# STAY CURRENT A Client Alert from Paul Hastings



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## Intellectual Property Outlook: Cases and Trends to Follow in 2012

BY ROBERT M. MASTERS, TAD RICHMAN, & LISA LEUNG

#### I. Introduction

In the coming year, we anticipate a series of events and decisions with varying degrees of impact on intellectual property law in the United States and, in turn, the way we advise our clients. This article highlights cases we are monitoring that present, in our view, significant issues relating to various aspects of intellectual property law. Most of these cases are pending appeal at some level, and each has the potential for considerable impact on the landscape of U.S. intellectual property law. A small number of recently decided cases have also been selected for inclusion in this discussion, as it remains to be seen precisely how these decisions will play out in practice over the coming year. Lastly, we take a look at continuing trends in the intellectual property marketplace and review key legislation, including what to expect from the recently enacted America Invents Act.

#### II. Cases to Watch in 2012

#### A. The Scope of Patentable Subject Matter

#### 1. <u>Medical Diagnostic and Treatment Methods Post-Bilski</u>

The Supreme Court heard oral argument in *Mayo Collaborative Svcs. v. Prometheus Labs., Inc.,* No. 10-1150, on December 7, 2011. This is not the first time the Supreme Court has taken on the question of the validity of Prometheus's asserted method claims. As before, Mayo challenges the Federal Circuit's holding that Prometheus's method claims recite patentable subject matter under §101. Unlike before, Mayo's appeal now derives from a post-*Bilski* decision below.<sup>1</sup>

Prometheus is the sole and exclusive licensee of two patents claiming methods for determining the optimal dosage of thiopurine drugs used to treat certain autoimmune diseases. The patented methods seek to overcome the problems of non-responsiveness and drug toxicity that complicate treatment in some patients. Specifically, the patents claim methods comprising both "administering" a drug and "determining" the level of the drug's metabolites in the patient, in order to optimize therapeutic efficacy while minimizing toxic side effects. The claims require no further action by the physician beyond the "administering" and "determining" steps.

Prometheus brought the underlying patent infringement action against Mayo in 2004 in the Southern District of California. The district court granted summary judgment of invalidity on the basis that Prometheus's claims were only directed to *correlations* between metabolite levels and therapeutic



efficacy and toxicity; and that the correlations were *natural phenomena* resulting from a natural body process and thus were not patent-eligible.

On appeal, the Federal Circuit applied its then-determinative "machine-or-transformation test" for patent eligibility under §101 and reversed. Specifically, the court held that *both* the "administering" and "determining" steps of the claims were transformative and thereby did not wholly preempt use of the recited correlations. Shortly thereafter, the Supreme Court's decision in *Bilski v. Kappos*<sup>2</sup> held that although the Federal Circuit's machine-or-transformation test was a "useful and important clue," it was not the sole test for determining the patent eligibility of process claims. The Supreme Court subsequently vacated the Federal Circuit's decision in *Prometheus* and remanded the case for further consideration in light of *Bilski*.

On remand, the Federal Circuit once again upheld the validity of the claims of the patents-in-suit, finding that they were properly drawn to patent-eligible subject matter. Just as in its pre-*Bilski* decision, the court's decision turned on its determination that the asserted claims were drawn to a *particular application* of naturally occurring correlations, rather than a law of nature (the patenting of which would preempt all uses of the recited correlations). Noting that nothing in *Bilski* undermined its original preemption analysis, the Federal Circuit again held that because Prometheus's asserted claims recite specific treatment steps and not merely the correlations themselves, they were patent-eligible. The court reasoned that because the claims involve the treatment of specific diseases by administering specific drugs and measuring specific metabolites, they do not preempt *all* uses of the naturally occurring correlations.

The Federal Circuit also explained that its machine-or-transformation test, while no longer the *exclusive* test, is nonetheless a "useful and important clue, an investigative tool," for determining patent eligibility post-*Bilski*. Accordingly, the court reaffirmed that the claimed treatment methods "transform an article into a different state or thing," and that the transformation was "central to the purpose of the claimed process," thus satisfying the transformation prong of the machine-or-transformation test. The court reasoned that claims to methods of treatment are *always* transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition, and that determining the level of metabolites in a subject necessarily involves some form of manipulation to extract the metabolites from a bodily sample and determine their concentration. Thus, the court found that both the "administering" step (for the purpose of treating the disease) and the "determining" step (for the purpose of assessing dosage) of the claimed process were significant transformative elements that were central to the claimed treatment methods. Thus, the court once again upheld the validity of Prometheus's patents.

During the December 7 oral arguments, the Supreme Court repeatedly struggled with the question of how much a patent applicant must add to a law of nature to make it patent-eligible under §101. In so doing, the Court focused on the relative roles of §101 on patent-eligibility and the fact-specific inquiries of a §102-103 novelty/obviousness analysis. A tighter patent-eligibility standard would give courts the power to cut off unworthy inventions at the knees in the summary judgment phase, without waiting for the fact-intensive inquiries of a §102-103 analysis. At one point, the Court acknowledged that it was difficult to "resist the temptation to peek into the novelty component or the non-obvious component and then go back and apply it to [section] 101."

However, the Court was receptive to argument from the U.S. Solicitor General, who reiterated the position advanced in the government's amicus brief that although the claims at issue should be found patent-eligible under §101, they are nonetheless invalid due to lack of novelty and obviousness under



§102 and §103. Hence, the argument goes, §101 should act only as a "coarse filter" for patent eligibility, rather than the more robust "gatekeeper" standard advocated by Mayo. A finding that the claims are patent-eligible under §101 would be a victory for Prometheus, as §102 and §103 issues are not properly before the Court.

Counsel for Mayo called attention to Justice Breyer's dissent in *LabCorp v. Metabolite Laboratories*,<sup>3</sup> in which Breyer advocated for more stringent patent-eligibility requirements in the area of medical knowledge and opined that the claims at issue there could be invalidated under §101. Breyer was not particularly receptive to Mayo's reference to his *LabCorp* dissent, pointing out that nothing in that opinion spelled out a working standard for the issue at hand: how much a patentee must add to a claim covering a law of nature to make it a patent-eligible claim *applying* a law of nature.

LabCorp was the first sign that diagnostic-type claims, similar to those at issue in *Prometheus*, could potentially be dealt with under §101 for lacking patent-eligibility, rather than under the traditional §102 or §103 for obviousness and anticipation. Although the Supreme Court initially granted certiorari in *LabCorp*, it later determined that patent-eligibility had not been properly raised in the courts below and dismissed. *Mayo* is the Court's first opportunity since *LabCorp* to address this very important question.

