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# Biotechnology and Pharmaceutical Litigation

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## **Summary Judgment Rule Update**

Amendments to Rule 56 of the Federal Rules of Civil Procedure have taken effect as of December 1, 2010. Subdivisions (a) through (g) of old Rule 56 have been replaced by Subdivisions (a) through (h) of new Rule 56.

According to the Committee Notes, these amendments are procedural, not substantive. They are intended to improve the procedures for presenting and deciding summary judgment motions, to make the procedures more consistent with those already used in many courts.

## **Expert Discovery Update**

Amendments to Rule 26 of the Federal Rules of Civil Procedure are in effect as of December 1, 2010. These amendments provide discovery protection to testifying expert witnesses regarding draft reports as well as attorney-expert communications. These amendments are designed to permit experts to work with their attorneys without fear of producing a discoverable record.

## **No Harm, No Foul**

On November 9, 2010, in *Cancer Research Technology Ltd. v. Barr Laboratories, Inc.*, the Federal Circuit reversed the decision by the District Court for the District of Delaware holding U.S. Patent No. 5,260,291 unenforceable for prosecution laches and inequitable conduct.

The Court held that the unreasonable and unexplained delay requirement of the prosecution laches

defense includes a finding of prejudice, and that to rely on the defense, an accused infringer must show evidence of intervening rights, *i.e.*, that either the accused infringer or others invested in, worked on, or used the claimed technology. In other words, no harm, no foul.

## **Update on Inequitable Conduct**

I have previously addressed the Federal Circuit's April 2010 order granting en banc review of the inequitable conduct holding in *Therasense v. Becton Dickinson & Co.* [Appeal No. 2008-1511]. Oral argument in the en banc review was held on November 9, 2010. The argument audio file is available at the court Web site, [www.ca9c.uscourts.gov](http://www.ca9c.uscourts.gov).

Questions posed during the argument hint that the Court will not be likely to make drastic changes to the current inequitable conduct law. Some of the judges were focused on the potential for applicants to commit inequitable conduct under a significantly narrowed rule of law. Other judges were focused on the lack of precedents for a "but for" standard.

As I stated in a previous column, I do not foresee the Court making sweeping changes in this area. I believe that the proper remedial action regarding inequitable conduct law will have to come from Congress.

## **Section 145 Update**

*Hyatt v. Kappos* 2007-1066—On November 8, 2010, in an en banc opinion by Judge Moore, the Federal Circuit interpreted Patent Act Section 145 to impose *no limitation* on

an applicant's right to introduce new evidence in a civil action against the US Patent and Trademark Office (PTO) in district court, apart from evidentiary limitations applicable to all federal civil actions.

In this case, the PTO had refused a patent to Hyatt for a computerized display system for processing image information. Following an adverse decision from the Board of Patent Appeals, Hyatt filed a civil action in the District of Columbia District Court and there submitted a declaration for the purpose of overcoming the written description rejections. The DC District Court rejected the declaration, stating that it should have been filed in the PTO proceedings.

The Federal Circuit rejected the District Court's argument that an applicant is allowed to introduce new evidence in a civil action *only* when the applicant could not reasonably have provided the evidence to the PTO.

According to the Federal Circuit, when a party introduces new evidence, the District Court *must* make de novo fact findings with respect to factual issues to which the new evidence relates. In general, the parties may not raise *new issues* in District Court, but this does not preclude parties from introducing additional evidence.

## **Myriad Case (Gene Patents) Update**

The Myriad case, which is likely to ultimately settle the issue of gene-based patent eligibility, is taking new twists and turns as it heads to a decision in the Federal Circuit.

In one strange twist, the US Department of Justice filed an amicus brief that argued that the lower court decision be upheld. This 39 page opinion includes support for the lower court decision regarding certain claims (e.g., claim 1), but then asserts that other claims (e.g., cDNA claims, and the like), should be found to meet the Section 101 test. In supporting the non-patentability of claim 1, the DOJ brief states (page 8) that:

...claim 1 of the '282 patent encompasses *any* isolated DNA molecule whose nucleotide sequence codes for the natural BRCA1 protein. See also U.S. Patent No. 5,873,492, claim 1 (same, BRCA2). This would include an ordinary BRCA gene isolated from a tissue sample taken from a woman in a hospital. (Emphasis in original).

