KING & SPALDING

Intellectual Property Newsletter

Supreme Court Opinion on "Law of Nature" Doctrine Creates Uncertainty for Biotechnology and Diagnostics Patents

Michael P. Dougherty

The Supreme Court's opinion in *Mayo Collaborative Services v. Prometheus Laboratories*[1] (March 20, 2012) expanded the traditional doctrine that "laws of nature" are not patentable subject matter under 35 U.S.C. § 101. The decision, which addressed the patentability of methods for optimizing the efficacy of a certain type of drug through measurement of the drug's metabolites in a patient's blood, is of most immediate interest to the medical diagnostics industry. *Prometheus* might affect more than diagnostics, however. For example, in a case of great importance to the biotechnology industry, *Association for Molecular Pathology v. U.S. Patent and Trademark Office and Myriad Genetics*,[2] the Supreme Court has vacated the Federal Circuit's 2011 ruling that isolated genes and shorter DNA sequences are patent eligible and remanded for reconsideration of that issue in light of *Prometheus*. This article examines *Prometheus* and explores its possible effects on the patentability of medical diagnostic methods and the isolated genes at issue in the *Myriad Genetics* remand.

Background

The claims at issue in *Prometheus* were directed to methods of optimizing the efficacy of thiopurine drugs for the treatment of immune-mediated

June 2012

PATENT Articles In This Issue

TRADEMARK Articles In This Issue

Upcoming IP Events

Katie McCarthy to present at Practicing Law Institute (PLI) Seminars

- **July 9, 2012: Understanding Copyright Law in the Data Era 2012**
- **September 13, 2012: Intellectual Property Law Institute 2012**

gastrointestinal disorders, such as Crohn's disease and ulcerative colitis. The efficacy of these drugs had long been known to depend on the concentrations of certain metabolites of the thiopurine drug in the patient's blood after the drug's administration. Moreover, it was known that metabolite production varied significantly among patients: the same dose administered to two patients of the same weight, age, and overall health could result in significantly different blood levels of the key metabolites. Physicians knew, therefore, that it was more useful to focus on the metabolite levels in a patient's blood than the dose of thiopurine drug administered.[3] This is analogous to blood alcohol testing, which is based on the fact that the level of alcohol in someone's blood is a better indicator of his or her condition than the number of drinks consumed.

The inventors of the patents at issue in *Prometheus* claimed to have identified the metabolite levels that correlate with the drug being either harmful or ineffective: concentrations above a certain level were likely to be toxic; concentrations below another level were likely to be ineffective.[4] This was the inventors' contribution to the art: "the precise correlations between metabolite levels and likely harm or ineffectiveness. The patent claims at issue here set forth processes embodying researchers' findings that identified those correlations with some precision."[5] A representative claim from one of the patents was as follows:

> A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
>
> (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
>
> (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
>
> wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
>
> wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

In simpler terms, the claimed invention involved two steps: (1) "administering" the drug to a patient; and (2) "determining" the level of active metabolite in the patient, wherein a level less than about X "indicates a need to increase" the dosage, and a level greater than about Y "indicates a need to decrease" the dosage.

The Federal Circuit held the claims patentable under the "machine or transformation" test of *Bilski v. Kappos*,[6] which looks to whether an invention is tied to a specific machine, or involves the transformation of matter into a different state or thing, as an "important and useful clue"[7] to patent-eligibility under 35 U.S.C. § 101. It held that the *Prometheus* claims were "transformative" and therefore patent-eligible because the administration of the drug to the patient (the "administering" step) transforms the human body, and the "determining" step transforms the blood sample. Those transformations, moreover, were central to the purpose of the claimed process.[8]

Supreme Court: Applicant Cannot Patent "Law of Nature" Combined Only with "Well-Understood, Routine, Conventional Activity, Previously Engaged in by Those in the Field"

The Supreme Court unanimously reversed the Federal Circuit, holding the claims unpatentable under the "law of nature" exclusion. The Court began by noting that the relationships between the concentrations of certain metabolites and the likelihood that a dosage of a thiopurine drug will be toxic or effective are laws of nature. "While it takes a human action (the administration of a thiopurine

drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes."[9] "[A] patent that simply describes that relation," the Court concluded, "sets forth a natural law."[10] While a law of nature cannot be patented, "an *application* of a law of nature . . . to a known structure or process may well be deserving of patent protection."[11] Accordingly, the Court turned next to the question of whether the claims added enough to the natural correlation between metabolite levels and toxicity or efficacy to constitute patent-eligible processes that *apply* natural laws. It determined that they did not.