The Court will likely use *Mayo* as an opportunity to expand upon the implications of its decision in *Bilski*, and to say what it lost the opportunity to say five years ago in *LabCorp* about the patent eligibility of medical diagnostic and treatment processes. We can expect the Court to issue its decision in *Mayo* in the spring of 2012.

#### 2. Patentability of Isolated Human Genes

The petition for certiorari in *Association for Molecular Pathology v. Myriad Genetics Inc.*, No. 11-725, raises a seemingly simple question: Are human genes patentable? The petitioners seek to overturn a 2-1 split decision by a three-judge panel of the Federal Circuit upholding patent eligibility of Myriad's claims to certain isolated DNA.<sup>4</sup>

The majority opinion relied on the standard set forth by the Supreme Court in *Diamond v. Chakrabarty*, wherein the claimed bacteria was found to be patent-eligible because the efforts of the patentee caused it to have markedly different characteristics from any bacterium found in nature. Applying the test from *Chakrabarty*, the majority concluded that the claims at issue were patent-eligible because the molecules they covered were markedly different, with a distinctive chemical identity and nature, from molecules that existed in nature. Specifically, the court pointed out that isolated DNA is a free-standing portion of a native DNA molecule, created either by chemically severing the covalent bonds or synthesized to consist of just a fraction of the naturally occurring molecule. According to the majority, human intervention in cleaving or synthesizing a portion of native DNA imports on the isolated DNA a *distinctive chemical identity* and thus satisfies *Chakrabarty*.

The dissent in *Association for Molecular Pathology* found that Myriad's claims fell clearly on the "unpatentable" side of the line drawn by the Court in *Chakrabarty*, likening the isolation of DNA to the extraction of a new mineral discovered in the earth or the finding, extracting, and propagating of a newly discovered plant. The dissent reasoned that isolated genes are not materially different from the native genes — although the extraction process itself may be difficult and itself patentable, the changes to the molecular structure emphasized by the majority are merely *incidental* to the extraction process. Just as physical and chemical changes that occur during the extraction of minerals or the



taking of cuttings from wild plants do not make those substances patentable, nor should they have that effect for isolated DNA.

The petition for certiorari in this case was filed by the American Civil Liberties Union and the Public Patent Foundation on December 7, 2011.

#### 3. Beauregard Claims and a "Practicality" Test for Mental Processes

In *CyberSource Corp v. Retail Decisions, Inc.*, <sup>6</sup> the Federal Circuit raised significant new questions about the patentability of computer software. The claims at issue in *CyberSource* are targeted toward circumventing fraud in online transactions, e.g., by detecting whether multiple credit card numbers have been used to make purchases from the same Internet address or detecting whether the Internet address has previously been used to make a fraudulent transaction. *CyberSource* asserted two claims: a method claim for verifying the validity of a credit card transaction as described above and a *Beauregard* style claim using a "computer readable medium containing program instructions" to implement the same method.

The court determined that the asserted method claim failed to meet either prong of the machine-or-transformation test, explaining that the mere collection and organization of data regarding credit card numbers and Internet addresses is insufficient to meet the transformation prong of the test. Also, the plain language of the method claim does not *require* the method to be performed by a machine. As *Bilski* previously held that the machine-or-transformation test is no longer dispositive, the court also found that all the steps of the method claim at issue could be performed by a human, rendering it an unpatentable mental process.

CyberSource's Beauregard-style claim fared no better. The court distinguished the claim in CyberSource from other cases where, as a practical matter, the use of a computer would be required to perform the claimed method, and thus the method would be patent-eligible. The court rejected CyberSource's contention that, because its claim recited a man-made article of manufacture (i.e., a computer readable medium), it was per-se patent-eligible. Rather, the court emphasized the need to look at the underlying invention, in this case a method for detecting credit card fraud, rather than the claim format. Because the method claim and Beauregard claim both attempted to capture the same unpatentable mental process, the court held both invalid under §101. CyberSource did not seek en banc review and its deadline to petition the Supreme Court for certiorari has passed.

#### B. New Evidence in § 145 Actions

In *Kappos v. Hyatt*, No. 10-1219, the Supreme Court will determine whether a patent applicant appealing the denial of a patent application under 35 U.S.C. §145 in federal district court may present new evidence to the district court that could have been presented — but was not presented — to the Patent and Trademark Office during initial examination of the application; and, if new evidence is admissible in §145 actions, whether the district court may decide related factual questions *de novo*.<sup>8</sup>

This appeal arises from an *en banc* opinion at the Federal Circuit. It held not only that the district court must allow new evidence in such actions, but also that factual questions related to the new evidence must be decided *de novo* — without deference to any prior determinations of the Patent and Trademark Office.<sup>9</sup>

Hyatt is the sole named inventor of a patent application pertaining to computer memory architecture. The examiner handling his application ultimately issued a final office action rejecting all 117 of his



claims, totaling 2,546 separate rejections on various bases. In a 129-page appeal to the Board of Patent Appeals and Interferences, Hyatt addressed each of the examiner's rejections. Although Hyatt prevailed on over 93 percent of the examiner's 2,546 rejections at the Board, the Board upheld written description and enablement rejections with respect to 79 claims. After his request for a rehearing was denied, Hyatt brought a civil action against the director of the U.S. Patent and Trademark Office ("PTO") pursuant to §145 in the District Court for the District of Columbia.

The director moved for summary judgment in district court for failure to satisfy the written description requirement. In his opposition, Hyatt submitted a declaration identifying the portions of his specification that satisfied the written description requirement. The district court refused to consider Hyatt's declaration and granted summary judgment. The court found that Hyatt could have submitted such a declaration in response to the written description rejections that were issued by the examiner during prosecution, and that he had no explanation for why he failed to do so. "[Mr.] Hyatt's failure to explain why he didn't submit his declaration earlier is negligent, and the district court need not consider evidence negligently submitted after the end of administrative proceedings." 10

Hyatt subsequently appealed to the Federal Circuit, and a divided panel affirmed.<sup>11</sup> The majority recognized a "general practice" in federal courts to exclude evidence which a party could and should have introduced before the Patent Office, but did not, despite an obligation to do so. The majority also noted that, under the Administrative Procedure Act ("APA"), judicial review of an agency action is generally restricted to the agency record.

Sitting *en banc*, the Federal Circuit vacated the panel's judgment and held that the only limitations on the admissibility of evidence in a §145 proceeding in district court, pertaining to issues raised before the Patent Office, are the limitations imposed by the Federal Rules of Evidence and Civil Procedure. Specifically, the *en banc* court found that nothing in the text or legislative history of §145 indicated that the civil action arising from it was somehow different from a traditional civil action, or that unique rules of evidence would apply. The court emphasized the distinction between a §145 action and an appeal under §141, in which the applicant *would* be limited to the Patent Office record. The court also found that there was no support for the standard proposed by the director, which would only allow new evidence that could not reasonably have been provided to the Patent Office.

