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Biotechnology and Pharmaceutical Litigation

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I enjoy IP litigation. I even enjoy reading IP case decisions. I especially like bio/pharma IP cases—as I entered the IP field as an in-house patent practitioner at Merck back in 1979. Moving from New Jersey to Boston in 1984 and entering private practice at a small IP boutique started the litigation side of my career.

In this column I will provide you with comments regarding bio/pharma cases in the Federal Courts—at the District Court level and at the appellate level, mostly in the Court of Appeals for the Federal Circuit. I've been working in this field for a long time, and I never find cases in this area to be boring. I hope you will say the same thing about my columns.

This column is no substitute for legal research, as I often will find something of interest to me in a particular case that has nothing to do with the decision in the case. My columns attempt to provide you with some useful information on a variety of bio/pharma patent cases and trademark cases, and occasionally other cases that I think might be of interest to readers.

Amgen v. Roche

The *Amgen v. Roche* litigation over the recombinant anemia drug erythropoietin (EPO) started in 2005 when Amgen filed a declaratory judgment action against Roche in the US District Court for the District of Massachusetts, alleging that Roche's product, Mircera, if imported into

the United States, would infringe five of Amgen's patents to EPO. [U.S. Patent No. 5,441,868 (the '868 patent); U.S. Patent No. 5,547,933 (the '933 patent); U.S. Patent No. 5,618,698 (the '698 patent); U.S. Patent No. 5,756,349 (the '349 patent); and U.S. Patent No. 5,955,422 (the '422 patent).] Roche asserted that Amgen's patents were invalid and not infringed.

In October of 2008, following rulings of summary judgment and judgment as a matter of law (JMOL), and a jury trial, the District Court entered judgment that the '868, '933, '698, and '422 patents were infringed and not invalid, and that the '349 patent was neither invalid nor infringed. [*Amgen, Inc. v. F. Hoffman-La Roche Ltd.*, No. 05-12237-WGY, slip op. at 1-2 (D. Mass. Oct. 17, 2008).] Accordingly, the court granted Amgen declaratory relief and permanently enjoined Roche from marketing Mircera in the United States. Roche appealed.

On September 15, 2009, the Court of Appeals for the Federal Circuit vacated the District Court's grant of summary judgment and of JMOL to Amgen of no invalidity for obviousness-type double patenting of claims 3, 7, and 8 of the '933 patent; claim 1 of the '422 patent; and claim 7 of the '349 patent. The Federal Circuit remanded the case to the District Court for an obviousness-type double patenting analysis of those claims. The Federal Circuit also vacated the District Court's grant of JMOL to

Roche of non-infringement of claim 7 of the '349 patent and remanded for a new trial on infringement of that claim.

Interestingly, the Federal Circuit did not overturn the injunction barring Roche from selling its anemia drug in the United States.

University of Pittsburgh— Inventorship Case

U.S. Patent No. 6,777,231 has 10 claims, all directed to various aspects of adipose-derived (liposuction fat) stem cells. When granted, the '231 patent listed seven inventors: three from the University of Pittsburgh and four from the University of California. Each of the universities licensed the '231 patent to a different party.

In the District Court case, the University of Pittsburgh claimed that only the Pittsburgh inventors should have been named on the patent, and thus, the sole owner of the patent was the University of Pittsburgh. The University of California disagreed. Based on the evidence presented, the District Court held that two of the Pittsburgh inventors were the parties that conceived the invention, and accordingly, order the PTO to correct the inventorship under 35 U.S.C. § 256.

In this case, the two confirmed inventors had written evidence before the leader of the California team (Dr. Hendrick) came to Pittsburgh—evidence that the Court accepted as proof that they believed their liposuction derived stem cells could trans-differentiate into various types of cells such as bone, cartilage, nerves, and muscles. Later, Dr. Hendrick and his team at UCLA confirmed that the speculative suggestions of the confirmed inventors were indeed correct. The University of California appealed.

On July 23, 2009, in the case of *University of Pittsburgh v. Hendrick*, the Federal Circuit affirmed the District Court's finding that the

University of Pittsburgh inventors were the sole inventors of the invention claimed in U.S. Patent No. 6,777,231.

The Federal Circuit held that despite the lack of scientific certainty, the invention had been conceived before Dr. Hendrick came to Pittsburgh.

Knowledge in the context of a possessed, isolated biological construct does not mean proof to a scientific certainty that the construct is exactly what a scientist believes it is. Conception requires a definite and permanent idea of the operative invention, and “necessarily turns on the inventor’s ability to describe his invention.” Proof that the invention works to a scientific certainty is reduction to practice. Therefore, because the district court found evidence that Katz and Lull had formed a definite and permanent idea of the cells’ inventive qualities, and had in fact observed them, it is immaterial that their knowledge was not scientifically certain and that the REBAR researchers helped them gain such scientific certainty.