The "administering" step, according to the Court, simply identifies the "audience" who will be interested in the natural law, namely doctors who treat patients with thiopurine drugs. Moreover, physicians had been administering thiopurine drugs to treat immune-mediated disorders long before the claimed invention was made.[12] The "determining" step tells the doctor to measure the blood levels of the relevant metabolites without specifying any particular process for doing so. This too was a routine activity that doctors had been carrying on for years before Prometheus's alleged invention. And the "wherein" clauses "simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient."[13] Considering the three parts of the claim as an "ordered combination" did not help: "Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients."[14]

The critical deficiency the Court found in Prometheus's claims was that, beyond the unpatentable law of nature (the correlation between the specified metabolite concentrations and toxicity or efficacy), the claims recited nothing but "well-understood, routine, conventional activity already engaged in by the scientific community."[15] The Court summarized the deficiency as follows:

> Beyond picking out the relevant audience, namely those who administer doses of thiopurine drugs, the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law. **These instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field.**[16]

The Court reiterated this principle when it warned that "simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable."[17]

Finally, the Court criticized the Federal Circuit's application of the "machine or transformation" test. The Court appeared to accept the notion that the "administering" step transforms the human body, but called that transformation "irrelevant" because the step "simply helps to pick out the group of individuals who are likely interested in applying the law of nature."[18] And the Court disagreed with the Federal Circuit's conclusion that the "determining" step was transformative, reasoning that "the second step could be satisfied without transforming the blood, should science develop a totally different system for determining metabolite levels that did not involve such a transformation."[19] Even if the "machine or transformation" test was satisfied, moreover, the Court warned that it is only an "important and useful clue" to patentability that does not trump the "law of nature" exclusion.[20]

Implications for Industry

Prometheus has the potential to fundamentally change the analysis of what constitutes patent-eligible subject matter under § 101. For example, in evaluating claims that recite a law or product of nature, it could be argued that courts and the PTO should now have to engage in an analysis similar to that for novelty under § 102 and obviousness under § 103 to assess whether additional elements of the claimed invention are "well-understood," "routine," or "conventional." If so, it would imply that the same claimed invention may constitute patent-eligible subject matter on one date but not at a later date. It remains to be seen whether the PTO or the lower courts will adopt such an analysis. In its only guidance on *Prometheus* to date, the PTO instructed its examiners to continue relying on its "Interim Bilski Guidance" issued July 27, 2010 (which does not involve evaluations of novelty or obviousness), with the added proviso that a claim that includes a law of nature, natural phenomenon, or abstract idea must also recite other elements "such that . . . the claimed product or process amounts to significantly *more than* a law of nature, a natural phenomenon, or an abstract idea with conventional steps specified at a high level of generality appended thereto."[21]

Prometheus may have especially profound effects in the fields of diagnostics and "personalized medicine," i.e., the use of information concerning a given patient's genes, proteins, or other characteristics to select treatment options for that patient. For example, a typical claim to a diagnostic method reads something like this:

> A method for diagnosing disease X in a patient comprising detecting in a sample taken from such patient the presence of sequence Y in gene Z, wherein the presence of sequence Y in gene Z indicates the likelihood of developing disease X.

Depending on the particular facts of each individual case, it is conceivable that some defendants may challenge such claims under the theory that they simply advise a physician of a natural law (the correlation between sequence Y and disease X), and recite the conventional step of "detecting" the sequence Y in the patient's sample. Given the large number of issued patents in this and similar forms, however, and the Supreme Court's earlier admonition that "courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community,"[22] it is not clear whether district courts and the Federal Circuit will be receptive to such arguments. In any event, at least with respect to pending applications and applications filed in the future, patent drafters might try to avoid the law of nature problem by reciting additional limitations such as use of a new, unconventional technique to determine whether the relevant DNA sequence is present, or perhaps even conventional techniques as long as they are not "specified at a high level of generality."[23]

Prometheus may also have profound effects on the biotechnology industry, which until now has relied heavily on patents claiming isolated genes and shorter DNA sequences. In *Association for Molecular Pathology v. U.S. Patent and Trademark Office and Myriad Genetics*[24] (the "*Myriad Genetics*" case), the Federal Circuit rejected contentions that isolated genomic DNA sequences (i.e., sequences that are identical to naturally-occurring gene sequences) are unpatentable products of nature. In the now-vacated majority opinion in that case, the court ruled that such an isolated gene is not a product of nature because it is a "distinct chemical entity" that is "markedly different" from the gene as it exists in nature.[25] The court based this ruling on the facts that, even though the nucleotide sequences of the native and the isolated genes are the same, the isolated gene was only one thousandth the size of the chromosome in which it exists in nature, and the covalent bonds between the gene and the rest of the chromosome had been severed.[26]