With respect to the effect of the APA, the *en banc* court explained that when the parties to a §145 action do not introduce new evidence, the district court reviews the case on the same record presented to the PTO and must apply the APA's substantial evidence standard to the PTO's fact findings. However, when a party to a §145 action does introduce new evidence, as in *Hyatt*, review is no longer limited to the record at the PTO, and the district court must decide factual issues related to the new evidence de novo.

The Supreme Court heard oral argument in *Kappos* on January 9, 2012. The government advanced its theory that new evidence should be limited to that which could not have been presented to the PTO, such as evidence that simply did not exist during prosecution. A second category of evidence admissible in the district court, according to the government, would be oral testimony (which is inadmissible at the PTO). The Court appeared skeptical of the government's position, commenting both that the government's standard was inconsistent with legislative history and legal precedent, and that it has no basis in the statutory language of §145. At one point, the Court proposed an alternate standard wherein new evidence would be excluded in the district court unless the applicant could show good cause — i.e., that any withholding from the PTO was not strategic, deliberate, or negligent. Even



if the Court completely rejects the government's hard-line position, elucidation of a different standard will likely mean reversal and additional proceedings below.

#### C. Challenging Patent Descriptions Submitted to the FDA by Name-Brand Rivals

The Supreme Court soon decides whether drug manufacturers can challenge the breadth of patent descriptions submitted by their rival companies to the FDA. In *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, No. 10-844, the Supreme Court will decide whether a drug company can file a counterclaim under the provisions of the Hatch-Waxman Act to force the FDA (or a new drug application holder) to correct the accuracy of the scope of patent information listed by the FDA. The Court's decision will have large implications in the ongoing battle between generic and brand-name drug manufacturers.

The Hatch-Waxman Act sought to strike a balance between two competing interests: those of companies involved in pioneering research and development, and companies marketing low-cost generic copies of those inventions at the close of a patent term. To sell a new drug, a pioneering manufacturer must file a new drug application ("NDA") for FDA approval. As part of the NDA process, the manufacturer must identify all patents that claim the drug itself or a method of use for the drug. If a patent claims a method, the manufacturer submits a "use code" description of the process. The FDA then assigns a unique "use code" number that is published along with the description in an "Orange Book."

In this case, Caraco filed an abbreviated NDA ("ANDA") for its generic drug, carving out a certain use for the drug such that it did not run afoul of Novo Nordisk's patent. Novo Nordisk later amended its use code narrative so that Caraco's carve-out would infringe on the patent. In the ongoing litigation between Novo Nordisk and Caraco, Caraco sought an injunction under the Hatch-Waxman Act requiring the FDA to correct the scope of the use code when "the patent does not claim. . . an approved method of using the drug."

The district court granted the injunction. The Federal Circuit reversed, holding that the Hatch-Waxman Act only applies where the listed patent did not claim any, rather than all, of the approved methods of using the drug. <sup>13</sup> Additionally, the Federal Circuit found that the Hatch-Waxman Act only allows for the correction of patent information, such as the patent number and the expiration date, and not the use code narrative.

This decision will considerably impact the balance between encouraging pioneering companies and encouraging competition with generic manufacturers, as well as the extent to which use code narratives must stay true to the patent claims. An affirmance of the Federal Circuit's decision would lead more NDA holders to draft expansive use code narratives in order to strategically delay generic drug introduction and increase the amount of infringement suits for ANDA holders. A reversal of the Federal Circuit would allow ANDA holders to seek relief from improperly drafted use code narratives, but may cause the FDA to adopt new use code regulations.

#### D. Doctrine of Equivalents

The petition for certiorari in *Saint-Gobain Ceramics & Plastics, Inc. v. Siemens Medical Solutions USA, Inc.*, No. 11-301, seeks review of a split-panel decision of the Federal Circuit refusing to reverse a district court decision. The district court instructed the jury that it could find infringement under the doctrine of equivalents using a "preponderance of the evidence" standard, rather than the



higher "clear and convincing" evidence standard, despite the fact that the product alleged to infringe was covered by a separate patent (the validity of which was not at issue).<sup>14</sup>

Siemens brought the underlying patent infringement action against Saint-Gobain, alleging infringement of its patent pertaining to PET scanners. The Siemens patent covers PET scanners with cerium-doped lutetium oxyorthosilicate scintillator crystals. Saint-Gobain's allegedly infringing crystals replaced 10 percent of the lutetium with yttrium and are the subject of a separate patent licensed by Saint-Gobain. Saint-Gobain unsuccessfully sought jury instructions that would have required Siemens to establish that the alleged equivalent crystals and PET scanners were merely *obvious* variants of the crystal and PET scanner claimed in Siemens' patent. This would have effectively required the jury to invalidate the patent licensed by Saint-Gobain in order to find infringement of the patent asserted by Siemens. The jury subsequently found infringement under the doctrine of equivalents on the basis that the change to 10 percent yttrium in Saint-Gobain's crystals was "insubstantially different" from the crystals described in the Siemens patent.

Denying Saint-Gobain's petition for rehearing *en banc*, the Federal Circuit was unable to reach consensus in identifying the core issue at play in *Saint-Gobain*. The majority of the court (six judges) agreed that the case was about the burden of proving infringement — specifically, when the accused product is itself the subject of a separate patent, whether the burden of proof for infringement should be raised from the well-established "preponderance of the evidence" standard to the higher "clear and convincing" standard. However, the remainder of the court (three judges) took the position that the case was about whether a patent claim's scope can (or should be able to) encompass, via the doctrine of equivalents, a new and separately patented (or patentable) invention.

Saint-Gobain filed its petition for certiorari on September 6, 2011. The intra-circuit split with four separate opinions in connection with the denial of an *en banc* rehearing considerably increases the chances for Supreme Court review. On November 7, the Court invited the Solicitor General to brief the government's position on the issues.