This statement from the DOJ *ignores* the express language of claim 1 in both patents. In each case, the claim is limited to an isolated DNA that has a specific and detailed nucleotide sequence, including SEQ ID NO:2 in the '282 patent.

In a not so strange turn, the Biotechnology Industry Organization (BIO) and the Association of University Technology Managers (AUTM) filed an amicus brief (B/A brief) in late October.

The B/A brief focused on the patent-eligibility of isolated DNA, citing the “chemical nature” of isolated DNA. The brief does not comment on the patent-eligibility of the method claim invalidated by the District Court.

The B/A brief states three grounds for the Court to decide that isolated DNA is patentable subject matter under 35 U.S.C. § 101:

First, that isolated DNA molecules are “man-made compositions of matter” that are not naturally occurring.

Second, that isolated DNA molecules are chemical compounds. “A gene is but a chemical compound, albeit a complex one”, which have “new and distinctive properties and uses compared to naturally-occurring DNA.”

Third, the District Court erred when it based its decision on the putatively unique properties of DNA (as the “physical embodiment of [genetic] information”) that distinguishes it from all other biological molecules, specifically by treating DNA as “mere information” rather than as a chemical compound.

I agree with the B/A brief that the District Court clearly erred in treating these molecules as being merely purified forms of naturally-occurring substances. I likewise agree with the B/A brief that isolated DNA molecules are “new, man-made chemical compositions that do not occur in nature.” The “hand of man” is certainly and clearly involved in the isolated DNA molecules claimed in this case. The DNA molecules as claimed, cannot be found in the human body.

### Supreme Court IP Update

On November 1, 2010, the Supreme Court granted certiorari in Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems Inc. [Appeal 09-1159].

This case involves invention assignments under the Bayh-Doyle Act, which provides that rights derived from government-sponsored research always flow to the university or small business that actually receives a government research grant or contract. The statute further provides that if the contractor/grantee declines to assert title, the government may waive its own rights, leaving ownership to the inventor.

In this case, the Stanford professor, Dr. Mark Holodniy, agreed to assign his future patent rights, which

resulted from his federally funded research, to the university. However, later, while working on the same project at Cetus, he both agreed to assign his future rights, and assigned a specific invention from the project, to the corporation.

Even though the Bayh-Dole Act governing patent ownership says that the patent rights should have been assigned to Stanford, the Federal Circuit ruled that the actual invention assignment granted to Cetus took precedence over the promise of assignment of his future patent rights to the university. Stanford has appealed to the Supreme Court, and we will see which position wins.

### Legislative Update

On Tuesday, November 2, 2010, control of the House of Representatives shifted to the Republican Party (except here in Massachusetts). Most of the senior members of the House Judiciary Committee with IP experience were re-elected. Given to power shift, no action on significant IP bills during the “lame duck” session is expected when Congress returns to Washington on November 15. We’ll see what the 112th Congress does, when it begins in January 2011.

### False Marking Case Updates

On November 16, 2010, Frisbee maker Wham-O Inc. filed a constitutional challenge in the US Court of Appeals for the Federal Circuit regarding the false marking statute. The Wham-O filing is in response to the appeal filed from the Western District of Pennsylvania court’s dismissal of the false marking case, *FLFMC LLC v. Wham-O Inc.* [2010 WL 3156162 (W.D.Pa.)]. FLFMC’s case against Wham-O was dismissed by the District Court in early August 2010, because the plaintiff hadn’t shown that Wham-O’s false patent marking on some of its products caused actual or imminent injury to the government or to the public.

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Such a showing is not required as per the holding in the Federal Circuit's August 31, 2010, decision in *Stauffer v. Brooks Brothers, Inc.* The constitutionality of the false marking whistleblower provisions arose briefly in the *Stauffer* case because amicus Ciba Vision Corp. raised the issue. The Federal Circuit

declined to rule on that issue in *Stauffer* because the "district court did not decide, and the parties did not appeal," the constitutionality of the clause. However, because Wham-O had made the same constitutionality argument in the District Court, that issue has been preserved for the appeal.

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*Ernest V. Linek is a principal shareholder of Banner & Witcoff, Ltd. This article is for educational and informational purposes only and should not be construed in any way as legal advice. The article reflects the opinion of the author and should not be attributed to the firm Banner & Witcoff, Ltd. or to any of its clients.*

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