The Supreme Court has vacated the Federal Circuit's *Myriad Genetics* ruling and remanded the case for reconsideration in light of *Prometheus*.[27] Supplemental briefs on the effect of *Prometheus* were filed on June 15, 2012; oral argument is

scheduled for July 20, 2012. If the Federal Circuit maintains its position that an isolated gene is a "distinct chemical entity" from the gene as it exists in nature, claims to such isolated genes should remain patent-eligible. Under the "distinct chemical entity" theory, claims reciting an isolated gene do not recite a product of nature and there is therefore no need for the claim to include additional, novel limitations. That was the principal argument of the patentee (Myriad) in its supplemental brief filed on June 15, 2012.[28] Myraid's supplemental brief also argued that *Prometheus* does not affect composition-of-matter claims. Rather, it argued that the proper test for composition claims is the test that the Federal Circuit applied in its now-vacated opinion, namely, the "distinctive name, character and use" test of *Diamond v. Chakrabarty*.[29]

The plaintiffs, on the other hand, focus on whether claims to isolated genes "improperly t[ie] up the future use" of a product of nature, a concern which the Supreme Court "has repeatedly emphasized."[30] The principal point of the plaintiffs' June 15, 2012, supplemental brief on the effect of *Prometheus* was that Myriad's isolated DNA claims had exactly this effect. The plaintiffs argued that these claims preempt both a law of nature and a product of nature. According to the plaintiffs, the natural law covered by the claims "is the correlation between the patented DNA and the BRCA protein it encodes, which in turn correspond to traits such as risk for breast and ovarian cancers. The product is the DNA itself."[31] It is impossible to "invent around" these claims, the plaintiffs asserted: "In [*Prometheus*], the Court suggested that a claim on a new drug would not raise the concern that invalidated [the patents at issue there] because another company could develop another drug treating the same condition without infringing. . . In contrast, the 'isolated' DNA claims . . . do preempt future use of laws and products of nature because another entity cannot invent a DNA molecule that encodes for the same protein and embodies a person's BRCA1 and BRCA2 genetic information."[32]

Unsurprisingly, the plaintiffs also argue that Myriad's isolated DNA claims do not "add enough" to the natural gene to render the claims patentable. They assert that "[i]solation of DNA was a well-known technique at the time these patents were sought, and continues to be a routine, conventional preparatory step for using human genes in research and clinical practice. The only addition of the 'isolated' DNA claims to the progress of science is disclosure of the natural law itself - the fact that this DNA encodes for the BRCA protein and embodies the information needed to understand a person's heredity and disease susceptibility."[33]

A second set of claims at issue in the *Myriad Genetics* remand is directed to methods of screening potential anti-cancer drugs. These claims, containing three steps and a "wherein" clause, can be summarized as follows:

> Growing cells that have been transformed with a cancer-causing BRCA1 gene in presence of the drug candidate;
>
> Growing the transformed cells in the absence of the drug candidate; and
>
> Determining cells' growth rate with and without the drug candidate;
>
> Wherein slower growth rate in presence of drug candidate is indicative of therapeutic activity.[34]

The Federal Circuit's now-vacated opinion held these claims patentable under the "machine or transformation" test because they are transformative. The "determining" step, for example, "necessarily involves physical manipulation of the cells."[35] *Prometheus* may lead to a different result on remand. For example, the Federal Circuit could rule that the claims apply the natural correlation between certain mutations in the BRCA1 gene and the likelihood of cancer, and add nothing to that natural correlation but routine, well-understood actions: growing the cells with and without the drug candidate, and comparing the cells' growth rates. To paraphrase *Prometheus*, it could be argued that the claims simply advise

researchers of the natural correlation between a BRCA1 mutation and cancer, and instruct them to apply it to the screening of drug candidates. This was the position that the plaintiffs adopted in their June 15, 2012, supplemental brief.[36] Myriad, on the other hand, argued that none of the method claims was a subject of the petition for certiorari, and that the Federal Circuit's previous decision upholding those claims was undisturbed by the Supreme Court's "grant, vacate, and remand" order.[37]

Conclusion

The foregoing observations show that *Prometheus* may have fundamentally changed the law under 35 U.S.C. § 101, with potentially important consequences for the medical diagnostics and biotechnology industries. Its full effects may take years for lower courts and the PTO to work out, but the decision may make it more difficult to obtain and enforce patent claims that include a law of nature, a product of nature, or a natural phenomenon among their limitations.