#### E. §112 Written Description Requirement for Biotech Patents

The petition for certiorari in *Janssen Biotech Inc. v. Abbott Laboratories*, No. 11-596, argues that the Federal Circuit improperly elevated the written description requirement of 35 U.S.C. §112 beyond disclosing the invention and enabling others to make and use it. Janssen Biotech (formerly Centocor Ortho Biotech) is appealing the Federal Circuit decision that overturned its \$1.67 billion verdict — the largest patent infringement verdict to date — obtained against Abbott Laboratories in the Eastern District of Texas.<sup>15</sup>

The technology in this case pertains to production of antibodies to human tumor necrosis factor a ("TNF-a") for use in human patients. TNF-a is known to cause various autoimmune deficiencies, including arthritis. The human body does not normally make antibodies to TNF-a. Pharmaceutical companies have long sought to develop an antibody to human TNF-a with high binding affinity, <sup>16</sup> neutralizing activity, <sup>17</sup> and reduced immunogenicity. <sup>18</sup> Centocor (now Janssen) sought to create such an antibody by identifying and modifying a mouse antibody that had a high binding affinity and neutralizing activity. In order to reduce rejection of the mouse antibody in human patients, Centocor exchanged the constant region of the mouse antibody with a known human constant region. <sup>19</sup> Centocor filed a patent application disclosing the mouse antibody it identified and the chimeric mouse-human antibody in 1991. Numerous continuation-in-part applications followed. In 2002, Centocor filed an application that claimed priority to its earlier applications and, for the first time, explicitly claimed



human variable regions and fully human antibodies. This patent, issued in 2006, was the subject of Centocor's patent infringement suit against Abbott in which Centocor obtained a jury verdict of \$1.67 billion.

The primary issue at the Federal Circuit was whether a continuation-in-part application filed by Centocor in 1994 provided adequate written description for the human variable regions claimed in the patent in suit. As discussed above, the first time Centocor claimed human variable regions and a fully human antibody was in its 2002 application — years after Abbott had already developed and patented the antibodies which Centocor now alleged to infringe.

In finding that Centocor's 1994 application lacked adequate written disclosures, the Federal Circuit emphasized several points. First, the court found that Centocor's identification of amino acid sequence information for a mouse variable region would not serve as a "stepping stone" to identifying a human variable region within the scope of the claims for one skilled in the art. Second, the court emphasized that while Centocor's specification mentioned that desirable antibodies could be produced by human B lymphocytes, it did not disclose any such lymphocytes that actually produced such an antibody. Finally, the court categorized Centocor's claims as "a wish list" of properties that a fully human, therapeutic TNF-a antibody should have and Centocor's specification as, at best "a plan for making fully human antibodies," containing nothing suggesting that Centocor possessed antibodies falling within the scope of its claims. "Because Centocor had not invented [an antibody satisfying the claims of its 2002 application] in 1994, a reasonable jury could not have concluded that it possessed one." The court ultimately held that Centocor's patent was invalid for lack of written description and reversed the jury verdict of infringement.

Janssen (formerly Centocor) describes the question presented in its petition for certiorari as follows: Whether §112 forecloses the Federal Circuit's written description mandate, which in implementation (i) has required a heightened, actual reduction-to-practice standard for biotechnology patents, (ii) has licensed *de novo* appellate review of what the Federal Circuit labels a fact question, and (iii) has led to substantial unpredictability and instability in patent protection.

#### F. Claim Indefiniteness

On November 9, 2011, Eastman Chemical Co. petitioned the Supreme Court for certiorari in *Eastman Chemical Co. v. Wellman, Inc.*, No.11-584, arguing that the Federal Circuit has created conflicting lines of authority on the proper standard for claim definiteness under 35 U.S.C. §112. The Federal Circuit reversed the district court's grant of summary judgment on invalidity, holding that the patent claims in question were not indefinite because they were "amenable to construction."<sup>21</sup>

Wellman originally sued Eastman in September of 2007, alleging that Eastman infringed its patents pertaining to polyethylene terephthalate ("PET") resins for use in plastic beverage containers. The district court granted summary judgment for Eastman on the basis that the patents in suit did not disclose the conditions and parameters required to obtain a particular temperature measurement which was required to determine whether any given PET resin fell within the scope of the claims. Specifically, the district court found that both moisture content and thermal history of the resins affected the temperature measurement recited in the claims and that there were a "multitude of choices" that would affect these values. In light of these ambiguities, the district court held that the claims in suit were indefinite under §112.

The Federal Circuit found that Wellman's claims were sufficiently definite because they were "amenable to construction" and reversed. 22 Specifically, the court found that the record showed that a



person of ordinary skill in the art would follow industry standards specified by the ISO for moisture content. The court distinguished the case at hand from *Honeywell International, Inc. v. International Trade Commission*, <sup>23</sup> wherein a person of skill in the art had to choose among four different known sample preparation methods, the selection of which would affect whether the accused products fell within the scope of the claims, without any intrinsic or extrinsic guidance indicating a preferred method. Unlike the situation in *Honeywell*, the court in *Wellman* found that a person of ordinary skill in the art would have known to use a particular ISO standard for moisture conditions.

Further, the court construed the claims at issue to require testing on an "amorphous PET material" such that differences in measurement techniques would not affect thermal history or the resultant temperature measurement. The court explained that construing the claim to require testing of an "amorphous PET material" does not *replace* any claim term with a different term, <sup>24</sup> but instead interprets the measuring technique in light of the specifications, which state that the tests should be performed on amorphous PET material.

In its petition for certiorari, Eastman argues that the "amenable to construction" standard recited by the court is "meaningless and vague" and conflicts with other Federal Circuit precedent (and the public notice requirement of the patent statute), requiring that claims be sufficiently definite to inform the public of the bounds of the protected invention.

#### G. Prosecution Laches

In its petition for certiorari in *Hynix Semiconductor Inc. v. Rambus*, No. 11-549, Hynix argues that the Federal Circuit wrongly decided issues relating to the equitable obligations of participants in standard-setting organizations ("SSOs") who later seek patent claims covering standards-compliant products.<sup>25</sup> Hynix also raises issues relating to claim construction in its petition, arguing that the opinion below conflicts with precedent established in *Phillips v. AWH Corp.*<sup>26</sup> regarding the relative roles of intrinsic and extrinsic evidence.

Hynix contends that Rambus concealed pending patent applications while participating in an SSO for dynamic random access memory ("DRAM"), secretly amended its claims to cover the emerging standard, delayed the issuance of its amended claims until after it exited the SSO, and subsequently alleged that standards-compliant products infringe its patent claims. Hynix argues that the Federal Circuit decision effectively authorizes SSO participants to lay "intellectual patent traps" for other participants collaborating to develop open industry standards. According to Hynix, principles of equity and prosecution laches case law should act to bar such behavior.

With respect to claim construction, Hynix argues that the Federal Circuit's opinion revives an intracircuit split. Specifically, Hynix contends that the court effectively revived a line of precedent where the specification and prosecution history are relevant to claim construction only if they amount to a clear disclaimer or disavowal of the dictionary meaning of claim terms. According to Hynix, this approach conflicts with precedent established in *Phillips*, in which the court explained that intrinsic evidence — in particular, the specification — was of primary importance and should serve as the principal guide in construing disputed terms. Hynix calls for the Supreme Court to announce a clear rule regarding the role of the specification in claim-construction analysis in order to make it easier for inventors, investors, and the public at large to determine the meaning of claim terms.



