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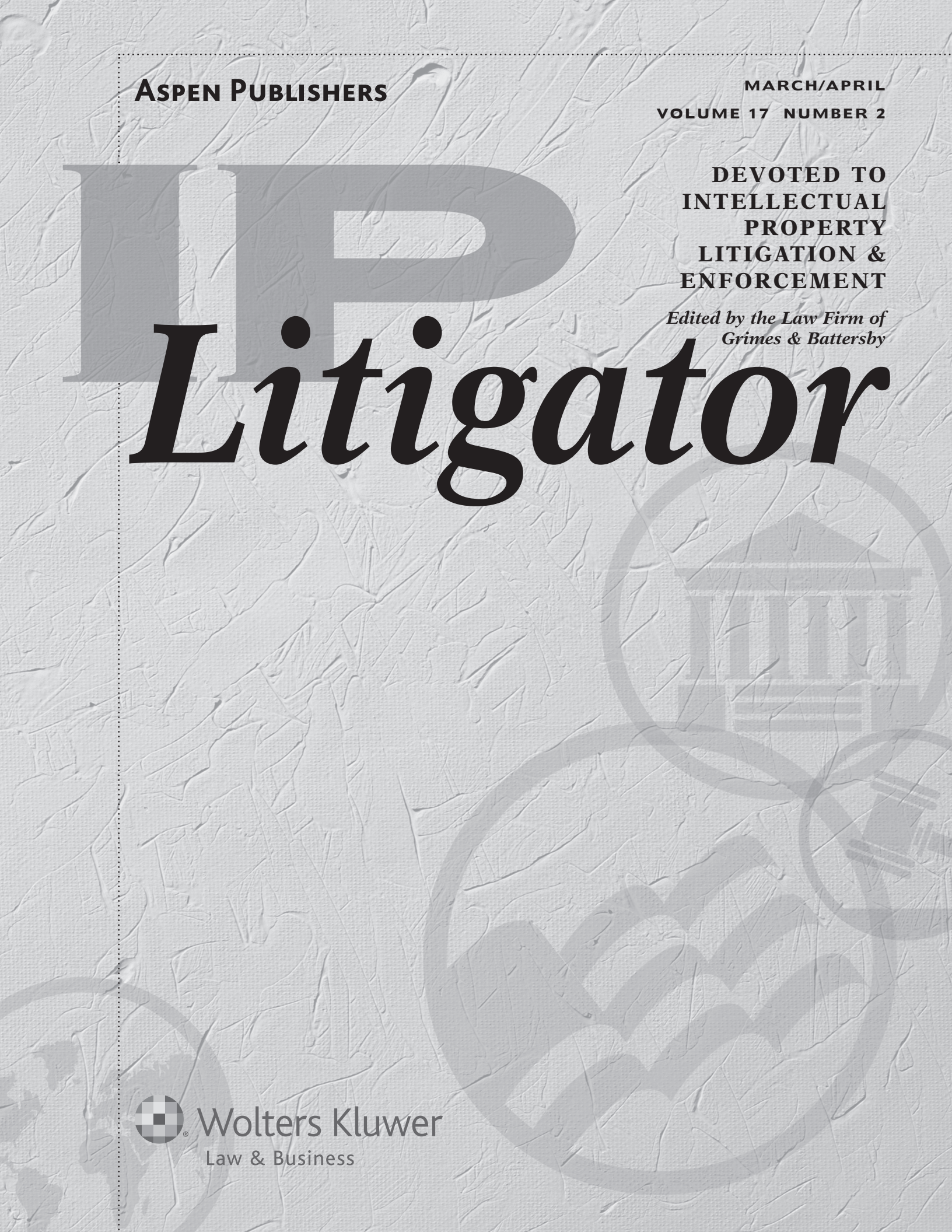

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Update on Inequitable Conduct

I have previously addressed the Federal Circuit's April 2010 order granting *en banc* review of the inequitable conduct holding in *Therasense v. Becton Dickenson & 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.cafc.uscourts.gov*. While we wait for a decision on the case, below are some of the arguments presented.

Selected Comments from the Therasense *Oral Arguments*

Mr. Whealan (for Abbott-Therasense): The time has come for this Court to restore the doctrine of inequitable conduct to its proper origins grounded in Supreme Court precedent. The doctrine, it applies only in egregious cases of fraud where the conduct that occurs caused the issuance of the patent.

The Court can accomplish this by taking three steps. First, reaffirming the subjective intent standard laid out in *Kingsdown*. Second, by applying a materiality standard that requires causation and reliance. And third, by eliminating the balancing sliding scale step that often allows a high finding of materiality to infer intent.

As to the first and third of these steps, there is significant agreement between the parties and the significant amicus briefs. As to the second, there is some agreement and some disagreement.