[1] 2012 U.S. LEXIS 2316 (Mar. 20, 2012).
[2] 653 F.3d 1329 (Fed. Cir. 2011), *vacated and remanded* 2012 U.S. LEXIS 2356 (Mar. 26, 2012).
[3] 2012 U.S. LEXIS 2316, at ***12-14.
[4] 2012 U.S. LEXIS 2316, at ***14.
[5] 2012 U.S. LEXIS 2316, at *** 14.
[6] 2010 U.S. LEXIS 5521.
[7] 2010 U.S. LEXIS 5521, at ***16.
[8] *Prometheus Labs., Inc. v. Mayo Collaborative Services*, 628 F.3d 1347, 1355 (Fed. Cir. 2010).
[9] 2012 U.S. LEXIS 2316, at ***18-19.
[10] 2012 U.S. LEXIS 2316, at ***19.
[11] *Bilski v. Kappos*, 130 S. Ct. 3218, 3230 (2010).
[12] 2012 U.S. LEXIS 2316, at ***20.
[13] 2012 U.S. LEXIS 2316, at ***21.
[14] 2012 U.S. LEXIS 2316, at ***22.
[15] 2012 U.S. LEXIS 2316, at ***23.
[16] 2012 U.S. LEXIS 2316, at ***27 (emphasis added).
[17] 2012 U.S. LEXIS 2316, at ***27-28.
[18] 2012 U.S. LEXIS 2316, at ***36.
[19] 2012 U.S. LEXIS 2316, at ***36.
[20] 2012 U.S. LEXIS 2316, at ***36.
[21] USPTO Preliminary Guidance on *Mayo Collaborative Services v. Prometheus Labs*. Mar. 21, 2012 (emphasis in original).
[22] *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997).
[23] 2012 U.S. LEXIS 2316, at *** 27-28.
[24] 653 F.3d 1329 (Fed. Cir. 2011), *vacated and remanded* 2012 U.S. LEXIS 2356 (Mar. 26, 2012).
[25] 653 F.3d at 1352.
[26] 653 F.3d at 1351-1353.
[27] 2012 U.S. LEXIS 2356 (Mar. 26, 2012).
[28] Supplemental Brief for the Appellants at 6-10, Assoc. for Molecular Pathology v. U.S. Patent and Trademark Office, No. 2010-1406 (Fed. Cir. June 15, 2012)
[29] *Id*. at 3 (citing 447 U.S. 303, 309-10 (1980)).
[30] 2012 U.S. LEXIS 2316, at ***31.
[31] Supplemental Brief for Appellees at 4, Assoc. for Molecular Pathology v. U.S. Patent and Trademark Office, No. 2010-1406 (Fed. Cir. June 15, 2012).
[32] *Id*. at 6.
[33] *Id*. at 12.
[34] 653 F.3d at 1334-1335.
[35] 653 F.3d at 1357.
[36] Supplemental Brief for Appellees at 19-20.
[37] Supplemental Brief for the Appellants at 18-19.

WildTangent v. Ultramercial: Subject Matter Eligibility after *Mayo*

Erik Dykema

Where precisely shall the line be drawn between patentable subject matter and unpatentable laws of nature or abstract ideas? Earlier this year, the Supreme Court revived the jurisprudence in this field with its unanimous decision on March 20 in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* 556 U.S. ____ (2012), invalidating a patent claim relating to dosing processes for medicine. More recently, this May the Court has likewise signaled its potential willingness to shake things up in computer related fields with its order granting certiorari, vacating, and remanding the case *WildTangent v. Ultramercial* (Supreme Court 2012, Docket 11-962.) for further consideration by the Court of Appeals for the Federal Circuit in light of its decision in *Mayo.*

In its *Mayo* analysis, the Supreme Court found that the claims at issue covered "processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high. … We must determine whether the claimed processes have

transformed these unpatentable natural laws into patent eligible applications of those laws." Ultimately, the Court concluded that the *Mayo* claims had not transformed the natural laws into patent eligible applications. Particularly, the Court found that, 1) a law of nature is unpatentable subject matter, and 2) an application of a law of nature is unpatentable if said application merely uses elements well known in the art. The "law of nature" in these claims was the relationship between levels of a certain chemical in the blood, and the knowledge that a drug dosage was too high or too low. The "elements well known in the art" were steps adjusting the dosage based on the law of nature. These elements could not make these claims patent eligible subject matter because, as Justice Breyer explained, "[t]he steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field."

Ultramercial's claims, on the other hand, are not about medicine or laws of nature at all - rather, they are directed to "a method for distributing copyrighted products (e.g., song, movies, books) over the Internet where the consumer receives a copyrighted product for free in exchange for viewing an advertisement, and the advertiser pays for the copyrighted content." *Ultramercial v. Hulu*, (CAFC 2011.) But, what does this have to do with *Mayo* and its limitation on claiming laws of nature?

