HUNTON& WILLIAMS

Pharmaceutical, Chemical and Biotech Year in Review 2011



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Introduction

In 2011, Congress enacted the America Invents Act ("AIA"), the first major overhaul of the patent laws in nearly 60 years. The passage of this Act alone has sparked enough discussion and debate to last *another* 60 years. Everywhere we look, there is yet another article, blog, seminar or Patent Office program dissecting all the ramifications of the new act on virtually every facet of our practice.

One would have thought, given the significance of the AIA, that judicial decisions would have taken a back seat in 2011. Nothing could be further from the truth. Once rare Supreme Court reviews are now regular occurrences. Last year, the Supreme Court reviewed the presumption of validity, the level of knowledge required for induced infringement and the patentability of personalized medicine methods that rely on natural correlations.

The subject of statutory subject matter, which seemed to be a settled issue just a few years ago, is now at the forefront of the debate. In 2010, a district court held that claims to isolated genes are not statutory. In 2011, the biotech community breathed a sigh of relief when the United States Court of Appeals for the Federal Circuit reversed the district court and held that such claims are statutory. However, in 2012, the Federal Circuit must revisit this issue in light of the Supreme Court's *Prometheus* decision, handed down in March 2012. The key issue is not just to isolated genes; also at play are method claims implicating the emerging field of personalized medicine. This will certainly be one of the most eagerly anticipated decisions in 2012.

Also making headlines last year was the Federal Circuit's *en banc* decision in *Therasense*, which raised the bar for establishing inequitable conduct. Now, to prevail on a claim of inequitable conduct, a defendant must prove by clear and convincing evidence that the patentee specifically intended to deceive the Patent Office by withholding a non-cumulative reference that, had it been disclosed, would have prevented the patent from issuing. One practical effect of this decision is to render largely superfluous the new Supplemental Examination provision of the AIA, which was intended to permit patentees to remedy all but the most egregious cases of inequitable conduct in a supplemental round of prosecution. In view of *Therasense's* tightening the reins on inequitable conduct, however, patentees are not likely to choose supplemental examination, which opens the patent up to all grounds of rejection, unless it wants to eliminate any doubt that its actions have not affected the patent.

The significance of these issues is, at this point, well understood by even casual observers of the courts. Under the radar, however, have been several other very important developments. For example, there has been little discussion of the fact that the Federal Circuit is giving closer scrutiny to factual and legal findings of the Board of Appeals, after many years of giving the board carte blanche. There have also been some interesting, albeit little noticed, developments in the court's obviousness jurisprudence. One development in particular is the sheer number of cases where the court has to consider simultaneous teachings both toward and away from the invention, or as we call them, "red light/green light situations." Regrettably, the court's handling of these cases leaves much to be desired.

The court has also established a new "reference formulation" standard for assessing the obviousness of formulations designed to mimic compositions approved by the FDA. In addition, the court seems to have radically changed the disclosure necessary to rely on an unexpected result.

On the written description front, the court continues to require that a biological molecule be described using "distinguishing characteristics," but often resorts to enablement criteria in making this assessment.

The one area that has been relatively quiet and stable is that relating to claim construction and infringement.

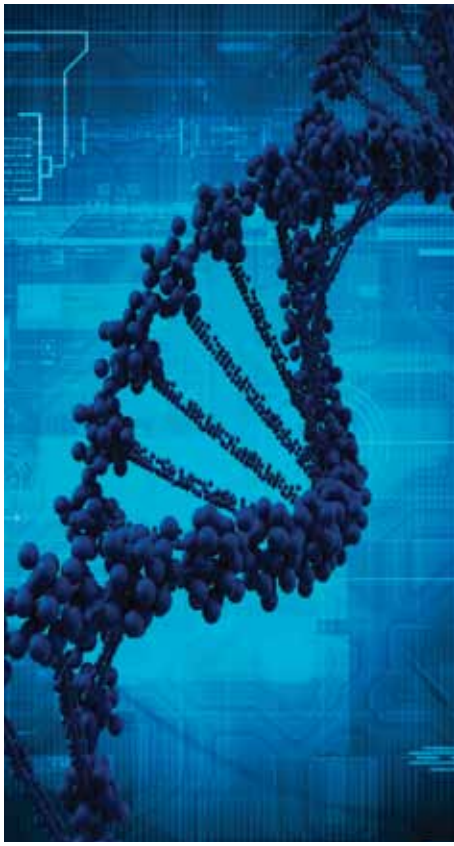
Supreme Court Cases

Supreme Court holds that inducement requires that the accused infringer know, or willfully blind itself from knowing, that the induced acts constitute patent infringement.

In *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 98 U.S.P.Q.2d 1665 (2011), the Supreme Court addressed the question of whether induced infringement under 35 U.S.C. § 271(b) requires the inducer merely to lead another to engage in conduct that happens to amount to infringement, or whether the inducer must persuade another to engage in conduct that the inducer knows is infringement. In an 8–1 decision, the Court ruled that, to be liable for induced infringement under 35 U.S.C. § 271(b), a party must know that the induced acts constitute patent infringement.

At issue was SEB's patent covering a deep fryer designed so that external surfaces remained cool. SEB's competitor Sunbeam asked a company in Hong Kong, Pentalpha (Global-Tech's subsidiary), to supply it with deep fryers copied in all but design features from one purchased from SEB in Hong Kong. Because the fryer was purchased in a foreign market, it lacked any U.S. patent markings. After copying SEB's fryer, Pentalpha hired an attorney to conduct a right-to-use study, but did not tell the attorney that it had copied SEB's product. Failing to uncover SEB's patent, the attorney concluded that Pentalpha had freedom to operate. Both the district court and the U.S. Court of Appeals for the Federal Circuit found that induced infringement requires a showing that the accused infringer knew or should have known that its actions would induce actual infringements, which includes proof that the alleged infringer knew of the patent. Here, while there was no direct evidence that Pentalpha knew of SEB's patent before the lawsuit, the evidence showed that Pentalpha deliberately disregarded a known risk that SEB had a patent, and this deliberate disregard was a form of actual knowledge.