#### H. Copyright Restored to Public Domain Works

In a historic win for foreign artists, authors and composers, the Supreme Court recently held in *Golan v. Holder*, No. 10-545, that Congress has the authority to withdraw works from the public domain and put them back under a copyright shield. In the past, foreign works were not protected under United States copyright law. In 1994, the United States finally fell in line with other countries that had been party to the Berne Convention for the Protection of Literary and Artistic Works, an agreement dating to 1886 that governs copyright. Congress passed the Uruguay Round Agreements Act ("URAA") which amended U.S. copyright law to restore copyright to foreign works to the extent they received protection in their home country.

A group of performers, educators, and archivists challenged the 1994 law, arguing that Congress did not have the authority to restore copyright to creative works in the public domain. Any attempt to do so, they claimed, would violate the free-speech and Fifth Amendment rights of those who had previously used the once publicly available work. They also argued that restoring copyrights does not promote the progress of science. Further, they argued that the withdrawal of creative work was an economic hardship, as many of the challengers could no longer afford to pay the required royalties.

The Supreme Court found that the URAA did not exceed Congress' authority under the copyright clause, as there was no exclusion against applying copyright protection to works already in the public domain. Historically, Congress has restored copyrights and patents to works and inventions previously in the public domain. Further, providing protection to all works, both foreign and domestic, harmonizes the copyright regime. Finally, the Court rejected the first amendment argument, stating that no one obtains any vested interest in works in the public domain.

#### I. Limits on First Sale Doctrine

In another copyright case, a petition for certiorari has been filed with the Supreme Court in *Kirtsaeng v. John Wiley & Sons, Inc.*, No. 11-697. The first sale doctrine, codified at 17 U.S.C. §109(a), allows the owner of a lawfully made copy of a copyrighted work to resell it without the authority of the copyright holder. However, 17 U.S.C. §602(a) makes it unlawful to import foreign-made copies of copyrighted work into the U.S. without the copyright holder's approval. The Second Circuit held that a book legally manufactured outside the United States cannot be imported without the copyright owner's approval, finding that "lawfully made" under the first sale doctrine refers to "legally manufactured within the United States." The Second Circuit acknowledged that a likely result of their finding would be that copyright holders would produce all of their goods abroad before importing them into the United States, but were not deterred from their interpretation of the Copyright Act.

#### J. Standards for Joint & Contributory Patent Infringement

On November 18, 2011, the Federal Circuit heard oral argument *en banc* in two related cases, *Akamai Technologies, Inc. v. Limelight Networks Inc.* and *McKesson Technologies, Inc. v. Epic Systems Corp.* Both cases pertain to the proper standard for joint infringement liability when a multi-step process claim is performed by multiple parties. Akamai and McKesson each sought to separately enforce patented methods directed to Internet-based communication and processing. Neither defendant Limelight nor Epic performed all of the steps of either of the alleged claims; both required action by a third-party.

Defendants in each case prevailed before their respective panels in the Federal Circuit. In 2007, the Federal Circuit in *BMC Resources, Inc. v. Paymentech, L.P.*, <sup>28</sup> held that an alleged infringer who does not perform all of the steps of a method claim will be liable for infringement only if the alleged



infringer has "direction or control" over the party performing the remaining steps. Subsequently, the Federal Circuit held in *Muniauction, Inc. v. Thomson Corp.*<sup>29</sup> that "direction and control" requires either a contractual obligation or an agency relationship between the parties performing the infringing steps. In both *McKesson* and *Akamai*, the Federal Circuit panels found that no such contractual obligation or agency relationship existed and thus there was no liability.

In its order granting an *en banc* rehearing in *Akamai*, the court asked the following question: "If separate entities each perform separate steps of a method claim, under what circumstances would that claim be directly infringed and to what extent would each of the parties be liable?" The question in the *McKesson* case is slightly different, as the alleged infringer in that case only sells the software that enables the patented method to be implemented. The court asked McKesson to address two questions: "1. If separate entities each perform separate steps of a method claim, under what circumstances, if any, would either entity or any third-party be liable for inducing infringement or for contributory infringement?" and "2. Does the nature of the relationship between the relevant actors — e.g., service provider/user; doctor/patient — affect the question of direct or indirect infringement liability?"

It is likely that the Federal Circuit's decisions in *Akamai* and *McKesson* will soften the "direction and control" standard set forth in *BMC* and *Muniauction* to encompass more than contractual or agency relationships. Akamai argued before the *en banc* court that the joint infringement standard should be loosened to encompass two additional scenarios: 1. parties acting in concert; and 2. a party who knowingly combines her claim steps with that of another so that together they perform all the steps of the claim. Notably, Akamai's suggestion would import a "knowing" state-of-mind requirement into one path leading to joint infringement under §271(a), a provision which has otherwise remained a strict-liability offense. It is also worth nothing that the Federal Circuit recently upheld a "presumed-knowledge" standard under §271(c) when there existed a lack of substantial non-infringing uses for the defendant's products.<sup>30</sup>

#### K. Claim Construction

On October 31, 2011, the Federal Circuit denied an *en banc* rehearing in *Retractable Technologies, Inc. v. Becton, Dickinson & Co.*, a case that could have presented the Federal Circuit an opportunity to reconcile what is widely perceived as an intra-circuit split in its approach to claim construction in patent cases. Retractable Technologies brought the underlying patent infringement suit against Becton, Dickinson in the Eastern District of Texas, asserting three patents pertaining to medical syringes with retractable needles. The claim construction issues focused upon whether the "body" limitation of the claimed syringe should be construed to include multi-piece bodies. The district court interpreted the term "body" to encompass both one-piece and multi-piece syringes, and a jury ultimately found that the alleged product infringed the patents in suit.

On appeal, a 2-1 panel of the Federal Circuit construed the term "body" to be limited to a one-piece body and reversed the jury verdict. The majority's opinion was based on its findings that no claims expressly recited a multi-piece body, the summary of the invention recited a one-piece body, all disclosed embodiments had a one-piece body, and that the specification taught that the prior art failed to recognize the advantages of a one-piece body. In his dissent, Chief Judge Rader argued that the majority had improperly imported limitations from the specifications into the claims under the standards for claim construction set forth in *Phillips*.



Retractable Technologies' subsequent petition for an *en banc* rehearing was denied. The dissenting opinion, authored by Judge Moore and joined by Chief Judge Rader, admonished the majority's refusal for an *en banc* rehearing, arguing that the panel's decision could not be reconciled with the Federal Circuit's *en banc* decision in *Phillips*. The dissenting judges were primarily concerned with inconsistent usage of the specification to interpret claims between Federal Circuit panels, noting that the rules governing claim construction are "ill defined and inconsistently applied, even by us." With respect to the case at hand, Judge Moore argued that the panel had improperly rewritten the claims at issue to correspond with the panel's own perception of the invention.