The answer to this question will not be known at least until *Ultramercial* is decided again by at least the Federal Circuit, and perhaps the Supreme Court, which is likely to be several years from now. One possibility, however, is to be found in a comparison of the Supreme Court's analysis in *Mayo* with the Federal Circuit's analysis of *Ultramercial's* claim. In *Ultramercial*, the Federal Circuit describes the '545 patent as "not simply claim[ing] the age-old idea that advertising can serve as currency. Instead the '545 patent discloses a practical application of this idea," and goes on to recite the ten steps required by the '545 claims, and discuss the complexity of the computer programming required to implement them.

The contrast arises because, in *Mayo*, the Supreme Court found that a patent effectively claiming **a law of nature** is not saved by simply adding other elements, unless those elements go beyond "well-understood, routine, conventional activity previously engaged in by researchers in the field." On the other hand, in *Ultramercial*, the Federal Circuit found that a practical application of **an abstract idea** is brought within the realm of patent eligibility when implemented by specific technological steps.

If the Court is thinking along these lines, it creates two possibilities. First, the Court may want to expand the *Mayo* style analysis to encompass not just claims that include "laws of nature" but also claims that encompass "abstract ideas." In other words, if *Mayo's* "law of nature" is not saved by well-known elements, then neither should *Ultramercial's* "abstract idea."

On the other hand, it is equally possible that the Court may have remanded *Ultramercial* because it wants to limit it's *Mayo* analysis to "law of nature" cases, and exclude the other traditional categories of non-statutory subject matter: "natural phenomena" and "abstract ideas." There is some historical precedent in this approach, if one looks to the Supreme Court's patent-eligibility trilogy. In *Gottschalk v Benson* and *Parker v Flook*, the Supreme Court seemed to "narrow" the field of patentable inventions by restricting subject matter eligibility. However, shortly thereafter, in *Diamond v. Chakrabarty*, the Court backed away from the narrowing analysis, giving the patent law a wide scope of eligibility which continues to this day.

A Reasonable Defense To Patent Infringement? *Federal Circuit Holds That The Judge Decides, And That May Be Good News For Accused Infringers*

Holmes Hawkins & Russell Blythe

On June 14, 2012, the U.S. Court of Appeals for the Federal Circuit again raised the bar for patent holders looking to obtain enhanced damages—up to three times the actual damages—by proving "willful" patent infringement. Under the new standard, before willfulness can be presented to the jury, the trial judge first must determine whether the accused party's asserted defenses were objectively reasonable. Only if the judge determines they were not objectively reasonable does the jury get to decide the ultimate question of willfulness.

This latest hurdle is the most recent in a line of cases elevating the standard for willful infringement.

In 2004, the Federal Circuit held in *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp*. that an accused infringer's failure to obtain or produce a favorable opinion of counsel does not create an adverse inference that an opinion of counsel may have been unfavorable or that the accused infringer behaved improperly, overruling several prior cases to the contrary.[1]

In 2007, the Federal Circuit in *In re Seagate Technology, LLC* heightened the standard for proving willful infringement, from what had been akin to negligence, to the more stringent requirement of showing at least "objective recklessness."[2] The court established a two-prong test under the new standard: an objective prong and a subjective prong. First, "a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its action constituted infringement of a valid patent."[3] Second, "[i]f this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer."[4]

The latest development was announced this month in a new opinion in a decades-old dispute between C.R. Bard, Inc. and W.L. Gore & Associates[5] over prosthetic vascular grafts, which are used to bypass or replace blood vessels to ensure sufficient blood flow to various parts of the body. Notably, the patent-in-suit issued in 2002 after the application had been pending for 28 years at the U.S. Patent and Trademark Office—the delay due in part to a lengthy inventorship dispute. The litigation has been pending in federal court since 2003.

At the district court level in Arizona, Gore was found to willfully infringe Bard's patent, and the jury awarded Bard $185.6 million for lost profits and unpaid royalties. District Court Judge (and now Ninth Circuit Judge) Mary Helen Murguia doubled the award to $371.2 million based on the finding of willful infringement.

In February 2012, the Federal Circuit first affirmed the district court's findings, including the finding of willful infringement. It also ruled that the district court didn't abuse its discretion in awarding enhanced damages, attorneys fees and costs, and an ongoing royalty. But, following a petition for rehearing and rehearing *en banc* filed by Gore and supported by an *Amici Curiae* brief for Verizon Communications Inc. and Intel Corp., the Federal Circuit agreed to a rehearing for the limited purpose of authorizing the original panel to revise the portion of its opinion addressing willfulness.