On review, the Supreme Court found the language of the statute ambiguous as to whether the inducer must lead another to engage in conduct that happens to amount to infringement, or whether the inducer must persuade another to engage in conduct that the inducer knows is infringement. Noting the common origin and language of contributory infringement under § 271(c) and induced infringement under § 271(b), the Court borrowed from its contributory infringement jurisprudence (requiring knowledge of the existence of the patent that is infringed) and concluded that induced infringement under § 271(b) must also require knowledge of the patent. However, this time, borrowing from its criminal law jurisprudence, the Court further held that knowledge could be either "actual knowledge" or "willful blindness." 131 S. Ct. at 2060. As to what constitutes "willful blindness," the Court specified "two basic requirements: (1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact." *Id*. at 2070. Applying this standard to the facts before it, the Court found that Pentalpha's deliberate copying of an overseas model of SEB's deep fryer met the willful blindness standard, as did its decision not to tell the attorney doing the right-to-use study that it had copied SEB's product. Accordingly, the Court affirmed the holding of the Federal Circuit.



Supreme Court confirms that patent invalidity must be proven by clear and convincing evidence regardless of whether the United States Patent & Trademark Office ("PTO") considered the prior art at issue, but leaves the door open for defendants to seek lower burden of persuasion in cases of new evidence not considered by the PTO.

In *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S.Ct. 2238, 98 U.S.P.Q.2d 1857 (2011), a unanimous Supreme Court reaffirmed that patents enjoy a presumption of validity that can only be overcome with clear and convincing evidence of invalidity regardless of whether the prior art was or was not considered during PTO proceedings. Both at the district court and at the Federal Circuit, Microsoft sought to invalidate i4i's claims based on prior art that was not before the Patent Office. Microsoft argued that the preponderance of the evidence standard should be the applicable burden of proof when a court reviews the validity of a claim over prior art that was not before the PTO

during prosecution. Relying on its settled interpretation of § 282 of the Patent Act, the Federal Circuit explained that it could "discern [no] error" in the jury instruction requiring Microsoft to prove its invalidity defense by clear and convincing evidence.

Referring to its 1934 decision in *RCA,*[1] which predates § 282, the Supreme Court noted that it had held that "there is a presumption of [patent] validity, a presumption not to be overthrown except by clear and cogent evidence." 131 S. Ct. at 2245. This common-law presumption, "reflected the universal understanding that a preponderance [of the evidence] standard of proof was too dubious a basis to deem a patent invalid" and that this presumption necessarily encompassed "the imposition of a heightened standard of proof." *Id*. at 2246. The Court inferred congressional assent to this jurisprudence by virtue of the fact that for nearly 30 years the Federal Circuit had interpreted § 282 as requiring proof of patent invalidity by clear and convincing evidence, and during that period Congress had often amended § 282, without ever considering lowering the standard of proof.

The Court similarly rejected Microsoft's alternative proposal that the presumption of validity be weakened for evidence that was not before the PTO during prosecution. "Our pre-1952 cases never adopted or endorsed the kind of fluctuating standard of proof," nor do they indicate "that anything less than a clear-and-convincing standard would ever apply to an invalidity defense raised in an infringement action." *Id*. at 2250. However, citing *American Hoist*, the Court endorsed the "commonsense principle that the Federal Circuit has recognized throughout its existence—namely, that new evidence supporting an invalidity defense may 'carry more weight' in an infringement action than evidence previously considered by the PTO." *Id*. at 2251 (quoting *American Hoist & Derrick Co. v. Sowa & Sons, Inc.,* 725 F.2d 1350, 1360, 220 U.S.P.Q. 763 (Fed. Cir. 1984). Elaborating on that "commonsense principle," the Court appeared to open the door for defendants to more easily persuade juries in cases involving evidence that was not considered by the PTO in stating that "if the PTO did not have all material facts before it, its considered judgment may lose significant force. And, concomitantly, the challenger's burden to persuade the jury of its invalidity defense by clear and convincing evidence may be easier to sustain." *Id*.

Although Microsoft lost its bid to lower the burden of proving invalidity, the above-quoted passage will no doubt be cited by defendants for years to come as support for lowering the burden of *persuasion* in situations where evidence was not considered by the PTO. What the practical difference is between a lowered burden of proof and a lowered burden of persuasion remains to be seen. It will be interesting to see what sorts of jury instructions courts will approve on the effect of new evidence.

Section 101- Statutory Subject Matter

Because isolated DNA is "markedly different" from DNA as it exists in nature, court finds that it constitutes statutory subject matter under Section 101.

In *Association for Molecular Pathology v. USPTO and Myriad Genetics*, 653 F.3d 1329, 99 U.S.P.Q.2d 1398 (Fed. Cir. 2011), the Federal Circuit, in a declaratory judgment action brought by the association, reviewed whether claims to isolated DNA and methods of screening a patient's predisposition to breast cancer using such isolated DNA recited unpatentable products of nature under 35 U.S.C. § 101. The district court held all of the claims to be non-statutory and also found that the plaintiffs had standing to bring the declaratory judgment action.

In reviewing the claims to the "isolated" genes, the court referred to the line drawn by the Supreme Court in *Chakrabarty,*[2] "between compositions that, even if combined or altered in a manner not found in nature, have similar characteristics as in nature, and compositions that human intervention has given 'markedly different,' or 'distinctive,' characteristics." 653 F.3d at 1351. In concluding that the claimed isolated DNA is "markedly, different," the court took inventory of all the properties that distinguished natural DNA from isolated DNA:

(1) "Native DNA exists in the body as one of forty-six large, contiguous

[1] *Radio Corp. of Am. v. Radio Eng'g Labs., Inc.*, 293 U.S. 1 (1934).

[2] *Diamond v. Chakrabarty*, 447 U.S. 303, 206 U.S.P.Q. 193 (1980).

DNA molecules. Each DNA molecule is itself an integral part of a larger structural complex, a chromosome. In each chromosome, the DNA molecule is packaged around histone proteins into a structure called chromatin, which in turn is packaged into the chromosomal structure"

(2) "Isolated DNA, in contrast, is a free-standing portion of a native DNA molecule, frequently a single gene. Isolated DNA has been cleaved (*i.e.*, had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule."

Id. at 1351. Based on these distinctions, the court held that "*BRCA1* and *BRCA2* in their isolated state are not the same molecules as DNA as it exists in the body; human intervention in cleaving or synthesizing a portion of a native chromosomal DNA imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA." *Id*. at 1352. Finally, the court distinguished isolated DNA from purified DNA, noting that:

> isolated DNA is not purified DNA. Purification makes pure what was the same material, but was previously impure. Although isolated DNA must be removed from its native cellular and chromosomal environment, it has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body. It has not been purified by being isolated.