Mr. Chen (for the USPTO): Picking up where Mr. Whealan just left off, I'd say first of all, we agree on the majority of things that Mr. Whealan is arguing about, which is the intent standard and a balancing need to be clarified and repaired, and we substantially agree with him on those positions. And materiality also needs to be clarified. And in terms of the materiality standard, our view is that to say those three Supreme Court cases called for a but-for standard is incorrect because 40 years of this court's jurisprudence understood that the kinds of inequitable conduct that could render a patent unenforceable is broader than merely just but-for.

[W]e're seeing essentially reference flooding because right now people don't understand what is the art they need to submit. They are in fear of the inequitable conduct standard. But if this court makes clear what the standard is for materiality and makes clear that the intent standard needs to be a high one, that we're really talking about bad-faith conduct, we believe that—and specifically on terms of materiality adopting or following the criteria set out in our current Rule 56, that's going to give the definiteness and more peace of mind for applicants to understand what is the art that they should be submitting.

So, the way we tried to resolve it was going back 20 year ago. In fact, if you look at our federal register notice back in '91 and '92, we—one of the goals of making a clearer standard on materiality was to hopefully minimize the burden of defending yourself against inequitable conduct. Because at that time, we were hearing the same kind of complaints that we're hearing today which is people just feel like the reasonable examiner standard is too unpredictable.

The Court: Are you saying a return to *Kingsdown* with its negation of gross negligence would work?

Mr. Chen: Absolutely. Yes. Driving up the intent standard, because we're really talking about is bad faith misconduct and that has to be proven by the single-most reasonable inference. And so when you make that clear to the courts and hopefully, *Exergen* can also help in terms of ratcheting up the pleading requirements for alleging this kind of defense along with a very clear standard of what is the kinds of information we need in order for you to fulfill your duty of candor, to fulfill your duty to act in equity in front of the government. Those pieces together, we feel like there's going to improve the system.

Mr. Badke (for Becton, Dickinson): I think the problem, just to pick up on the but-for issue, I think the problem with the over-disclosure, aside from clarifying the issue of intent, is the inconsistency between the patent office standard and the standard that may be applied by this Court in any given case.

I mean, a linchpin of our patent system is disclosure, and we don't have an opposition system like they have in Europe, and we depend on the duty of disclosure, and the but-for test will, as the patent office or as some of the amicus briefs have indicated, will cause or will permit people to lie to the patent office. There'll be under-disclosure and all sorts of other issues. So the but-for test doesn't really solve the problem, and solving the problem is if we are more consistent in the standard

that's applied between the patent office and the courts that will set out the rule for the practitioners.

And I am worried about the practitioners. I'm worried about these accusations of inequitable conduct, but I'm also worried about the public interest. And we rely on this disclosure for a very strong patent system, and that's why it's necessary.

One thing that Abbott points out is that they agree that by restoring *Kingsdown* intent standard that the Court can mitigate the outbreak of inequitable conduct. So it's twofold. If the Court clarifies the intent standard, specific intent, single most reasonable inference and also makes the—and adopts Rule 56 or whatever the patent office is enforcing, and if the Court is consistent with the patent office that will also control the outbreak of these charges.

I'm also concerned about nonmeritorious charges against prosecuting attorneys. Something could be highly material, but if the prosecuting attorney doesn't know of it, doesn't appreciate it, that is not grounds for inequitable conduct. So it's the high materiality or materiality along with some of this other evidence of intent.

Prediction

As I have stated in previous columns, 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.

Bilski *Does Not Bar Patentability of "Method for Treatment Claims"*

On December 17, 2010, the Federal Circuit concluded in Prometheus Laboratories, Inc. v. Mayo Collaberative Services, that the Supreme Court's Bilski decision does not require it to reverse its decision that a method for treating Crohn's disease is patent eligible subject matter. This decision was issued in response to the remand of this case from the Supreme Court.

The patent, which claims the administering of a drug and determining the level of its metabolites, was originally found by the Federal Circuit to be patent-eligible under the court's "machine or transformation" test. While the case was pending review at the Supreme Court, the Court issued its opinion in Bilski, holding that the Federal Circuit's "machine or transformation" test was not the sole test for determining Section 101 eligibility of method claims. The Supreme Court thereafter remanded the case to the Federal Circuit for reconsideration in light of the Bilski ruling.

In the Federal Circuit remand decision, the court held that the patent claims the claimed method of optimizing the therapeutic efficacy of treating an immune-mediated gastrointestinal disorder are in effect, claims to "methods of treatment," which are *always transformative* when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition.