On rehearing before the same panel of Federal Circuit judges, the Court noted that "[f]ollowing *Seagate*, this court established the rule that generally the 'objective' prong of *Seagate* tends not to be met where an accused infringer relies on a reasonable defense to a charge of infringement. . . . Thus, the question on appeal often posed is whether a defense or noninfringement theory was 'reasonable.'"[6]

The Court acknowledged that even after *Seagate*, willfulness has continued to be treated as a question of fact.[7] The Court found, however, that "the objective determination of recklessness, even though predicated on underlying mixed questions of law and fact, is best decided by the judge as a question of law subject to *de novo* review."[8]

"In considering the objective prong of *Seagate*, the judge may when the defense is a question of fact or a mixed question of law and fact allow the jury to determine the underlying facts relevant to the defense in the first instance, for example, the questions of anticipation or obviousness. But, consistent with this court's holding today, the ultimate legal question of whether a reasonable person would have considered there to be a high likelihood of infringement of a valid patent should always be decided as a matter of law by the judge."[9]

In a 2 to 1 majority, the Court vacated the willfulness finding and remanded the case for the district court to determine "whether a reasonable litigant could realistically expect [its] defenses to succeed. . . . [And, i]f, in view of the facts, the asserted defenses were not reasonable, only then can the jury's subjective willfulness finding be reviewed for substantial evidence."[10]

In a dissent, Judge Pauline Newman concurred on the decision to vacate the willfulness finding, but argued that remand was unnecessary to determine that Gore was not liable for willful infringement. "Gore's actions involve a host of potentially relevant facts that Gore could reasonably have believed would invalidate the Goldfarb patent or support Gore's right to continue to produce the Gore-Tex® grafts as it had for the 28 years of patent pendency. . . ."[11]

Looking ahead, it will be interesting to see how findings of willful infringement are impacted by the *Bard* decision, particularly whether the decision leads district court judges to be more willing to grant summary judgment of no willfulness before the case reaches the jury.

According to one study, determinations of willfulness are already down from 63.8% of the time the issue was decided from 1983-1999 (*i.e.*, before the *Knorr-Bremse* decision), to 48.2% after *Knorr-Bremse* and before *Seagate*, and to 37.2% after *Seagate*.[12]

That same study indicates that post-*Seagate*, willfulness was found 61.9% of the time when a jury was the decision-maker, but when a judge decided (*e.g.*, on JMOL), "willfulness was found much less often: less than one in five cases (19%)."[13]

[1] *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004) (en banc).
[2] *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007).
[3] *Id.* at 1371.
[4] *Id.*
[5] *Bard Peripheral Vascular, Inc., et al., v. W.L. Gore & Assocs.*, No. 2010-1050 [slip op.] (Fed. Cir. Jun. 14, 2012).
[6] *Id.* at 4-5 (citations and quotations omitted).
[7] *Id.* at 5.
[8] *Id.* at 6-7.
[9] *Id.* at 9 (citations omitted).
[10] *Id.* at 10.
[11] *Id.* [dissent] at 2.
[12] *See* Christopher B. Seaman, *Willful Patent Infringement and Enhanced Damages After* In Re Seagate*: An Empirical Study*, 97 IOWA L. REV. 417, at 444 & tbl. 2 (2012); *see also* Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, at 390 & tbl.4 (2000).
[13] *See* Seaman, supra note 12 at 445 & tbl. 3.

New Customs Regulations Permit Disclosure Of Samples And Other Information To Combat Counterfeit Articles

Patrick Togni

Interim regulations provide U.S. Customs and Border Protection ("CBP") with a new tool to interdict counterfeit imported goods by permitting CBP to disclose certain information to trademark holders to assist CBP in its efforts to identify and, where appropriate, seize goods bearing infringing marks (the "Interim CBP Rules").

Interim CBP Rules Are In Effect During The Final Rulemaking Process; CBP Requested Comments From The Public

The Interim CBP Rules became effective upon publication in the Federal Register on April 24, 2012. *See* 77 Fed. Reg. 24375 (Apr. 24, 2012). As part of the rulemaking process, however, CBP invited interested persons to participate in the final rulemaking process by "submitting written data, views, or comments on all aspects of the interim rule." *Id.* CBP also sought comments on "the economic, environmental, or federalism effects that might result from this rule." *Id.*

CBP required any comments to be filed by June 25, 2012. *See id.* No date for publication of the final rules has been announced.