Id.

Claims directed to methods of screening a tumor sample including "comparing" or "analyzing" sequences fall outside the scope of Section 101 because they claim only abstract mental processes.

In reviewing the claims directed to methods of "comparing" or "analyzing" sequences, the court found such methods "fall outside the scope of § 101 because they claim only abstract mental processes." *Id*. at 1355.

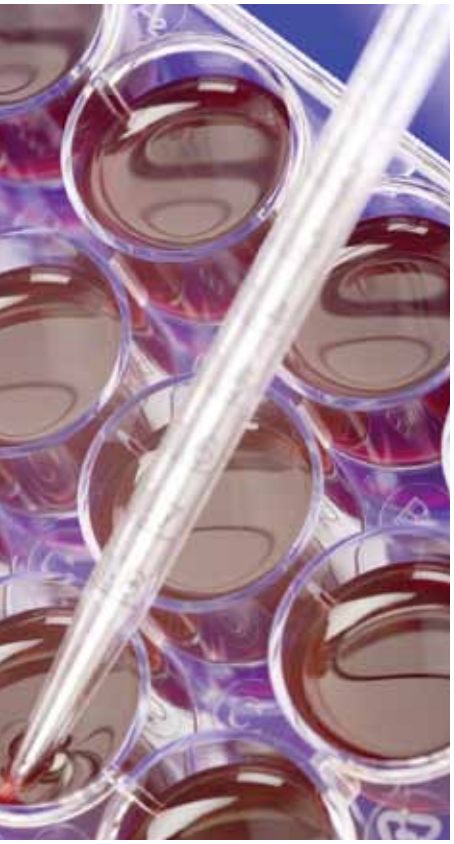
The court observed that the claim reciting a "method for screening a tumor sample," *id*. at 1344, by "comparing" a first *BRCA1* sequence from a tumor sample and a second *BRCA1* sequence from a nontumor sample, wherein a difference in sequence indicates an alteration in the tumor sample, "recites nothing more than the abstract mental steps necessary to compare two different nucleotide sequences. . ." *Id*. at 1356. Here, "Myriad's claims do not apply the step of comparing two nucleotide sequences in a process. Rather, the step of comparing two DNA sequences is the entire process claimed." *Id*. The court rejected Myriad's attempts to read into its method claims additional, transformative steps such as extracting DNA from a human sample and sequencing the *BRCA* DNA molecule, holding that "[t] he claims themselves . . . do not include either of these steps . . . Rather, the comparison between the two sequences can be accomplished by mere inspection alone." *Id*. at 1357.

Claims-directed to methods of screening cancer therapeutics via changes in cell growth rates are statutory under Section 101 because the method requires the transformative step of "growing cells."

Finally, the court reviewed Myriad's claims directed to a method for screening potential cancer therapeutics via changes in cell growth rates. Applying the machine-or-transformation test of *In re Bilski*,[3] the court held that the claim includes more than the abstract mental step of looking at two numbers and "comparing" two host cells' growth rates, but rather includes the steps of "growing" transformed cells in the presence or absence of a potential cancer therapeutic, an inherently transformative step involving the manipulation of the cells and their growth medium. The claim also includes the step of "determining" the cells' growth rates, a step that also necessarily involves physical manipulation of the cells.

The biotech community obviously breathed a sigh of relief when the court held that claims to isolated DNA do not recite mere products of nature beyond the purview of § 101. Even with respect to the invalidated process claims, it is clear that the problem was more one of claim drafting and construction rather

[3] 545 F.3d 943, 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008), *aff'd on other grounds sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010).



than a problem of statutory eligibility. Myriad itself tried to convince the court to read into its claims the steps of (1) extracting DNA from a human sample and (2) sequencing the *BRCA* DNA molecule. Although the court rejected this construction, it seems manifest, especially given the court's later discussion of *Prometheus*,[4] that recitation of such steps as well as recitation of the DNA as a chemical entity rather than as a sequence of letters on a piece of paper might have made the method claims patent-eligible.[5]

Court's rationale upholding the patentability of isolated DNA based on its having a "distinctive chemical identity," making it "markedly different" from natural DNA could potentially pave the way for the court to deny patentability for small molecules isolated from nature, which presumably are the same entities chemically.

The one disturbing aspect of this case that may prove problematic in the future is the somewhat fuzzy line the court seems to be walking between statutory subject matter on the one hand and obviousness on the other hand. In particular, the origins of the requirement that a molecule be "markedly different" from a natural molecule, as opposed to merely being different, stems from *Chakrabarty's* attempt to distinguish the earlier *In re Bergy*[6] case. However, *Bergy* dealt with obviousness of combining natural bacteria, not patent eligibility. Based on this court's past behavior in distorting and expanding precedent to change well-entrenched doctrines, the fear is that this case has laid the foundation for this court to later find that isolated small molecules, which presumably are the same in a natural environment as in isolated form, will no longer be viewed as statutory. Keep in mind that part of the court's rationale in finding isolated DNA to be statutory was its conclusion that isolated DNA has "a distinctive chemical identity" as compared to natural DNA. The admixing of obviousness precedent with statutory subject matter precedent by the Supreme Court and the Federal Circuit is a recipe for mischief that this court has proven all too willing to follow.

Claims reciting compiling data based on alternative immunization protocols for infants are statutory where such claims further recite immunizing infants based on a preferred immunization protocol, but are nonstatutory "data gathering" where the claims recite merely compiling data from alternative immunization schedules.

In *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 100 U.S.P.Q.2d 1492 (Fed. Cir. 2011), the court reviewed for patent eligibility Classen's claims based on the observation that there is a relation between the infant immunization schedule for infectious diseases and the later occurrence of chronic immune-mediated (noninfectious) disorders. The court reviewed two different types of claim sets:

1. A method whereby information on immunization schedules and the occurrence of chronic disease is ***"screened"*** and ***"compared,"*** the lower risk schedule is ***"identified,"*** and subjects are ***"immunized"*** by administering the vaccine on that schedule; and

2. A method whereby mammals in a treatment group are ***"immunized"*** according to a schedule, and the incidence, prevalence, frequency or severity of the disorder in the treatment group is ***"compared"*** with that in a control group.

