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UNITED STATES COURT OF APPEALS FOR THE FEDERAL States Court of Appeals CIRCUIT For The Federal Circuit

2010-1406

THE ASSOCIATION FOR MOLECULAR PATHOLOGY,
THE AMERICAN COLLEGE OF MEDICAL GENETICS,
THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY,
THE COLLEGE OF AMERICAN PATHOLOGISTS,
HAIG KAZAZIAN, MD, ARUPA GANGULY, PhD,
WENDY CHUNG, MD, PhD, HARRY OSTRER, MD,
DAVID LEDBETTER, PhD, STEPHEN WARREN, PhD,
ELLEN MATLOFF, M.S., ELSA REICH, M.S.,
BREAST CANCER ACTION,
BOSTON WOMEN'S HEALTH BOOK COLLECTIVE,
LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD,
PATRICE FORTUNE, VICKY THOMASON, AND KATHLEEN RAKER,
Plaintiffs-Appellees,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE, Defendant,

and

MYRIAD GENETICS, INC.,

Defendant-Appellant,

and

LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG,

in their official capacity as Directors of the University of Utah Research Foundation,

Defendants-Appellants.

Appeal from the United States District Court for the Southern District of New York in case no. 09-CV-4515, Senior Judge Robert W. Sweet.

MOTION BY PLAINTIFFS-APPELLEES FOR RECUSAL OF CHIEF JUDGE RANDALL R. RADER

Plaintiffs-Appellees respectfully move that Chief Judge Rader recuse himself from any involvement in this case.¹

This case involves a challenge to the legality and constitutionality of the patenting of human genes and correlations between mutations of those genes and breast and/or ovarian cancer. The United States Patent and Trademark Office (USPTO) granted patents covering two human genes that correlate with an increased risk of breast and/or ovarian cancer to Defendants-Appellants Myriad Genetics and the University of Utah Research Foundation (Myriad). Plaintiffs challenged the patents, in part, on the grounds that human genes and the correlations between the genes and the diseases are products of nature and laws of nature. In March, 2010, the United States District Court for the Southern District of New York granted summary judgment to Plaintiffs on the ground that the patents covered unpatentable subject matter and were therefore invalid. Myriad has now appealed.

¹ Plaintiffs-Appellees are aware, of course, that Chief Judge Rader has not been yet assigned to the panel that will hear the case and may not be. Plaintiffs-Appellees move at this time in order to allow Chief Judge Rader time to consider the matter now, rather than having to make the decision, if he is assigned to the panel, on the day of argument. As required by Fed. Cir. R. 27(a)(5), Plaintiffs-Appellees have consulted with counsel for appellants. The Myriad appellants do not consent to this motion and have not yet determined whether they will file an opposition.

The case occasioned a great deal of commentary and discussion in the popular press and in the patent community. Chief Judge Rader has attended events at which the case was discussed. In addition, Plaintiffs-Appellees are aware of one occasion in which Chief Judge Rader expressed his views on the correctness of the district court's decision in this case and another occasion when the case was being discussed when he insinuated disagreement with Plaintiffs/Appellees' view of the law. In a very similar circumstance, Justice Scalia recused himself from a case pending before the Supreme Court. Elk Grove Unified Sch. Dist. v. Newdow, 542 U.S. 1 (2004). Because, like Justice Scalia's comments in connection with the Newdow case, Chief Judge Rader's statements in this case have created an appearance of partiality that calls into question his ability to engage in impartial legal analysis based on the record and the argument of the parties, recusal is appropriate.

The relevant federal statute, 28 U.S.C. § 455(a), states that "Any justice, judge or magistrate of the United States shall disqualify himself in any proceeding in which his impartiality might reasonably be questioned." For the reasons that follow, plaintiffs respectfully suggest that the impartiality of Chief Judge Rader "might reasonably be questioned" in this case.

On May 4, 2010, the Biotechnology Industry Organization (BIO), which filed an *amicus curiae* brief in the district court supporting

Defendants-Appellants, held its annual conference in Chicago. *Ass'n for Molecular Pathology v. United States PTO*, 2010 U.S. Dist. LEXIS 35418, *20 (S.D.N.Y. April 5, 2010) (indicating BIO as an amicus that supported Defendants-Appellants); John T. Aquino, *Finding Gene Patents Unpatentable Too Blunt an Approach, Panelists Say*, BNA's Patent,

Trademark & Copyright Journal, May 14, 2010, at 47 (attached Exhibit 1); See also http://bio2010.bdmetrics.com/SOW-29100530/Patenting-Genes-In-Search-of-Calmer-Waters/Overview.aspx. One session of that conference was titled "Patenting Genes: In Search of Calmer Waters." Chief Judge Rader was listed as a panelist and attended that session. *See*