CBP Justified The Interim CBP Rules By Reference To Public Health, Safety, And National Security

CBP stated that a principal policy justification for the Interim CBP Rules is to better "protect the public from unsafe and substandard products, which, in some cases, can be a threat to public health and safety, and also a threat to national security." *Id.* at 24376. CBP cited threats posed by counterfeit integrated circuits and other electronic components to "critical manufacturing, military, infrastructure, and consumer product applications." *Id.*

CBP placed particular emphasis on Congressional and U.S. Department of Defense investigations which found the presence of counterfeit components in "military and government supply chains" that pose "a serious threat to our military and government personnel and infrastructure." *Id.*

CBP also justified the new rule because the "sophisticated techniques of some counterfeiters and the highly technical nature of some imported goods" have made it more challenging for CBP "to determine whether some goods suspected of bearing counterfeit marks in fact bear counterfeit marks." *Id.*

CBP explained that its prior regulations did not permit the disclosure of information as a means to help "CBP in its efforts to identify goods bearing infringing marks, prior to CBP's making a determination to seize." *Id.* CBP believes that the Interim CBP Rules "will enhance CBP's enforcement capability against increasingly sophisticated counterfeit products that threaten the public health and safety and national security." *Id.*

The Trade Secrets Act And The Interim CBP Rules

The Interim CBP Rules are designed to address limitations imposed by The Trade Secrets Act (18 U.S.C. § 1905) upon the ability of CBP to share relevant information with intellectual property right holders. The Trade Secrets Act prohibits the unauthorized disclosure of trade secrets and other sensitive information by government officials that receive the information in the course of their employment or official duties. The law is designed to protect parties from whom the government requests or requires the submission of information, the disclosure of which could cause competitive disadvantage or other harm. The protection is designed to incentivize the submission of accurate and reliable information to the government.

In promulgating the Interim CBP Rules, however, CBP explained that the protections "must be balanced against the important and legitimate interests of government." *Id.* CBP also explained that The Trade Secrets Act does not prohibit disclosure of protected information if otherwise "authorized by law" by statute or under "properly promulgated substantive agency regulations authorizing disclosure based on a valid statutory interpretation." *Id.* CBP stated that The National Defense Authorization Act For Fiscal Year 2012 ("NDAA") contains specific language permitting it to "share information appearing on, and unredacted samples of, products and their packaging and labels, or photographs of such products, packaging, and labels, with the rightholders of the trademarks suspected of being copied." *Id.* The purpose of the NDAA information-sharing provision is to

determine "whether the products are prohibited from importation" into the United States in violation of section 42 of the Lanham Act, which prohibits the importation of merchandise bearing a mark that copies or simulates a registered mark. *Id.*

In the Interim CBP Rules, CBP appears to have anticipated potential opposition by providing "further statutory analysis" to justify the new rules. In particular, CBP stated its view that disclosure authorized by the NDAA is not limited to trademarks, and includes certification, collective, and service marks. *See id.* CBP also stated that, to the extent that the legislative history of the NDAA may suggest that Congress intended the information-sharing mechanism "to apply only to military sales," CBP is removing any ambiguity and to clarify that "the disclosure authority extends to all imports and not just those associated with military sales." *Id.*

Key Provisions Of The Interim CBP Rules

1. Registration And Recordation Requirement

The Interim CBP Rules only apply to trademarks that are registered with the U.S. Patent and Trademark Office and recorded with CBP.

2. Detention Of Articles Bearing A Suspected Counterfeit Mark

CBP may detain any article made in the United States or abroad that is imported into the United States and "that bears a mark suspected of being a counterfeit version of" a registered and recorded trademark. *Id.* at 24379. The detention lasts 30 days from the date the merchandise is presented for examination but may be extended for up to an additional thirty days for good cause shown by the importer. *Id.*

3. Notice To Importer Of Detention And Possible Disclosure

Under the Interim CBP Rules, CBP will notify the importer in writing of the detention within five days. CBP will also notify the importer of the potential for disclosure of information to the owner of the mark to assist with the counterfeit determination.

The importer has seven days from the date of the notification to present information "establishing to CBP's satisfaction that the detained merchandise does not bear a counterfeit mark." *Id.* at 24377 and Interim Rule 19 C.F.R. § 133.21(b)(1).

An exception to the notice requirement is available in certain situations, such as criminal or national security investigations. *See id.* at 24377 and Interim Rule 19 C.F.R. § 133.21(c).

4. CBP Discretion Regarding Timing And Scope Of Information Disclosure To Trademark Owner

The Interim CBP Rules provide significant discretion to CBP regarding the timing and scope of any disclosure to a trademark holder for assistance in determining whether marks are counterfeit.

For example, during the time between presentment of merchandise for examination until a notice of detention is issued, CBP may disclose to the trademark holder information including: (1) the date of importation, (2) the port of entry, (3) a description of the merchandise, (4) the quantity, and (4) the country of origin of the merchandise. *See id.* and Interim Rule 19 C.F.R. § 133.21(b)(2).