The Federal Circuit further held that the "determining step" is likewise transformative. Some form of manipulation, such as the high pressure liquid chromatography method specified in several of the asserted dependent claims or some other modification of the substances to be measured, is necessary to extract the metabolites from a bodily sample and determine their concentration. At the end of the process, the human blood sample is no longer human blood; human tissue is no longer human tissue.

Responding to Mayo's argument, the Federal Circuit rejected the contention that the claim involves mere data-gathering; stating:

> While it is true that the administering and determining steps gather useful data, it is also clear that the presence of those two steps in the claimed processes is not "merely" for the purpose of gathering data. Instead, the administering and determining steps are part of a treatment protocol, and they are transformative.

Myriad Update

The Court of Appeals for the Federal Circuit will hear oral arguments in the Myriad case in the spring of this year. Briefs have been filed by the litigants, the government, and other interested parties, setting the scene for the issues to be argued before the Court.

The Myriad case is on appeal from a District Court decision that invalidated patent claims protecting Myriad's test to determine whether a patient's BRCA genes have a mutation associated with an elevated likelihood of breast cancer under 35 U.S.C. § 101.

In the District Court, Judge Sweet, held that the Supreme Court's "'markedly different' language in Chakrabarty created a test for patentability that isolated genes do not pass because they are "products of nature." Myriad's claims directed to the isolated BRCA genes were therefore held ineligible for patent protection under Section 101 of the patent statute.

How the Federal Circuit handles this case will be of great interest to the bio/pharma community, and the case will be reported on in future columns.

Abolition of the 25% Rule of Thumb for Damages

On January 4, 2011, in *Uniloc USA v. Microsoft*, the Federal Circuit held that the so-called 25% rule of thumb that for many years had been a starting point for calculating reasonable-royalty damages assessed against infringers, is not scientifically rigorous enough to be used any longer:

> This court now holds as a matter of Federal Circuit law that the 25 percent rule of thumb is a fundamentally flawed tool for determining a baseline royalty rate in a hypothetical negotiation. Evidence relying on the 25 percent rule of thumb is thus inadmissible under *Daubert* and the Federal Rules of Evidence, because it fails to tie a reasonable royalty base to the facts of the case at issue.

Uniloc's damages expert, Dr. Gemini, performed "a check to determine whether" his 25% rule of thumb based royalty figure of $564,946,803 was reasonable by comparing it to his calculation of Microsoft's approximate total revenue for Office and Windows of $19.28 billion. During trial, Dr. Gemini testified that his calculated royalty accounted for only 2.9 percent of Microsoft's revenue, and accented his point by reference to a prepared pie chart, showing Microsoft's $19.28 billion in revenue with a 2.9% sliver representing his calculated royalty rate. He concluded that 2.9 percent was a reasonable royalty based on his experience that royalty rates for software are "generally above—on average, above 10% or 10, 11%." Microsoft was granted a new trial on damages.

This case provides a good example of the danger of admitting consideration of the entire market value of the accused where the patented component does not create the basis for customer demand.

i4i v. Microsoft *Update*

The case i4i v. Microsoft, which was granted certiorari by the US Supreme Court late last year could reshape an important tenet of patent law. Specifically at risk is the Federal Circuit's holding that an invalidity defense must be proved by the heightened standard of "clear and convincing evidence," rather than by a mere "preponderance of the evidence" standard.

Microsoft contends that the current requirement for clear and convincing evidence for patent invalidity was the exclusive and mistaken creation of the US Court of Appeals for the Federal Circuit. Microsoft also contends that the standard is at odds with the law of all twelve regional circuits as of the time of creation of the Federal Circuit.

It will be interesting to see if Microsoft will be successful in changing the invalidity standard from the current "clear and convincing evidence standard" to the less rigorous "preponderance of the evidence" standard. This case will be monitored and reported in later columns.

False Marking Case Updates

Just over 750 false marking cases were filed in 2010. The filings of these cases have continued unabated through January of 2011. Last year's congressional efforts to curb these cases terminated when the new Congress was sworn in on January 3. I look forward to new legislative efforts to deal with these cases.

Patent Reform Update

On January 25, 2011, Sen. Patrick Leahy (D-VT) introduced The Patent Reform Act of 2011 (S. 23), a repeat of last year's Manager's amendment version of S. 515. Legislation of this type has stalled in Congress since it was first introduced back in 2005. I will monitor the progress of the 2011 version.

The new bill aims to achieve three goals, Leahy stated in a press release: "The first is to change the system of awarding of patents to a first-inventor-to file system; the second goal is improve the quality of the patent-approval process at the Patent and Trademark office; and the third is to "provide more certainty in litigation."

Ernie Linek is a principal shareholder of Banner & Witcoff, Ltd. This column 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. ELinek@bannerwitcoff.com