659 F.3d at 1060-61. The noteworthy difference in the above claim sets is that claims of the second set do not include performing actual immunizations in accordance with the information learned by the claimed method. The district court found all the claims nonstatutory as directed to the "abstract idea" of a relationship between the infant immunization schedule for infectious

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[4] *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 97 U.S.P.Q.2d 1097 (Fed.Cir.2010), *cert. granted*, 131 S. Ct. 3027 (June 20, 2011) (No. 10-1150).

[5] On March 20, 2012, the Supreme Court decided the *Prometheus* case *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 101 U.S.P.Q.2d 1961 (U.S. Mar. 20, 2012), which found that Prometheus' methods were not statutory under Section 101. It is not believed that this will affect the patentability of Myriad's isolated DNA claims nor the claims reciting growing the cells. However, it is probably no longer the case that simply reciting active isolating and sequencing steps would render invalidated Myriad claims statutory.

[6] 596 F.2d 952, 201 U.S.P.Q. 352 (C.C.P.A. 1979), *dismissed as moot*, 444 U.S. 1028 (1980).

diseases and the later occurrence of chronic immune-mediated (noninfectious) disorders. On appeal, Classen argued that because all the claims include the physical step of immunization, they recite more than abstract steps occurring only in the mind.

On review after the Supreme Court's *Bilski* decision,[7] the Federal Circuit held that "[t]he [second set of] claims. . . are directed to the abstract principle that variation in immunization schedules may have consequences for certain diseases. In contrast, the claims of the [first set] require the further act of immunization in accordance with a lower-risk schedule, thus moving from abstract scientific principle to specific application." *Id*. at 1067-68. "As discussed in *Association for Molecular Patholog, supra,* methods that simply collect and compare data, without applying the data in a step of the overall method, may fail to traverse the § 101 filter. *Id*. at 1067. We conclude that the immunization step moves the [first set of] claims through the coarse filter of § 101, while the abstraction of the [second set of claims] is unrelieved by any movement from principle to application." *Id*. at 1068.[8]

Supreme Court agrees to review Mayo Collaborative Services v. Prometheus Laboratories, Inc.

For the fourth time, the *Prometheus* case will be adjudicated in a federal court. *Prometheus* claimed a personalized medicine method involving administering a drug (AZA or 6-MP) to a patient, detecting the level of that drug's metabolite (6-TG or 6-MMP) and, depending on the observed level of metabolite as compared to a predetermined level, adjusting the dose of the drug up or down. In its initial review, the Federal Circuit found that the method met its "machine-or-transformation" test because the steps of administering a drug and detecting the level of the drug's metabolite were necessarily transformative. After the Supreme Court's decision in *Bilski*,[9] the case was remanded to the Federal Circuit for reconsideration. Once again, the Federal Circuit held that the process was patent-eligible, holding that (1) "[w]hen administering a drug such as AZA or 6-MP, the human body necessarily undergoes a transformation. The drugs do not pass through the body untouched without affecting it" and (2) "determining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation, for those levels cannot be determined by mere inspection." *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336, 1346-47, 92 U.S.P.Q.2d 1075 (Fed.Cir. 2009).

The case is now under review by the Supreme Court. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 97 U.S.P.Q.2d 1097 (Fed.Cir.2010), *cert. granted*, 131 S. Ct. 3027 (June 20, 2011) (No. 10-1150). According to Mayo, Prometheus's patents recite a natural phenomenon—the biological correlation between metabolite levels and health—without describing what is to be done with that phenomenon beyond considering whether a dosage adjustment may be necessary. Because Prometheus's claims culminate with this open-ended "mental step," their "practical effect" is to "wholly pre-empt" use of the natural correlation with regard to any autoimmune disease. Brief for Petitioners at 33, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* No. 10-1150 (U.S. Sept. 2, 2011) (internal citations omitted). Mayo focused the Court on the fact that the so-called transformative steps of "administering" and "determining" are not the invention because they have been used for years. Rather, these steps are mere "data gathering" and "ordinary means of observing the natural correlation." *Id*. at 35.

For its part, Prometheus argued that the "point of novelty" approach advocated by Mayo, whereby the claims' physical steps should be disregarded because they were old in the art, was one that was "flatly rejected" by the Supreme Court in *Diamond v. Diehr*[10]. Prometheus also argued that there was no legal requirement as advocated by Mayo that the physical

[7] *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

[8] Whether Classen's first set of claims will survive the Supreme Court's 2012 *Prometheus* decision is clearly questionable Perhaps Classen can argue that steps of the process are in fact different in that the vaccines are administered at different time intervals which the prior art did not suggest. This remains to be seen.

[9] *Bilski*, 130 S. Ct. at 3218.

[10] 450 U.S. 175 (1981).

steps be "central" to the patents' purpose. Rather, Prometheus argued that "[t]his Court has made clear that a process must be evaluated for patent eligibility under § 101 as a whole." Brief for the Respondent at 1, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, No. 10-1150 (U.S. Oct. 31, 2011). Prometheus also pointed out that "the process's first two steps (administering thiopurines and determining metabolite levels) *standing alone* would constitute patentable 'process[es]' under §101." *Id*. at 28. Those steps do not become abstract or any less a "process" when they are combined and followed by an additional step that uses an algorithm to generate information useful for patient treatment.

It is hard to imagine that the Supreme Court would have granted certiorari in the *Prometheus* case had the Court been of the view that the Federal Circuit correctly decided *Prometheus* on remand after the Supreme Court's decision in *Bilski*.[11] If one starts with the premise that a reversal is forthcoming, then the question arises as to what doctrine the Court will apply. One possible solution is akin to what the Federal Circuit did in *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*,[12] where a patented method also relating to the administration of a known drug for a known purpose relied on the content of printed matter (instructing a patient to take the drug with food) as the point of novelty. There, the court found the process to be statutory under § 101 but nonetheless separated out the printed matter component of the claim from the rest of the claim and found the claim invalid for lack of novelty. Presumably, the Supreme Court could likewise separate out the correlation from the active steps and then find the claims unpatentable either for lack of novelty as the Federal Circuit did in *King* or for lack of statutory subject matter under § 101. While it would be foolhardy to predict which poison (§ 101 or § 102) the Court will apply to kill the patent, the end result will most likely be that the point of novelty must be a transformative step and not mere information gathering or manipulation.[13]

[11] This of course turned out to be the case.