The panel was described in the conference materials as follows: "Description: Although the patent systems of most industrialized countries today routinely permit the patenting of genetic sequences and related methods, the public perception of 'gene patents' continues to be emotionally charged and characterized by a poor understanding of underlying legal, economical and scientific rationales. Many interest groups are openly challenging the wisdom of allowing gene patents, or of permitting such patents to be exclusively licensed to commercial entities. Yet many diagnostic, agricultural and therapeutic products have been and are being developed that rely on gene patents, with demonstrable benefits for patients and consumers. This session will offer insights from leaders in the field outlining how gene patents have affected biotech research and will offer suggestions for reconciling different sides of this debate." *See* http://bio2010.bdmetrics.com/SOW-29100530/Patenting-Genes-In-Search-of-Calmer-Waters/Overview.aspx.

http://bio2010.bdmetrics.com/SOW-29100530/Patenting-Genes-In-Searchof-Calmer-Waters/Overview.aspx. According to a widely circulated press report of the event, at the start of the session, the moderator, attorney Jennifer Gordon of Baker Botts LLP -- the same attorney who was the lead author of the BIO amicus brief in this case at the district court -- asked for a vote of those in the audience asking if they agreed with the decision of the district court in this case. John T. Aquino, Finding Gene Patents Unpatentable Too Blunt an Approach, Panelists Say, BNA's Patent, Trademark & Copyright Journal, May 14, 2010, at 47. Chief Judge Rader observed this popular vote by a roomful of people who had already expressed their collective view in an amicus brief. Chief Judge Rader listened to his fellow panelists discuss the facts of the case and the details of the patents as well as the wisdom and propriety of the decision. According to the news reports, Chief Judge Rader participated directly in this discussion:

Rader, who had been mostly quiet in the discussion up to this point, said, 'A troublesome question for me is the lack of legal standard for making this decision. In an obviousness analysis, there are some neutral steps that I can apply. But using Section 101 to say that the subject matter is unpatentable is so blunt a tool that there is no neutral step to allow me to say that there is a line here that must be crossed and that this particular patent claim crosses it or does not.' [Chief Judge] Rader continued, 'This approach is subjective, and, to be frank, it's politics. It's what you believe in your soul, but it isn't the law.'

Id.

In other words, without reading the briefs submitted by the parties or hearing argument, Chief Judge Rader expressed his view of the district court's decision. That Chief Judge Rader not only expressed his views on this specific case, but did so in front of an audience that was heavily biased in favor of one party, further raises questions about his impartiality in this case.

The BIO conference is not the only time that Chief Judge Rader has listened to non-parties and interested parties discuss their views concerning the facts in the case, the facts concerning the patents, and the correctness of the district court's decision. Plaintiffs are aware of at least one other occasion when Chief Judge Rader attended a discussion concerning the facts and legal theories of the case.

In April, 2010, Chief Judge Rader attended the Fordham University School of Law Eighteenth Annual Conference on International Intellectual Property Law & Policy. At that conference, Chief Judge Rader attended a panel entitled "Patent Eligible Subject Matter," and a principal issue addressed by the panel was specifically this case. *See* attached Exhibit 2, Transcript of Session 9-B. In fact, one of the attorneys of record for Plaintiffs-Appellees, Professor Dan Ravicher of the Public Patent

Foundation at Benjamin N. Cardozo School of Law, was a speaker during that session.

Not only did Chief Judge Rader attend the session, but when Prof. Ravicher began to make his remarks about this case, Chief Judge Rader interjected with a question hinting at disagreement with Prof. Ravicher's expected remarks and position in the case. *Id.* at 14.

The possibility that Judge Rader should recuse himself pursuant to 28 U.S.C. § 455(a) is further supported by examination of the Code of Conduct for United States Judges. Canon 3(A)(6) states (in pertinent part) that "A judge should avoid public comment on the merits of a pending or impending action." Chief Judge Rader's comments on April 9, 2010, at the Fordham IP Conference, combined with his comments again on May 4, 2010, at the BIO Conference, are troubling in light of that Canon and raise further questions about the appearance of his impartiality.

Under current case law, the totality of these circumstances supports recusal. *Liteky v. United States*, 510 U.S. 540, 546 (1994), reviewed the meaning of 28 U.S.C. § 455, especially in view of the "massive changes" made in 1974. "[W]hat matters is not the reality of bias or prejudice but its appearance. Quite simply and quite universally, recusal [i]s required whenever 'impartiality might reasonably be questioned." 510 U.S. at 548.

Moreover, subsection (a) of § 455 "covers all aspects of partiality." 510 U.S. at 553, n. 2.

Justice Kennedy's concurrence in *Liteky* also made the point that recusal is mandatory here:

[T]he central inquiry under § 455(a) is the appearance of partiality, not its place of origin...