The Federal Circuit relied on the District Court’s factual finding that the Pittsburgh lab notebooks sufficiently described to those skilled in the art how to isolate the claimed cells from adipose-tissue, and thus they had disclosed a completed thought expressed in such clear terms as to enable those skilled in the art to make the invention.

Bilski Updates

Chief Judge Michel says some read too much into the *Bilski* opinion. “Don’t believe most of what you hear and half of what you read” on the meaning of the *In re Bilski* opinion, its author, Chief Judge Paul R. Michel of the Federal Circuit told

an audience of patent practitioners at a July 21 conference in Arlington, VA—the eighth annual George Mason Law School “Hot Topics in Patent Law” symposium.

The *Bilski* case has to be “read side-by-side with the foundational cases” on patentable subject matter, particularly the US Supreme Court cases on that issue from 1972 to 1981, said Judge Michel. Speaking specifically about business methods, he said that the test leaves “not all methods ineligible, and not all eligible” as patentable subject matter under Section 101.

Medical treatment method met *Bilski* patent-eligible subject matter test of “transformation into different state or thing.” On September 16th, the Federal Circuit, in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services* [Appeal No. 2008-1403] overturned a district court summary judgment that Prometheus’ claimed subject matter was unpatentable under Section 101, based on case law prior to the *Bilski* decision. The claims were for methods of “administering” 6-MP or another drug to a patient for treating autoimmune diseases, and “determining” the level in the patient to indicate whether the level was less than or greater than specific claimed levels that indicated a need to change dosage.

The Federal Circuit found the claims met the “machine or transformation” test of the *Bilski* case (and prior Supreme Court cases) because the claimed methods transform an article into a different state or thing and this transformation is central to the purpose of the claimed process. . . .

The specific transformation is of the human body following administration of a drug and the various chemical and physical changes of the drug’s metabolites that enable their concentrations to be determined.

This decision should settle some of the *Bilski* fears of the bio/pharma community regarding the application

of Section 101 to method of treatment claims and method of diagnosis claims—if a drug is administered as part of the method. The Federal Circuit went on to comment on the District Court’s reliance on dicta from a Supreme Court decision:

In reaching its conclusion, the district court relied heavily on the opinion of three justices dissenting from the dismissal of the grant of certiorari in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.* [548 U.S. 124 (2006) (Breyer, J., dissenting)]. See Invalidity Opinion, 2008 WL 878910, at *8 (discussing the dissent in *Laboratory Corp.* at length and stating that although the dissent “does not have precedential value, the Court finds Justice Breyer’s reasoning persuasive”) That dissent is not controlling law and also involved different claims from the ones at issue here.

Wyeth based Patent Term Adjustment Litigations

One active area in patent litigation is Patent Term Adjustment (PTA) law suits, filed in view of the case *Wyeth v. Dudas* (D. DC 2008), in which the District Court for the District of Columbia granted summary judgment in favor of Wyeth, determining that the US Patent and Trademark Office had misconstrued the calculations of the Patent Term Adjustment statute 35 U.S.C. § 154(b)(2)(A), and as a result, had denied Wyeth a portion of patent term to which it was entitled.

Recent *Wyeth* based cases include the following:

Plaintiff: Nova Measuring Instruments, Ltd.
Defendant: John Doll (USPTO)
Patent Number: 7,477,405
Date Filed: 7/13/2009

Plaintiff: Mosaid Technologies Inc.
Defendant: John Doll (USPTO)
Patent Number: 7,480,233
Date Filed: 7/20/2009

Plaintiff: Juridical Foundation the Chemo-Sero-Therapeutic Research Institute
Defendant: John Doll (USPTO)
Patent Number: 7,482,436
Date Filed: 7/27/2009

Plaintiff: Dyax Corp.
Defendant: John Doll (USPTO)
Patent Number: 7,485,297
Date Filed: 7/31/2009

Plaintiff: Intermune, Inc.
Defendant: David Kappos (USPTO)
[NOTE—Mr. Kappos was not sworn in until 8/13!]
Patent Number: 7,491,794
Date Filed: 8/11/2009

Plaintiff: Boehringer Ingelheim Pharma GmbH & Co. KG
Defendant: David Kappos (USPTO)
Patent Number: 7,491,824
Date Filed: 8/14/2009

Plaintiff: Lifenet Health
Defendant: David Kappos (USPTO)
Patent Numbers: 7,498,040; 7,498,041
Date Filed: 8/28/2009

Plaintiff: Unilever Patent Holdings B.V.
Defendant: David Kappos (USPTO)
Patent Number: 7,501,556
Date Filed: 9/2/2009

Plaintiff: Boehringer Ingelheim et al.
Defendant: David Kappos (USPTO)
Patent Number: 7,504,378
Date Filed: 9/11/2009

These cases will be monitored to see if anything interesting comes up for future columns.

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