[12] 616 F.3d 1267, 95 U.S.P.Q.2d 1833 (Fed. Cir. 2010).

[13] The Court indeed interjected the novelty inquiry into the analysis.

Anticipation/Obviousness

A component claimed as being present in a "stabilizing effective amount" in a composition is anticipated by the same composition including that same component even where the prior inventor did not appreciate the link between that component and stability.

In *Teva Pharmaceuticals Industries Ltd. v. AstraZeneca Pharmaceuticals LP*, 661 F.3d 1378, 100 U.S.P.Q.2d 1852 (Fed. Cir. 2011), the court reviewed the validity of Teva's claim directed to statin formulations including "a stabilizing effective amount" of an amido-group containing polymeric compound ("AGCP compound") or by an amino-group containing polymeric compound. 661 F.3d at 1380, 1384. At issue was whether AstraZeneca's ("AZ") earlier development of the accused CRESTOR® drug (" the AZ drug") formulation satisfied the requirements for prior invention under 35 U.S.C. § 102(g)(2) against Teva.

The district court concluded that the prior invention of the AZ drug anticipated Teva's claims even though AZ did not appreciate the stabilizing effect of crospovidone (the AGCP compound), explaining that "an appreciation of the stabilizing effect of crospovidone by [AZ], as opposed to its appreciation of the stabilization of its overall pharmaceutical composition that contained crospovidone, was not required." *Id*. at 1381 (quoting *Teva Pharmaceutical Industries Ltd. v. AstraZeneca Pharmaceuticals LP*, 748 F. Supp. 2d. 453, 469 (E.D. Pa. 2010)). On appeal, the Federal Circuit framed the issue as whether AZ "had to understand that crospovidone stabilized its drug in order to win a priority dispute under § 102(g)(2)." *Id*. at 1382.

In resolving this question, the court first restated the law on reduction to practice as (1) requiring construction of an embodiment that met all the claim limitations and (2) determining that the invention would work for its intended purpose. The court then distinguished the requirement that the inventor "appreciate" that the invention work for its intended purpose from any requirement that the inventor describe the invention "using the same words as the

patentee would later use to claim it." *Id*. at 1384. The court found that AZ needed to appreciate only that the compound it asserted as its invention was stable and what the components of this formulation were. AZ did not "need to appreciate which component was responsible for the stabilization . . . in the same words in which Teva later chose to claim it." *Id*. at 1385. The court distinguished earlier cases such as *Invitrogen*,[14] noting "that when [AZ] made the claimed invention first, it did so not by accident and it knew what it had made."[15] *Id*.

This case stands for the proposition that "appreciation" requires that one know that an invention works for its intended purpose – it does not require that one understand ***how*** or ***why*** it works. If the rule were otherwise, one could simply avoid prior invention by making an observation about a particular teaching that had not been previously made. The other issue that played against Teva here is the fact that AZ admitted infringement. Without expressly stating so, the court seemed to rely on the maxim of "that which infringes if later, anticipates if earlier." So it is logical that if it is not necessary to know the role of a claim element in an overall composition for that composition to infringe, it should likewise not be necessary to understand the role a component plays in the prior art for that art to anticipate.

A tale of two Federal Circuits: one that holds that uses absolutely cannot be read into a product claim and the other that holds that uses absolutely must be read into a product claim.

Because it is improper to read unclaimed properties into a product claim, a claim directed to a formulation containing 6-8 milligrams of a drug is obvious over the prior art showing a range of 5-15 milligrams even if that use was unobvious.

In *Tyco Healthcare Group LP v. Mutual Pharmaceutical Company, Inc.*, 642 F.3d 1370, 99 U.S.P.Q.2d 1212 (Fed. Cir. 2011), the court reviewed the validity of two claims directed to temazepam formulations used for inducing sleep. Tyco claimed the formulation as a hard gelatin capsule containing a temazepam formulation "consisting essentially of 6 to 8 milligrams of crystalline temazepam . . . in admixture with a pharmaceutically acceptable carrier therefor." 642 F.3d at 1371. The other claim at issue specifically recited 7.5 mg of the drug.

The district court concluded that Tyco's claims to the 6 to 8 mg formulation were obvious in view of (1) prior art Restoril® capsules containing 15 mg of temazepam in the capsule in view of (2) the British National Formulary ("BNF") reference that taught that temazepam should be administered to elderly patients at a dose of 5-15 mg. On appeal, Tyco argued that its formulation claims should be read so as to include their properties. *Id*. at 1373 ("the properties of a composition of matter relevant to patentability must be considered in evaluating whether that composition would have been obvious in light of the prior art"). It thus argued "that the unclaimed property of effectiveness in treating insomnia renders the claims at issue nonobvious." *Id*. The Federal Circuit found that argument to be "unavailing," holding that "[t]he discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to the known composition." *Id*. Accordingly, the claimed formulation was obvious even in the absence of documentation in the BNF of the effectiveness of such dosages.

Court rejects "teaching away" argument regarding claims to a temazepam formulation with a particular dosage because claim did not exclude elderly patients for whom teaching away did not apply.

The court also rejected Tyco's argument that the prior art taught away from the claimed formulation. The court found that none of the references cited by Tyco studied the effects of temazepam on elderly patients and concluded that "[e]ven if the references cited by Tyco could be viewed as teaching away from the use of 7.5 mg temazepam capsules generally, it would not cast doubt on the BNF reference's dosage range for elderly patients." *Id*. at 1376. The court rejected Tyco's reliance on unexpected results

[14] Invitrogen *Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 77 U.S.P.Q.2d 1161 (Fed. Cir. 2005).

[15] The alleged prior inventors in *Invitrogen* were unaware that they had accidentally created two genes encoding RNase H minus reverse transcriptase.

purporting to show that the drug would not be effective on transient insomnia, holding that "since the products disclosed by the claims at issue are not limited to treatment for transient insomnia, that statement is of little relevance to the question whether 7.5 mg capsules were unexpectedly effective." *Id*. at 1377.