A second dissenting opinion, authored by Judge O'Malley, focused on the level of deference that the Federal Circuit must give the district court's claim construction. Judge O'Malley argued that claim construction is a mixed question of law and fact and that the Federal Circuit in *Cyber Corp*<sup>31</sup> improperly interpreted the Supreme Court's decision in *Markman*. In *Cyber Corp*, the court held that claim construction was purely a matter of law to be reviewed *de novo*. Both dissenting opinions agreed that the Federal Circuit should give deference to the district court's factual determinations on claim construction.

Retractable Technologies identifies a fundamental split in the Federal Circuit about the nature of claim construction. If Retractable Technologies successfully petitions the Supreme Court for a writ of certiorari, this case will have the potential to resolve one of the biggest issues in patent litigation today.

#### III. Legislation to Watch in 2012

#### A. What to Expect as Provisions of the America Invents Act Take Effect

The Leahy-Smith America Invents Act ("AIA") was signed into law on September 16, 2011.<sup>33</sup> The AIA makes a number of key changes to the patent regime, including switching the U.S. patent system from a "first to invent" to a "first to file" system, expanding prior art, and creating a post-grant review system to remove invalid patents. The AIA transferred venue for civil actions appealing decisions of the PTO, the Board of Patent Appeals and Interferences ("BPAI"), and Trademark Trial and Appeal Board ("TTAB") from the District Court for the District of Columbia to the Eastern District of Virginia for any civil actions commenced on or after September 16, 2011. The AIA did not provide any clarification on the ongoing *Bilski* and business methods cases.

The AIA makes the following key changes to the patent regime:

#### 1. <u>First-Inventor-to-File System</u>

One of the largest changes in the AIA is that the U.S. will switch from a "first-to-invent" system to a "first-inventor-to-file" system ("FITF") for patent applications with effective filing dates after March 16, 2013. However, there is some ambiguity as to the effective date. It applies to patents filed or issued on or after March 16, 2013 containing at least one claim with an effective filing (i.e. priority) date on or after March 16, 2013, or patents claiming priority to an application with such a claim.

The AIA also expanded the definition of prior art for purposes of determining patentability. Starting on the effective FITF date, on-sale and public-use bars may occur anywhere in the world. Also, there is no one-year grace period for third-party "use" and "sale" art unless the inventor publicly disclosed the invention before such use or sale, or the third-party derived the art from the inventor. Based on the language of the AIA, it appears that an inventor's private disclosure to third parties who later improve upon the invention and file before the original inventor are not protected.



The AIA has also created what appears to be a catch-all, prior art category that includes art "otherwise available to the public." Although there is some dispute as to what type of prior art is included in this category, the current assumption is that it includes art known to, or available for use by, the public, even if it is not used and there are no commercial arts. The catch-all art is likely not limited to those in the U.S.

Under these rules, more prior art is available, both because of the worldwide scope of sales and public uses and because there is no longer a third-party grace period. However, anticipation is less likely with the elimination of 35 U.S.C. §102(g)(2). This change should encourage inventors to file or disclose early, as disclosures provide a one-year grace period even against third-party prior art.

Along with the other changes, obviousness under §103 is now tested as of the effective filing date of the patent, rather than the date of the invention. This change could make findings of obviousness more likely as it potentially increases the level of knowledge of the person having ordinary skill in the art. However, although there are derivation exceptions, an applicant can no longer rely on an invention date. There is also no longer a bar based on lack of diligence or abandoning, suppressing or concealing an invention. Finally, there is no ability to transfer an application based on derivation to the true inventor — applications based on derivation can only be invalidated.

#### 2. Best Mode

The AIA's amendment to 35 U.S.C. §282(a)(3) eliminates a patentee's failure to disclose the best mode as a basis for cancellation, invalidity, or unenforceability of a patent in lawsuits and reexamination proceedings beginning September 16, 2011. The best mode disclosure requirement is still preserved as an evaluation element during patent prosecution. While it is nominally still a requirement in PTO examinations, the PTO has rarely policed it in the past and it is unlikely best mode will remain an issue in the future.

#### 3. <u>Pre-Grant Review</u>

During patent prosecution, effective September 16, 2012 for any pending patent application, a third party may submit for consideration and inclusion into the record of the application any patent application, patent or printed publication of potential relevance to the examination within six months after publication of the patent or before the first rejection. This change opens the door for the examination to be similar to the current peer-to-patent pilot program that involves pre-issuance prior art submissions.

#### 4. Advice of Counsel and Inducement

The failure to obtain or to present advice of counsel can no longer be used as evidence of willful infringement or inducement. The effective date of this change is not specified. Thus, it applies only to patents issued on or after September 16, 2012. This significant delay was probably unintentional. While this change does not create any substantive change in the law of willfulness, it does clarify that the courts should not allow evidence of failure to seek or rely on advice of counsel. This change will likely reverse the Federal Circuit decision in *Broadcom Corp. v. Qualcomm Inc.*, Nos. 2008-1199, 2008-1271, 2008-1272 (Fed. Circ. 2008), in which the Federal Circuit reaffirmed that obtaining an opinion of counsel is one of the factors to be considered when determining inducement.



#### 5. <u>Proceedings</u>

The AIA changed the availability of post-issuance reviews. The Board of Patent Appeals and Interferences will be turned into the Patent Trial and Appeal Board ("PTAB"). The PTAB will have the responsibility for two new types of *inter partes* proceedings: "Post-Grant Review" and "Inter Partes Review." Derivation proceedings now replace interference proceedings.

#### 6. Post-Grant Review

Starting September 16, 2012, post-grant review is available for patents subject to the first-to-file rules, although there is a special provision for existing "business method" patents. A petition must be filed within nine months of issuance, or re-issuance, of the patent. Any third party can file the petition, but they must identify the real-parties-in-interest. Any ground of invalidity can be raised as prior art. The threshold for the review is that it must be "more likely than not" that at least one challenged claim is unpatentable or that the petition raises a novel or unsettled legal question that is important to other patents or patent applications. A refusal to open a proceeding is not appealable. Post-grant review is not available to parties who have already filed for a declaratory judgment of invalidity. Unless the patentee counterclaims for infringement, any action for a declaratory judgment of invalidity filed after a petition for post-grant review is automatically stayed.

The post-grant review is heard by the PTAB, and a final determination must be issued no later than one year after the beginning of the proceeding— with a potential extension for good cause of no more than six months. A decision in a post-grant review is an estoppel on the petitioner from asserting the same claim in other proceedings before the PTO, civil actions, or the ITC. A post-grant review can be terminated with a settlement, and if the settlement occurs before the final determination, there would be no estoppel.

