending in the District of Utah) oppose centralization and variously suggest in the alternative that we select either the Central District of California, the Northern District of California, or the Southern District of New York as the transferee forum. Respondents contend, *inter alia*, that: (1) the factual variance among the actions, such as the different types of genetic sequencing employed by the defendants' various diagnostic tests and the different patents and claims at issue in each action, weighs against centralization; (2) little discovery will be necessary in order for the courts to rule on Respondents' invalidity challenges because the United States Supreme Court has already addressed the validity of certain claims of the BRCA patents in *Association for Molecular Pathology v. Myriad Genetics, Inc. ("AMP")*, 133 S. Ct. 2107 (2013); and (3) alternatives to centralization, such as informal cooperation and coordination among the parties and courts, are available to address any potential for duplicative discovery or inconsistent pretrial rulings.

We do not find the arguments against centralization persuasive. With regard to the differences between the various diagnostic services and tests offered by Respondents, the Panel has often centralized litigation involving different products that allegedly infringe a common patent or patents. *See In re Bear Creek Techs., Inc., ('722) Patent Litig.*, 858 F. Supp. 2d 1375, 1379-80 (J.P.M.L. 2012). Here, each of the accused services is intended to diagnose the risk of hereditary breast and ovarian cancer by analyzing mutations of the BRCA1 and BRCA2 genes. Moreover, regardless of any differences in the patents and claims asserted in each action, a review of the pleadings shows that eighteen claims in seven patents are asserted (or challenged) in each of the actions. Accordingly, these actions will share common questions of fact regarding the genetic technology underlying the BRCA patents and the parties' diagnostic testing services, as well as the anticipated arguments regarding the validity and enforceability of these patents. *See id.*

And, while it is possible that application of the *AMP* decision in these actions will reduce the need for significant discovery and pretrial practice, this is not a foregone conclusion. The *AMP* decision, which held that "genes and the information they encode are not patent eligible under [35 U.S.C.] § 101 simply because they have been isolated from the surrounding genetic material," 133 S. Ct. at 2120, primarily addressed claims of the BRCA patents that are not asserted in the actions

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[3] The colon cancer, or "MYH," patents include: U.S. Patent No. 7,470,510, entitled "Methods for Diagnosing Cancer and Determining a Susceptibility for Developing Cancer"; U.S. Patent Nos. 7,622,258 and 7,838,237, entitled "Screening Methods and Sequences Relating Thereto"; and U.S. Patent Nos. 7,563,571 and 7,670,776, entitled "MYH Gene Variants and Use Thereof."

on the motion.[4] Determining whether the claims (and the patents) not at issue in *AMP* are likewise invalid as pertaining to non-patentable subject-matter may require a substantial amount of pretrial motion practice and parsing of the language of the patents. Given the obvious complexity of these patent issues, centralization will undoubtedly conserve the resources of the parties and the judiciary, as only a single judge will have to become familiar with the patented technology. Informal coordination of this litigation, as proposed by Respondents, cannot provide the same efficiency benefits.

For all of these reasons, on the basis of the papers filed and the hearing session held, we find that these actions involve common questions of fact, and that centralization in the District of Utah will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. All of the actions involve factual questions surrounding the alleged infringement, validity and/or enforceability of the BRCA patents concerning diagnostic tests for hereditary breast or ovarian cancer risks caused by certain mutations of the BRCA1 and BRCA2 genes. While there is some difference in the asserted patents and claims between the actions, and some difference in the accused products, the core factual and legal inquiries in each action will be similar, if not identical, and centralization will allow a single judge to preside over the discovery relating to these patents and to consistently rule on challenges to the validity thereof. *See In re Maxim Integrated Prods., Inc., Patent Litig.*, 867 F. Supp. 2d 1333, 1334 (J.P.M.L. 2012). Furthermore, all of the actions are in the initial stages of litigation. Thus, centralization at this time will eliminate duplicative discovery, prevent inconsistent pretrial rulings (particularly on the complex and time-consuming matter of claim construction, should these actions advance that far), and conserve the resources of the parties, their counsel, and the judiciary.

We are persuaded that the District of Utah is the most appropriate transferee district for pretrial proceedings in this litigation. Three of the five actions on the motion are pending in this district, as are two of the three potentially related actions identified by the parties, while the remaining actions are pending only a (relatively) short distance away in California. Thus, this district appears to be convenient for the majority of the parties. Additionally, the Honorable Robert J. Shelby, who is presiding over the actions pending in the District of Utah, has invested considerable time and effort to familiarize himself with the complex technology and the complicated patent issues at the heart of this litigation. Judge Shelby has already participated in a technology "tutorial" and spent several days hearing both fact and expert testimony, as well as attorney argument, regarding pending preliminary injunction motions that raise infringement and invalidity issues likely to be common to all the actions. Accordingly, Judge Shelby is the best choice to serve as transferee judge in this docket.

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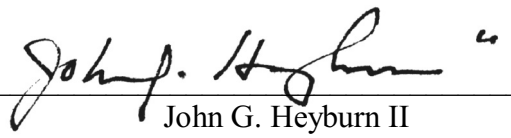
[4] The exceptions are claims 5 and 6 the '282 patent, which were asserted (and ruled invalid) in *AMP* and are asserted again in this litigation.

IT IS THEREFORE ORDERED that pursuant to 28 U.S.C. § 1407, the actions listed on Schedule A and pending outside the District of Utah are transferred to the District of Utah and, with the consent of that court, assigned to the Honorable Robert J. Shelby for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION



John G. Heyburn II
Chairman

Charles R. Breyer
Ellen Segal Huvelle

Sarah S. Vance

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SCHEDULE A

Central District of California

Quest Diagnostics Incorporated, et al. v. Myriad Genetics, Inc., C.A. No. 8:13-01587

Northern District of California

Counsyl, Inc. v. Myriad Genetics, Inc., C.A. No. 5:13-04391

District of Utah

University of Utah Research Foundation, et al. v. Ambry Genetics Corporation, C.A. No. 2:13-00640
University of Utah Research Foundation, et al. v. GeneDX, Inc., C.A. No. 2:13-00954
University of Utah Research Foundation, et al. v. Quest Diagnostics Incorporated, et al., C.A. No. 2:13-00967