The court's holding that it is not proper to consider the use or property of a claimed formulation to distinguish the prior art is interesting in view of last year's decision in *Sun Pharmaceutical Industries Ltd. v. Eli Lilly & Co.*,[16] in which the court held that "where a patent features a claim directed to a compound, a court must consider the specification because the disclosed uses of the compound affect the scope of the claim for obviousness-type double patenting purposes."[17] In the 2010 Year in Review, we made the observation, in reference to the *Lilly* case, that

> "[t]he intellectual dishonesty here is that the court is construing the same claim differently depending on the context in which the construction is carried out—without regard to the uses when construing the compound in view of the prior art but with regard to the uses when construing the claim as prior art in the obviousness double patenting context.[18]"

Given that the whole point of double patenting is to prevent extension of patent term for a nonobvious later claim, how does this court conclude that a claim to a product that *Tyco* says DOES NOT include its uses or properties get improperly extended by a later method claiming that use or property? In addition, because of the statutory presumption of validity, it would seem that if the court were to afford two different constructions to the same claim, it would afford the construction that preserves validity when using that construed claim as a reference in a double patenting rejection. It makes no sense.

We continue to believe that the court departed from precedent in the *Lilly* case (as did a number of judges in the *en banc* request, which was denied) and that it should consistently construe product claims without reading uses and properties into the claims. It will be interesting if there is a case where the same claim is both reviewed in view of the prior art and used as the basis of a double patenting rejection against a later patent. If such a case arises, this court will find itself in the embarrassing predicament of having to afford two different constructions to the exact same claim, both in a patentability context.

For drug formulations designed to mimic a formulation already approved by the FDA, the court establishes a "reference composition" framework whereby the obviousness of the claimed mimicking composition must be assessed by comparing it to the FDA-approved reference composition.

In *Unigene Laboratories Inc. v. Apotex, Inc.*, 655 F.3d 1352, 99 U.S.P.Q.2d 1858 (Fed. Cir. 2011), the court reviewed the validity of Unigene's patent covering Fortical®, an FDA-approved nasal spray with salmon calcitonin as active ingredient as well as 20 mM of citric acid (absorption enhancer and stabilizer/buffer). The closest prior art was Miacalcin®, which also contained salmon calcitonin as the active ingredient but which used benzalkonium chloride ("BZK") (preservative, absorption enhancer, and surfactant) rather than citric acid.

Referring to its precedent, the court made reference to its "lead compound" approach for assessing the obviousness of a novel compound over prior art compounds and concluded that a similar analysis should apply to FDA-approved formulations. Thus, just as the obviousness of a chemical compound is assessed by comparing it to the lead compound or compounds in a prior art teaching (the lead compounds being the most characterized or the ones providing the best properties as opposed to the structurally closest), the court should assess the obviousness of an FDA-approved formulation by comparing it to the previously approved formulation it was made to mimic, i.e., the "reference composition" 655 F.3d at 1361-62. ("In the context of a composition or formulation patent where the patented formulation was made to mimic a previously

[16] 611 F.3d 1381, 95 U.S.P.Q.2d 1797 (Fed. Cir. 2010).

[17] 611 F.3d at 1387.

[18] Robert M. Schulman, Jeff B. Vockrodt & David A. Kelly, Pharmaceutical, Chemical and Biotech Year in Review 2010 (2011).

FDA-approved formulation . . . the term 'reference composition' is more appropriate than 'lead compound' when considering obviousness for a chemical composition that the infringer deliberately imitates.")

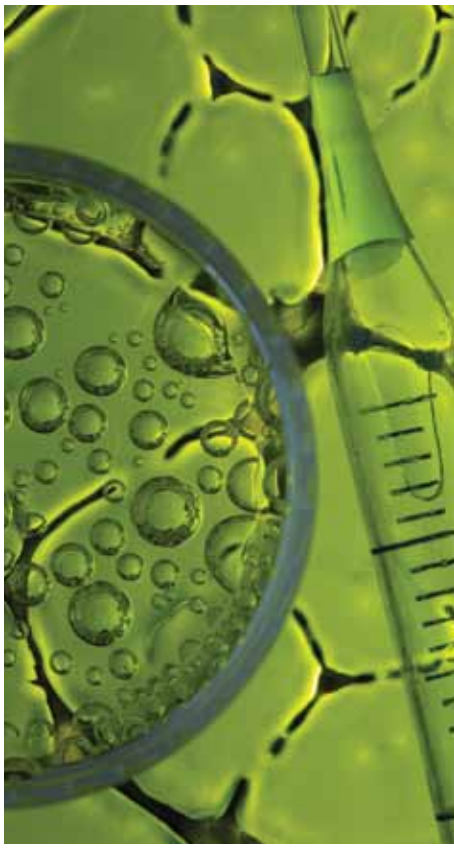
The fact that an applicant can obtain more rapid FDA approval by designing a formulation that mimics a reference composition already approved by the FDA provides the requisite reason or motivation to modify the reference composition to obtain the claimed composition.

Using Miacalcin® as the "reference composition," the court addressed whether it would have been obvious to substitute the BZK of the reference composition with the citric acid of the claimed composition. The court found that a person of ordinary skill would have had reasons—specifically, design need and market demand—to create an FDA-approved liquid nasal composition that delivers salmon calcitonin and is bioequivalent to Miacalcin®, knowing that a bioequivalent of Miacalcin® would have the best chance to gain FDA approval quickly because it could use the abbreviated drug application procedure.

Court finds that aspects of invention that teach away from adding citric acid to active component outweigh the fact that prior art found a ten-fold increase in active availability with only a five-fold increase in citric acid concentration.

Despite the fact that there was a reason to find a bioequivalent formulation to Miacalcin®, the court concluded that the prior art did not specifically provide a reason or motivation to substitute BZK with citric acid in the claimed liquid nasal salmon calcitonin composition. Although one reference disclosed a ten-fold increase in salmon calcitonin bioavailability caused by a mere five-fold increase in citric acid concentration, the court rejected such teaching because (1) the reference relates to a solid formulation and not a liquid as claimed; (2) the reference employed amounts of citric acid much higher than the claimed amount; and (3) the disclosed bioavailability with citric acid did not relate to human use in a liquid pharmaceutical formulation. The court thus concluded that "[t]o a person of ordinary skill in the art, citric acid, even at about 20 mM concentrations, would not be an obvious substitute for BZK's functions as an absorption enhancer and as a surfactant because citric acid has a vague role in even the closest prior art." *Id*. at 1363. Another reference disclosed the claimed concentration of citric acid in a liquid nasal salmon calcitonin formulation but nonetheless made clear that citric acid was not used as an absorption enhancing agent, but as the acidic component of the buffer. The court also found that the other reference taught away from the claimed formulation because it referred to an additional patent that itself listed more than 50 examples, including citric acid, but reported discouraging results for all of those examples except for ammonium tartrate.

