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# Practice Areas

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## Biotechnology and Pharmaceutical Litigation

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### **Reverse Payments— Still Legal**

On March 7, 2011, the Supreme Court denied certiorari in *Louisiana Wholesale Drug Co. v. Bayer AG*. The case arose from the Second Circuit's decision that a "reverse payment" agreement between Bayer and Barr Laboratories, preventing the introduction of a generic version of Cipro® into the marketplace by Barr, was not illegal under the antitrust laws.

### **Inducement of Infringement Update**

On February 23, 2011, oral argument was held in the Supreme Court in *Global-Tech v. SEB*. In this case the Court will determine if a new standard for proving induced infringement should be formulated, or if the standard set forth recently by the Federal Circuit [*SEB v. Montgomery Ward & Co.* (Fed. Cir. 2010)] is sufficient.

Comments made by several of the justices seemed to indicate that the Federal Circuit's standard of "deliberate disregard of a known risk" perhaps creates too much uncertainty for business. New options apparently being considered by the Court are some kind of "willful blindness" standard or the possibility of importing some version of the "actual knowledge" standard from Section 271(c) into Section 271(b).

### **Written Description Update**

On February 23, 2011, the Court of Appeals for the Federal Circuit

issued its decision in *Centocor Ortho Biotech Inc. v. Abbott Laboratories*, [*Appeal No. 2010-1114*] holding *Centocor's patent invalid under 35 U.S.C. § 112, first paragraph, for lack of an adequate written description of the claimed invention. This decision overturns the damage award of more than \$1.67 billion dollars awarded by the jury in the Eastern District of Texas.*

The court found that the pivotal issue in the case was whether Centocor's patent provided adequate written description for the *human* variable regions of the claimed antibodies. Two statements in the opinion provided the basis for holding the claims invalid:

1. There is nothing in the specification that conveys to one of skill in the art that Centocor possessed fully-human antibodies or human variable regions that fall within the boundaries of the asserted claims.
2. At bottom, the asserted claims constitute a wish list of properties that a fully-human, therapeutic TNF- $\alpha$  anti-body should have: high affinity, neutralizing activity, and the ability to bind in the same place as the mouse A2 antibody. The specification at best describes a plan for making fully-human antibodies and then identifying those that satisfy the claim limitations.

The court went on to emphasize that the written description requirement

of 35 U.S.C. §112 first paragraph does not require either examples or an actual reduction to practice. What the statute does require is that one of skill in the art can visualize or recognize the claimed invention (here—*human* antibodies) based on the disclosure in the specification. In other words, the patent specification must demonstrate constructive possession of the claimed invention, and this specification failed to so do.

### **False Marking Update (1)—Enhanced Pleadings Requirement**

On March 15, 2011, the Federal Circuit held that the "particularity" provisions of Rule 9(b) of the Federal Rules of Civil Procedure, apply to false marking claims filed under 25 U.S.C. §292 and that a complaint alleging false marking is insufficient when it only asserts conclusory allegations that a defendant is a "sophisticated company" and "knew or should have known" that the patent expired. This decision was issued in response to a writ of mandamus filed by the defendant, based on the ND Illinois District Court's denial of defendant's motion to dismiss filed in *Simonian v. BP Lubricants USA Inc.* [Civil Action No. 10-CV-1258].

According to the Federal Circuit, the gate-keeping function of Fed. R. Civ. P. Rule 9(b) is necessary to assure that only viable Section 292 claims reach discovery and adjudication. The Court held that a complaint must at least "provide some objective indication to reasonably infer" that the defendant had knowledge of the falsity. In the language of Exergen, the false marking plaintiff must provide detail on "the specific who, what, when, where, and how" of the alleged fraud. [*Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009).]

This heightened pleading requirement may lead to a number of pending false marking cases being dismissed. According to the Court,

permitting a false marking complaint to proceed without meeting the particularity requirement of Rule 9(b) would sanction discovery and adjudication for claims that do little more than speculate that the defendant engaged in more than negligent action.

The Federal Circuit accordingly granted BP's petition for writ of mandamus in part and directed the district court to dismiss the complaint with leave for the plaintiff to amend in accordance with the enhanced pleading requirements of Rule 9(b).

### ***False Marking Update (2)—Statute Unconstitutional***

On February 23, 2011, Judge Polster of the Northern District of Ohio, in *Unique Product Solutions v. Hy-Grade Valve*, granted the defendant's motion to dismiss the complaint based on the ground that the qui tam provision of 35 U.S.C. §292(b) is unconstitutional.

Pursuant to the Court's solicitation, defendant Hy-Grade filed its motion to dismiss on January 13, 2011, arguing that 35 U.S.C. §292(b) violates the Appointments and Take Care Clauses [Article II, Section II, Clause 2 and Section 3] of the United States Constitution.

The "Appointments Clause" states that President has the power to appoint certain public officials with the "advice and consent" of the US Senate. This clause also allows lower-level officials to be appointed without the advice and consent process. The "Take Care Clause" states that the President "shall take care that the laws be faithfully executed."

A Court Order regarding the constitutionality question was issued on November 16, 2010, and served on John Fargo, Director of the Commercial Litigation Branch of the Department of Justice, Civil Division. In addition to serving the order on Mr. Fargo, the Court contacted

Mr. Fargo and invited a response to the constitutionality issue. Mr. Fargo orally expressed an intention to intervene. As of the February 23rd date of the Court's order, the Justice Department had not filed a response to the Motion to Dismiss, nor has it moved to intervene in the action.