Disqualification is required if an objective observer would entertain reasonable questions about the judge's impartiality. If a judge's attitude or state of mind leads a detached observer to conclude that a fair and impartial hearing is unlikely, the judge must be disqualified. Indeed, in such circumstances, I should think that any judge who understands the judicial office and oath would be the first to insist that another judge hear the case... and Section 455(a) ... addresses the appearance of partiality, guaranteeing not only that a partisan judge will not sit, but also that no reasonable person will have that suspicion.

Liteky, 510 U.S. at 563, 564, 567 (Kennedy, J., concurring).

another Supreme Court case that considered 28 U.S.C. § 455 in depth – similarly emphasized that "a violation of § 455(a) is established when a reasonable person, knowing the relevant facts, would expect that a justice, judge, or magistrate knew of circumstances creating an appearance of partiality, notwithstanding a finding that the judge was not actually conscious of those circumstances." 486 U.S. at 850

Along these lines, the lower courts have determined that:

[T]he judge's actual state of mind, purity of heart, incorruptibility, or lack of partiality are not the issue. ... The standard is purely objective. The inquiry is limited to outward manifestations and reasonable inferences drawn therefrom. In applying the test, the initial inquiry is whether a reasonable factual basis exists for calling the judge's impartiality into question.

United States v. Cooley, 1 F.3d 985, 993 (10th Cir. 1993); See also In re Boston Children First, 244 F.3d 164 (1st Cir. 2001)(mandamus granted requiring district court judge to recuse herself based on public statements about a pending case).

It is not only the content of the statements Chief Judge Rader has made that are of concern. His decision to appear at an event sponsored by *amici* supporting one party in this case and his use of that forum to decry the district court's ruling are also important. In fact, it was "the judge's expressive conduct in deliberately making the choice to appear in such a forum at a sensitive time to deliver strong views on matters which were likely to be ongoing before him" that resulted in the Tenth Circuit's determination that the District Judge in *Cooley* should have recused himself. 1 F.3d at 995. And, it was the same circumstance that led Justice Scalia in *Newdow* to recuse himself.

Plaintiffs-Appellees are not suggesting that a judge, even in an extrajudicial setting, is prohibited from enunciating his views on general legal matters. To the contrary, "expressions of opinion on legal issues are

not disqualifying," *Leaman v. Ohio Dep't of Mental Retardation & Developmental Disabilities*, 825 F.2d 946, 950 n,1 (6th Cir. 1987), and "[a] judge's views on legal issues may not serve as the basis for motions to disqualify," *United States v. Conforte*, 624 F.2d 869, 882 (9th Cir. 1980).

However, Chief Judge Rader's actions go far beyond such an enunciation. He has publicly indicated that he has already applied his patentable subject matter analysis to the specifics of this case and reached a conclusion before ever reading the briefs or hearing the arguments. That is what provides the grounds for recusal.

There are additional factors that counsel for Chief Judge Rader to recuse himself. Judicial Canon 3(A)(4)(c) provides guidance concerning a judge's ability to obtain advice on cases that are pending or impending. It provides that a judge may "obtain the written advice of a disinterested expert on the law, but only after giving advance notice to the parties of the person to be consulted and the subject matter of the advice and affording the parties reasonable opportunity to object and respond to the notice and to the advice received..." This Canon by implication prohibits a judge from obtaining advice from an "interested" expert on the law. But, Chief Judge Rader did exactly that by attending the session sponsored by BIO, one of defendants' amici, and moderated by BIO's counsel (and, of course, without advance

notice to the parties). He also apparently listened to interested non-parties discuss the evidentiary facts of the case. *See* Canon 3(C)(1)(A) (judge should disqualify himself if he has personal knowledge of disputed evidentiary facts).

The Supreme Court has noted the importance of "ensur[ing] that our deliberations will have the benefit of adversary presentation and full development of the relevant facts." Bender v. Williamsport Area Sch. Dist., 475 U.S. 534, 542 (1986). Here, a judge has indicated that he is prepared to rule in a given matter absent such deliberations, precisely the situation for which 28 U.S.C. § 455(a) was promulgated. If "[t]he test is whether an objective, disinterested, lay observer fully informed of the facts underlying the grounds on which recusal was sought would entertain a significant doubt about the judge's impartiality," Parker v. Connors Steel Co., 855 F.2d 1540, 1524 (11th Cir. 1988), then it would seem that the facts in this case would lead to exactly that doubt. "[T]he appearance of partiality is as dangerous as the fact of it." Conforte, 624 F.2d at 881. "...a judge is under an affirmative, self-enforcing obligation to recuse himself sua sponte whenever the proper grounds exist." U.S. v. Kelly, 888 F.2d 732, 744 (11th Cir. 1989). For a these reasons, Chief Judge Rader should recuse himself from any involvement in this litigation.

CONCLUSION

For the foregoing reasons, Chief Judge Rader should recuse himself from any involvement in this matter.

Dated:

June 28, 2010

Respectfully submitted,

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