This case has three interesting takeaways. First, when looking at the obviousness of a chemical formulation designed to mimic an already-approved FDA formulation, the obviousness analysis must start by comparing the mimicking formulation with the already-approved formulation or "reference composition." Second, the fact that mimicking an already-approved formulation will provide an easier process through the FDA seems, by itself, to be sufficient reason or motivation to modify such approved formulation. Finally, this case is yet another page in the very confusing chapter that the Federal Circuit is writing when assessing the obviousness of an invention where the prior art simultaneously suggests the invention and teaches away from the invention. We have counted at least four such cases — *Bayer Schering Pharma*[19], *Eli Lilly*,[20] *Billups-Rothenberg*,[21] and the present case, — and so far the score is 2-2.[22] If there is a distinguishing thread explaining why two cases went for the patentee and two went for the infringer, it is not one that the author has been able to glean.

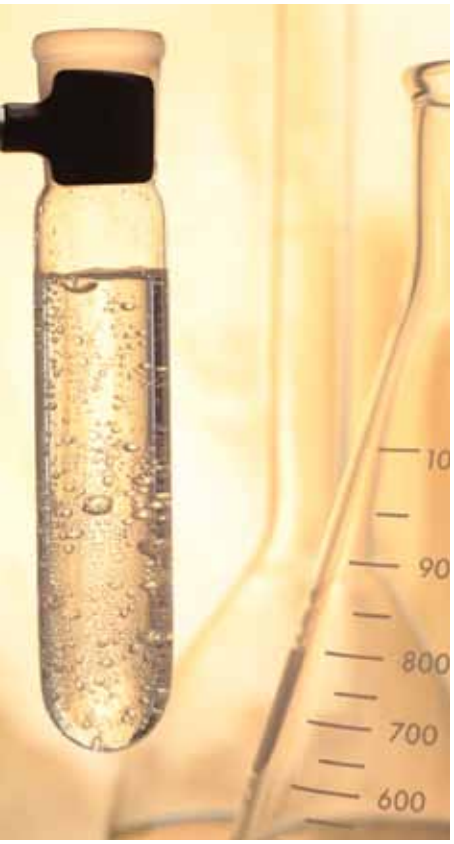


[19] *Bayer Schering Pharma AG v. Barr Labs., Inc*., 575 F.3d 1341, 91 U.S.P.Q.2d 1569 (Fed. Cir. 2009).

[20] *Eli Lilly & Co. v. Teva Pharm. USA, Inc*., 619 F.3d 1329, 96 U.S.P.Q.2d 1375 (Fed. Cir. 2010).

[21] *Billups-Rothenberg, Inc. v. Associated Reg'l & Univ. Pathologists, Inc*., 642 F.3d 1031, 98 U.S.P.Q.2d 1578 (Fed. Cir. 2011),

[22] In the *In re Brimonidine Litigation*, 643 F.3d 1366, 98 U.S.P.Q.2d 1878 (Fed. Cir. 2011), discussed *infra*, the court reviewed two such red light/green light situations and found that one rendered the claim at issue obvious whereas the other did not, so the tie remains.



Claimed truncated Factor VIII excluding amino acids 740 to 1649 found nonobvious over truncated Factor VIII excluding amino acids 740 to 1690 even though prior art disclosed restriction enzyme cutting at 1649 because there was no reason to make cut there and art generally sought smaller, not larger, fragments.

In *Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc*., 655 F.3d 1291, 99 U.S.P.Q.2d 1713 (Fed. Cir. 2011), the court reviewed the validity of Novartis's claims reciting a truncated Factor VIII protein and DNAs encoding such protein as well as cells and methods producing the protein. At issue was whether Genetics Institute's ("GI ") claims interfered-in-fact with (i.e., anticipated or rendered obvious) Novartis's claims such that GI could rely on its alleged prior invention to invalidate the Novartis claims.

In carrying out its interference-in-fact analysis between the Novartis claims and the GI claims, the court focused on the fact that GI's claim permitted deletions between amino acids 740 and **1690** whereas Novartis's claim permitted deletion of a smaller fragment corresponding to amino acids 740 to **1649**. At the time of the invention, the prior art taught that the region of Factor VIII between amino acids 740 and 1689, corresponding to the "B domain" region, were inactive and therefore all or part of such domain could be deleted without affecting the desired activity of Factor VIII protein. As it turned out, however, the region between 1649 and 1689 that GI's claim permitted to be deleted but Novartis's claim required to be present, was not part of the inactive B domain but actually formed part of a critical "a3 region" of the C domain of the protein.

The court held that GI failed to establish any reason for modifying the GI-claimed protein group to produce the group claimed by Novartis because "those of skill in the art understood the inactive B domain of the Factor VIII protein to be 'essentially delimited by residues 740 and 1689'—i.e., to include the amino acids in the a3 region. … [T]he 1649–1689 amino acid region was understood to be part of the B domain." The court also rejected GI's argument that because "amino acid 1649 was one of the known in vivo cleavage sites on the Factor VIII protein … it 'would be readily apparent' to make a truncated Factor VIII protein that retained amino acids in the 1649–1689 region." The court noted that (1) it was not known "that amino acids 1649–1689 were critical to maintain vWF binding" and (2) GI offered "no basis for its assertion that the mere existence of in vivo cleavage points between particular amino acid residues would have provided one of ordinary skill with a reason or motivation to make the particular truncated proteins claimed" by Novartis. The court also found that GI's arguments required an enlargement of its protein by one of ordinary skill in the art to obtain Novartis's protein but this ran "contrary to the research objectives of those in the field of truncated Factor VIII proteins," where the focus is to find *smaller* fragments mimicking " 'the biological activity of Factor VIII in humans.' "

Evidence of unexpected results can rebut a prima facie case of obviousness even if evidence not available or not expressly contemplated or appreciated at the filing of the patent application.