With no response from the Justice Department, the Court held the False Marking Statute, 35 U.S.C. §292(b) unconstitutional under the Take Care Clause of the United States Constitution, Article II, Section 3 and granted defendant's motion to dismiss. As per footnote 8, the court's decision rendered it unnecessary to address the Appointments Clause arguments.

### ***Supreme Court Review—Bayh-Dole Act***

On February 28, 2011, oral argument was held in the Supreme Court case *Stanford University v. Roche Molecular Systems, Inc.* This case involving a patent ownership dispute between Stanford University whose researcher worked with federal funding and Cetus—a company for which the same researcher later worked on a related project. The inventor, who was employed by the University, signed an assignment agreement with Stanford, and later did further work at a Cetus laboratory (now owned by Roche), which had a collaborating relationship with Stanford. The inventor at that time was also required to sign a Cetus assignment agreement for work he did there. Cetus obtained a patent on the inventor's work, and Stanford subsequently did the same.

In Stanford's infringement suit against Cetus, the district court refused to consider a Cetus challenge to Stanford's patent ownership. The Federal Circuit reversed, finding that the Cetus assignment prevailed over the Stanford assignment.

At oral argument, several of the Justices appeared to be uncomfortable with the thought that the

government's interest in federally-funded inventions could be subverted by unexpected contracting arrangements between the inventor and third parties.

Stanford's principal ownership argument was that, under the Bayh-Dole Act, the work of its inventor was within the scope of its government-funded project. As such, Stanford claimed both a legal and equitable right to the patented invention.

Several justices seemed skeptical of Stanford's position. Justice Ginsburg noted that the case could be decided narrowly based on the differences in assignment language used by the parties. Under Stanford's instrument, the inventor said "*I will assign*"; under the Cetus instrument, the inventor said "*I hereby do assign*." With this language, Justice Ginsburg said, the Cetus assignment prevails because it was earlier in time.

### ***New PTO "Fast Track" Processing Plan***

On February 4, 2011, the US Patent and Trademark Office (USPTO) published a *Federal Register* notice inviting public comments by March 7 on a proposal to provide "prioritized" examination of patent applications on payment of a \$4,000 fee. The goal would be "to provide a final disposition within twelve months of prioritized status being granted."

The USPTO plans to cap the number of prioritized applications at 10,000 for the first year, giving the USPTO \$40 million in additional income if the cap was reached and the income was within the congressional appropriations limit. The fee would cover "the cost of hiring and training a sufficient number of new employees to offset the production time used to examine prioritized applications."

### ***Patent Law Reform Update***

On March 8, 2011, the US Senate passed the Patent Reform

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Act—S. 23. Next to come will be a Patent Reform bill from the House of Representatives. If the House and Senate can agree on a final bill, the President has indicated that such legislation will be signed into law this year. Included in the 116 pages of S. 23 are the following:

- Sec. 2—First inventor to file
- Sec. 3—Inventor’s oath or declaration
- Sec. 4—Virtual marking and advice of counsel
- Sec. 5—Post-grant review proceedings
- Sec. 6—Patent Trial and Appeal Board
- Sec. 7—Pre-issuance submissions by third parties
- Sec. 8—Venue
- Sec. 9—Fee setting authority
- Sec. 10—Supplemental examination
- Sec. 11—Residency of Federal Circuit judges
- Sec. 12—Micro entity defined
- Sec. 13—Funding agreements
- Sec. 14—Tax strategies deemed within the prior art
- Sec. 15—Best mode – failure to teach - does not invalidate
- Sec. 16—Technical amendments
- Sec. 17—Clarification of jurisdiction
- Sec. 18—Transitional program for covered business-method patents
- Sec. 19—Travel expenses and payment of administrative judges
- Sec. 20—Patent and Trademark Office funding
- Sec. 21—Satellite offices

- Sec. 22—Patent Ombudsman Program for small business concerns
- Sec. 23—Priority examination for technologies important to American competitiveness
- Sec. 24—Naming of the USPTO Detroit Office as the Elijah J. McCoy Satellite Office

### ***Patent Damages Update***

On January 28, 2011, an Eastern District of Texas jury handed down a verdict in *Saffran v. Johnson & Johnson*, and awarded a \$482 million willful infringement damages verdict against the defendants for infringing Dr. Bruce Saffran’s drug-eluting cardiac stent patent US 5,653,760. The willful infringement verdict gives the court discretion to treble the amount.

Dr. Saffran’s expert did not rely on the once-customary 25 percent “rule of thumb” as a starting point for a reasonable royalty rate because that “rule” had been struck down by the Federal Circuit in early January 2011 in *Uniloc USA Inc. v. Microsoft Corp.* Instead, the expert went through all 15 of the *Georgia-Pacific* factors traditionally used to calculate reasonable royalties in patent cases.

A bench trial on inequitable conduct was held before Judge Ward on March 2, 2011. The case remains in Texas with post verdict motions filed by the parties.

### ***Rule 26(f)—Metadata Production***

On February 7, 2011, in *Nat. Day Laborer Org. Network v. US*

*Immigration and Customs Enforcement Agency*, Judge Scheindlin ruled that metadata is integral to document production requests filed under the Freedom of Information Act. The judge found that future government production of TIFF images would be sufficient if they included the corresponding load files.

The Sedona Conference Glossary defines a Load File as: A file that relates to a set of scanned images or electronically processed files, and indicates where individual pages or files belong together as documents, to include attachments, and where each document begins and ends. A load file may also contain data relevant to the individual documents, such as metadata, coded data, text, and the like. Load files must be obtained and provided in prearranged formats to ensure transfer of accurate and usable images and data.

Rule 26(f) of the Federal Rules of Civil Procedure requires counsel to meet and confer regarding e-discovery issues. If metadata is relevant to your case—ask for the load files.

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