#### 7. Transitional Post-Grant Review for Business Methods

Starting September 16, 2012, transitional post-grant review for review of the validity of covered business method patents is available under the same post-grant review procedures as described above. All forms of prior art are allowed. To invoke the review, a petitioner must have been sued or "charged" with infringing the patent. Courts have the option to stay such proceedings, but the statute creates a right to an interlocutory review of the stay decision. There is a certain amount of ambiguity to the idea of a "covered business method patent." The definition includes "a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service," but excludes "patents for technological inventions." The PTO will promulgate regulations for determining what a patent for a "technological invention" is. Further, it is unclear what "charging" someone with infringing constitutes, as it apparently means something other than filing suit. The post-grant reviews for business methods will likely be the initial set of cases before the PTAB under the post-grant review procedures.

#### 8. Inter Partes Review

Effective September 16, 2012, *inter partes* review will replace *inter partes* reexamination and applies to any patent. The threshold for review is that there is "reasonable likelihood that the requester would prevail with respect to at least 1 of the claims challenged." *Inter partes* review is heard by the PTAB, instead of the Central Reexamination Unit, and appeals are made to the Federal Circuit. *Inter partes* review petitions must be filed after the post-grant window/proceedings, but cannot be filed if the petitioner has filed for declaratory judgment of invalidity or more than one year after the date on which petitioner is served with a complaint alleging infringement of the patent. A decision is an



estoppel on the petitioner from asserting the same claim in other proceedings before the PTO, civil actions, or the ITC. A refusal to open a proceeding is not appealable.

It will be substantially harder to obtain *inter partes* review under this new system. Those who institute a civil action, such as filing for declaratory judgment of invalidity, will not be able to file for *inter partes* review, but a defendant in an infringement suit would still be able to do so. The shift from the Central Reexamination Unit to the PTAB suggests that *inter partes* reexaminations may be taken more seriously at the PTO.

#### 9. Supplemental Examination

Starting September 16, 2012, a patent owner can request supplemental examination to cleanse her patent of inequitable conduct charges. However, this procedure may not be used to cure existing allegations of inequitable conduct. Any information may be submitted, but must raise a "substantial new question of patentability." A patent will not be held unenforceable based on any information considered in the supplemental examination. A supplemental examination must be completed before the patent owner files suit, and must be initiated before any declaratory judgment action pleads inequitable conduct with particularity. While supplemental examination may not add much to the current law of inequitable conduct, it will provide a convenient forum for patent owners who wish to cleanse their past misconduct in an *ex parte* setting rather than in an adversarial proceeding.

#### 10. <u>Derivation Proceedings</u>

While derivation proceedings will eventually replace interference proceedings, interference proceedings continue to apply to all claims having an effective filing date before March 16, 2013. Derivation proceedings are instituted when an inventor named in an earlier application "derived" the invention from the applicant and, without authorization, the earlier application was filed. The proceedings must be instituted within one year of the publication of the allegedly derived claim. This provision appears to replace §102(f) — it remains unlawful to obtain a patent not of one's own invention by filing an application first in time.

#### B. Proposed Bill Could Improve Enforcement of IP Rights

On November 8, 2011, Michigan Senator Debbie Stabenow introduced the Protect American Innovation Act of 2011 (S. 1830), a bill to improve enforcement of intellectual property rights. This bill is the intellectual property portion of a three-bill plan unveiled by Stabenow in October to bolster American competitiveness. According to Stabenow's press release, these bills stand up for American businesses by thwarting trade violations that give foreign companies an anti-competitive advantage. The first part of Stabenow's plan, cracking down on foreign countries engaging in artificial currency manipulation, passed in the Senate by an overwhelming bipartisan majority (79-19).

The Protect American Innovation Act contains several key provisions to combat foreign theft of intellectual property. One provision is a "three strikes" law for foreign importers of counterfeit goods. Punishment quickly escalates from a fine on the first offense to a lifetime ban on conducting business in the U.S. for the third offense. Other provisions describe new civil fines for violators, a "watch list" to notify customs and border security about shipments from suspected violators, a voluntary certification program for importers, establishment of a new director of Intellectual Property Rights Enforcement appointed by the Secretary of the Treasury, and additional resources for customs agents to focus on intellectual property theft. Although the Senate has not yet voted on the Protect American Innovation Act, Stabenow has already demonstrated her ability to garner substantial bipartisan support for other provisions of her American Competitiveness plan.



#### IV. Evolving Trends in the IP Marketplace

#### A. A Financial Exchange for Intellectual Property Rights

The Intellectual Property Exchange International ("IPXI") has positioned itself to become the world's first intellectual property exchange in 2012. Scheduled to launch this year, founding members include Philips Electronics, Com-Pac International, Rutgers University, Northwestern University, and the University of Utah. Based in Chicago and backed by the Chicago Board Options Exchange, IPXI seeks to create a financial exchange where patents are traded like stocks — as shares of Unit License Rights ("ULR"). Each ULR contract will give the buyer a non-exclusive license to use the IP for a pre-defined number of instances in the manufacturing or sale of a product or service.

IPXI's exchange model has the potential to transform traditional bilateral patent licensing by allowing patent owners to license select technology in a non-discriminatory manner using standard form licenses on publicly disclosed terms. According to IPXI, ULR contracts address various inefficiencies associated with technology transfer today, including the time, expense, redundancy, and uncertain outcome of traditional private licensing negotiations. Putting aside increased efficiency, one key benefit of the ULR model is that unused ULR contracts may be resold on the market to accommodate reduced future needs.

IPXI is currently soliciting submissions for ULR contract offerings. IP owners may alternatively submit ULR contracts for consideration to IPXI. A selection committee at IPXI will then perform due diligence on the proposed IP assets, including identification of encumbrances and publication of the proposed ULR contract with an opportunity for comment from other IPXI members. Upon approval by the selection committee, the IP owner assigns or exclusively licenses the patent(s) to an IPXI affiliate under a standard IPXI contract to offer ULR contracts on the exchange.

The success of IPXI will likely hinge on the quality and quantity of IP it is able to offer on the exchange. According to IPXI, it has initial commitments from ULR contract issuers with an aggregate targeted market value in excess of \$250 million, with numerous additional company portfolios in various stages of the submission process.

#### B. Nortel Patent Auction

Earlier this year, bankrupt telecom manufacturer Nortel auctioned off its patent portfolio for the hefty sum of \$4.5 billion. Nortel's portfolio consisted of over 6,000 patents pertaining to mobile computing and telecommunications. "Rockstar Bidco," a consortium of rivals Microsoft, Apple, Ericsson, EMC, Sony, and RIM, submitted the winning bid. Google was an early participant, kicking off the auction with a \$900 million bid for the portfolio. Google's loss could present issues in the coming year for Google and for handset manufacturers using its Android operating system, depending on how Rockstar Bidco uses the Nortel patent portfolio.