Once a notice of detention is issued, however, CBP must provide this information to the trademark holder, if available, within thirty days. *See id.*

Likewise, CBP may also provide the trademark holder with "images or a sample of the detained merchandise or its retail packaging" any time after presentation of the merchandise for examination. *See id.* and Interim Rule 19 C.F.R. § 133.21(b)(3). "Identifying information" on the images or sample disclosed in this manner must be "removed, obliterated, or otherwise obscured." *Id.* Under the Interim CBP Rules, some examples of "identifying information" include serial numbers, dates of manufacture, lot codes, batch numbers, universal

product codes, the name or address of the manufacturer, exporter, or importer of the merchandise, or any mark that could reveal the name or address, in alphanumeric or other formats. *See id.*

The Interim CBP Rules also permit CBP to provide an unredacted sample, although no guidance is provided regarding what situations prior to seizure might warrant the provision of an unredacted sample in lieu of a redacted sample. *See id.* and Interim Rule 19 C.F.R. § 133.21(c). The language of the interim rule, therefore, appears to conflict with narrative in the Federal Register notice, in which CBP stated that "information, images, or samples" will be "shared with the right holder" only where the importer fails to demonstrate that the article in question does not bear a counterfeit mark. *See id.* at 24377.

5. Bond Requirement

To obtain a sample, the trademark holder must first furnish CBP a bond in the form and amount specified by the port director. The bond must contain statements holding "the United States, its officers or employees, and the importer or owner of the imported article harmless from any loss or damage to the sample resulting from the furnishing of a sample by CBP to the owner of the mark." *Id.* at 24379 and Interim Rule 19 C.F.R. § 133.21(b)(3).

The owner must return the sample upon demand by CBP, or after any examination, testing, or other procedures performed on the sample. *See id.* If the sample is damaged, destroyed, or lost while in the possession of the trademark holder, the owner must file a certification with CBP. *See id.*

6. Post-Seizure Information Disclosures

CBP will seize any merchandise that it determines to be bearing a counterfeit mark. *See id.* at 24379 and Interim Rule 19 C.F.R. § 133.21(d). When merchandise is seized, CBP will make additional information disclosures to the trademark owner within thirty days from the date of the notice of seizure, if available: (1) the date of importation, (2) the port of entry, (3) a description of the merchandise, (4) the quantity, (5) the name and address of the manufacturer, (6) the country of origin of the merchandise, (7) the name and address of the exporter, and (8) the name and address of the importer. *See id.*

7. Post-Seizure Sample For Examination, Testing, Or Use In Trademark Infringement Case

Following seizure, CBP may also "provide a sample and its retail packaging, in its condition as presented for examination, to the owner of the mark." *See id.* at 24380 and Interim Rule 19 C.F.R. § 133.21(e). The sample may be used "for examination, testing, or other use in pursuit of a related private civil remedy for trademark infringement." *Id.*

As with other samples under the Interim CBP Rules, the owner must furnish a bond and return the sample or certify damage, destruction, or loss of the sample during examination, testing, or use. *See id.*

8. Importation Of Seized Merchandise Upon Written Consent Of Trademark Holder

The Interim CBP Rules permit the trademark owner to consent to the importation of the seized merchandise "in its condition as imported or its exportation, entry after obliteration of the mark, or other appropriate disposition." *See id.* at 24380 and Interim Rule 19 C.F.R. § 133.21(f).

Contacts

Dawn-Marie Bey
Editor, Partner
dbey@kslaw.com
+1 202 626 8978

Michael P. Dougherty
Partner
mdougherty@kslaw.com
+1 212 556 2103

Kathleen McCarthy
Partner
kmccarthy@kslaw.com
+1 212 556 2345

Holmes J. Hawkins, III
Partner
hhawkins@kslaw.com
+1 404 572 2443

Russell E. Blythe
Associate
rblythe@kslaw.com
+1 404 572 3590

Patrick J. Togni
Associate
ptogni@kslaw.com
+1 202 626 2958

Erik Dykema
Associate
edykema@kslaw.com
+1 212 556 2189

King & Spalding offers clients a full-service intellectual property (IP) practice that combines proven first-chair trial and business lawyers with true scientific specialists. The firm's Intellectual Property Practice Group consists of more than 100 IP professionals, including more than 70 lawyers and patent agents with technical degrees, located in our Atlanta, Austin, Charlotte, Houston, New York, Silicon Valley and Washington, D.C., offices.

King & Spalding has specialized expertise in Section 337 cases before the International Trade Commission. Unique among firms, we have leading practices in the three disciplines necessary in Section 337 cases: we combine our broad-based patent litigation experience and technical expertise, international trade expertise and expertise in the ITC's procedures, and a strong governmental relations group. King & Spalding has been involved in some of the largest, most complex and precedent-setting Section 337 cases.