#### C. Acacia Acquires 4G Patent Cache

On January 13, 2012, Acacia Research Corp. agreed to purchase Texas-based Adaptix Inc., along with its portfolio of over 230 patents pertaining to 3G and 4G wireless technology, for \$160 million. Adaptix has long been recognized in the industry as a front-runner in the development of 4G wireless communications systems. Adaptix' portfolio includes issued and pending patents in 13 countries dating back to 2000. Since January, 2011, Acacia has acquired more than 330 patents spanning multiple technology areas, including semiconductor packaging, 3G and 4G wireless, drug delivery, and flash



memory. Through its subsidiaries, Acacia acquires, develops, licenses, and enforces patented technologies.

#### D. Microsoft Licenses Smartphone and Tablet Patents to LG

On January 12, 2012, LG signed a licensing agreement with Microsoft covering LG mobile devices running Google's Android and Chrome operating systems. According to Microsoft, this agreement means that more than 70 percent of all Android smartphones sold in the US are now receiving coverage under Microsoft's patent portfolio. Barnes & Noble and Motorola Mobility, both manufacturers of Android-based devices, are currently battling Microsoft in court over the same patents.

#### V. Conclusion

As in years past, we can expect 2012 to bring significant developments in the intellectual property arena. Both the courts and practitioners will continue to grapple with the bounds of patentable subject matter under *Bilski* and other issues that have far-reaching impact on how companies choose to pursue, litigate, and invest in intellectual property. As provisions of the America Invents Act continue to go into effect, the year promises to shed light on the interaction between patent-related legislation and the intellectual property marketplace.



If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

#### Washington, D.C.

Robert M. Masters Lisa Leung 1.202.551.1763 1.202.551.1739

robmasters@paulhastings.com lisaleung@paulhastings.com

Tad Richman 1.202.551.1973 tadrichman@paulhastings.com

18 Offices Worldwide

www.paulhastings.com

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<sup>&</sup>lt;sup>1</sup> Prometheus Labs, Inc. v. Mayo Collaborative Svcs., 628 F.3d 1347 (Fed. Cir. 2010).

<sup>&</sup>lt;sup>2</sup> 130 S. Ct. 3218 (2010).

<sup>&</sup>lt;sup>3</sup> 548 U.S. 124 (2006).

<sup>&</sup>lt;sup>4</sup> Association for Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011).

<sup>&</sup>lt;sup>5</sup> 447 U.S. 303 (1980).

<sup>&</sup>lt;sup>6</sup> 654 F.3d 1366 (Fed. Cir. 2011).



- <sup>7</sup> See In re Beauregard, 53 F.3d 1583 (Fed. Cir. 1995).
- <sup>8</sup> §145 allows patent applicants to file a new action in federal district court to challenge a final rejection at the PTO.
- <sup>9</sup> Hyatt v. Kappos, 625 F.3d 1320 (Fed. Cir. 2010).
- <sup>10</sup> Id. at 1324 (citing Hyatt v. Dudas, 2005 U.S. Dist. LEXIS 45319, at \*26 (D.D.C. Sept. 30, 2005)).
- <sup>11</sup> Hyatt v. Doll, 576 F.3d 1246 (Fed. Cir. 2009).
- <sup>12</sup> Hyatt, 625 F.3d at 1326.
- <sup>13</sup> Novo Nordisk A/S et al. v. Caraco Pharmaceutical Labs., Ltd., 601 F.3d 1359 (Fed. Cir. 2010).
- 14 Siemens Medical Solutions USA, Inc v. Saint-Gobain Ceramics & Plastics, Inc., 647 F.3d 1373 (Fed. Cir. 2011) (denying en banc rehearing).
- <sup>15</sup> Centocor Ortho Biotech, Inc. v. Abbott Labs., 636 F.3d 1341 (Fed. Cir. 2011).
- $^{\rm 16}$  "Binding affinity" refers to how well the antibody "sticks" to the TNF-a.
- 17 An antibody must bind to TNF-a in a specific location to yield a positive therapeutic effect.
- <sup>18</sup> Human patients often have adverse immunological reactions when treated with antibodies produced in foreign species (e.g., mice). Scientists thus try to "trick" the human immune system by engineering the antibodies to "look more human."
- <sup>19</sup> As explained in the Federal Circuit's decision, antibodies consist of two regions: a constant region and a variable region. The variable region primarily dictates binding affinity and neutralizing activity.
- <sup>20</sup> *Id.* at 1351.
- <sup>21</sup> Wellman, Inc. v. Eastman Chemical Co., 642 F.3d 1355 (Fed. Cir. 2011).
- <sup>22</sup> Id. at 1366 ("Claims need not be plain on their face in order to avoid condemnation for indefiniteness; rather, claims must only be amenable to construction. Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001)").
- <sup>23</sup> 341 F.3d 1332 (Fed. Cir. 2003).
- <sup>24</sup> Courts are prohibited from rewriting claims and must interpret the claims as written.
- <sup>25</sup> Hynix Semiconductor Inc. v. Rambus Inc., 645 F.3d 1336 (Fed. Cir. 2011).
- <sup>26</sup> 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*).
- <sup>27</sup> John Wiley & Sons, Inc. v. Kirtsaeng, 654 F.3d 210 (2d Cir. 2011).
- <sup>28</sup> 498 F.3d 1373 (Fed. Cir. 2007).
- <sup>29</sup> 532 F.3d 1318 (Fed. Cir. 2008).
- The Supreme Court recently denied certiorari in two related cases pertaining to contributory infringement, *Spansion Inc. v. International Trade Commission*, No. 11-127, and *Qualcomm Inc. v. International Trade Commissions*, No. 11-128. In *Spansion* and *Qualcomm*, the ITC found that although the alleged infringers lacked the knowledge required to be liable for inducement of infringement under §271(b), knowledge of infringement under §271(c) could be *presumed* from the lack of substantial non-infringing uses for the accused products. There was no finding that the alleged infringers either knew that their products were to be used in infringing devices or that the accused infringers were aware of the asserted patent at the time of sale. The Federal Circuit upheld the ITC decision.
- 31 Cyber Corp. v. FAS Techs., Inc., 138 F.3d 1448 (Fed. Cir. 1998).
- <sup>32</sup> Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996).
- 33 The text of the AIA is available at <a href="http://www.uspto.gov/aia">http://www.uspto.gov/aia</a> implementation/bills-112hr1249eh.pdf
- Note that Stabenow's Protect American Innovation Act is separate and distinct from SOPA (Stop Online Privacy Act) and PIPA (PROTECT IP Act), two recently tabled bills that were the subject of widespread public criticism and Internet protests in recent weeks.