The court also rejected GI's contention that because Novartis did not know the importance of the a3 region to vWF binding as of its filing date, Novartis could not properly rely upon the retention of the a3 region in its claimed proteins and their corresponding ability to bind vWF to demonstrate the unexpected results of those proteins. The court noted its precedent, stating that "the structure of a claimed compound and its properties are inseparable for purposes of § 103." 655 F.3d at 1307. Further, "every property of a claimed compound need not be fully recognized as of the filing date of the patent application to be relevant to nonobviousness." *Id*. Accordingly, the court held that "evidence of unexpected results may be used to rebut a case of *prima facie* obviousness even if that evidence was obtained after the patent's filing or issue date." *Id*. The court concluded that "it would be error to prohibit a patent applicant or patentee from presenting relevant indicia of nonobviousness, whether or not this evidence was available or expressly contemplated at the filing of the patent application." *Id*. Consequently, it was not error to consider, "as evidence

of unexpected results, the ability of the claimed proteins to bind vWF, even if, as [GI] contends, the role of the a3 region was not appreciated as of the '620 patent's priority date." *Id*. at 1308.

Although a showing of unexpected results must be commensurate in scope with the claims, such showing does not require exact identity of scope; therefore a single point within the claim that does not provide the result does not defeat the general showing.

GI further argued that Novartis's proffered unexpected results are not commensurate with the full scope of its claims because the Novartis patents permit amino acid substitution that may reduce or eliminate vWF binding. GI pointed to evidence demonstrating that the substitution of the amino acid phenylalanine for tyrosine at position 1680 in the a3 region eliminated vWF binding but retained procoagulant activity in the resulting B-domain deleted protein. The court seemed to dismiss this data point as an outlier, holding that,

> even taking [GI's] assertions as true," this evidence demonstrates at most that one particular amino acid substitution at one particular position eliminates vWF binding—in a claimed truncated protein of between 1,424 and 1,444 total amino acids. This solitary fact does not undermine the district court's decision to credit the vWF binding properties of the proteins claimed in the Novartis patents—properties that [GI] itself concedes are possessed by truncated Factor VIII proteins retaining the a3 region.

Id. The court noted that "[w]hile we have held that unexpected results must be commensurate in scope with the claims, we have not required absolute identity of scope; rather, we have rejected unexpected results where the evidence was plainly disproportionate to the scope of the claim." *Id*.

To establish obviousness of one amino acid sequence in view of a prior art amino acid sequence, the prior art must provide a reason to delete a particular amino acid region

The court next addressed whether GI's patent claiming the Factor VIII protein deleting the complete B domain (909 amino acids) rendered obvious Novartis's claim to three specific proteins, two of which have smaller deletions (581 and 880 amino acids) and one of which has a ***larger*** deletion (915 amino acids) than the B domain. The larger deletion ranges from amino acid 759 to 1675, which includes part of the a3 acidic region. The court held that GI failed to present evidence showing why one of ordinary skill would modify the GI protein to make the three different Novartis proteins. "Common sense dictates that 'want[ing] to delete' a particular amino acid region implies that a reason must exist for that deletion." *Id*. at 1310. Here, the court found that GI failed to identify "some reason why one of ordinary skill would make the necessary chemical modifications to arrive at the claimed compound," *id*., noting that a researcher intent on designing a new truncated Factor VIII protein would first identify the amino acid regions he or she wished to delete, and only then would consider particular protein design strategies.

The most significant aspect of this case is that it represents a very significant departure from precedent in that the court is now holding that "it would be error to prohibit a patent applicant or patentee from presenting relevant indicia of nonobviousness, whether or not this evidence was available ***or expressly contemplated*** at the filing of the patent application." *Id*. at 1307 (emphasis added). While it was always permitted to supplement an allegation of unexpected results with additional evidence, even generated post-filing, it had never been the case that the unexpected result did not have to be "contemplated at the filing of the patent application." *Id*. The court here is confusing evidence demonstrating an unexpected result (which could always be generated post-filing) with the recognition or contemplation of an unexpected result (which always had to be recognized as of the filing). It will be very interesting to see if this holding trickles down to the examination corps at the PTO.

The other curious aspect of this case is that Novartis identified and claimed the critical amino acid corresponding to where a3 began, unlike GI, but apparently did not specifically state what its significance

was (bonding to vWF). It would be an extraordinary coincidence if Novartis happened upon such specific position without there having been some recognition.

Prior art's teaching away, due to eye irritation, from using SCD (stabilized chlorine dioxide) as the sole preservative in an ophthalmic solution does not undercut the force of its disclosure, suggesting the invention as well as a prophetic example in another reference.

In *In re Brimonidine Patent Litigation*, 643 F.3d 1366, 98 U.S.P.Q.2d 1878 (Fed. Cir. 2011), between Allergan as the patent holder and Apotex and Exela PharmSci, as the ANDA filers, the court reviewed the validity of five Allergan patents listed in the Orange Book that protect its glaucoma drug, Alphagan® P. The first patent is directed to a sterilized ophthalmic solution at physiologic pH and osmolality. The other four "related patents," are directed to medicated ophthalmic solutions. Apotex's and Exela's ANDAs sought approval for a generic version of Alphagan® P in the 0.1% and 0.15% brimonidine concentrations.

The first patent claimed a method for preserving an aqueous ophthalmic solution by incorporating into it (1) an amount of stabilized chlorine dioxide ("SCD") sufficient to serve as the sole preservative, (2) an ophthalmically acceptable buffer component effective to maintain a pH range of about 6.8 to 8 and (3) an ophthalmically acceptable tonicity component effective to maintain an osmolality of at least 200 mOsmol/kg. Apotex cited two references, Stockel and Ratcliff. The court found that Ratcliff disclosed the use of SCD as the sole stabilizer in an ophthalmic solution but did not specify the claimed pH range or include a buffer and tonicity component. However, because Stockel discloses SCD as a preservative in an ophthalmic solution and teaches that it is desirable to make the solution isotonic and to include other materials commonly used in contact lens solutions such as buffering, chelating and thickening agents, the court concluded that the invention would have been obvious.

In finding the claims of the first patent obvious, the Federal Circuit reversed the district court's holding that the secondary reference Stockel taught away from using SCD "as the sole preservative" as required by the claims. In particular, the district court cited a passage from Stockel indicating that the use of SCD as the sole antimicrobial agent would require amounts of SCD that would irritate the eye. Stockel thus required use of a preservative in addition to SCD. In response, the Federal Circuit found that "Stockel's teachings with respect to the required quantity of SCD do not undercut the force of its disclosure that maintenance of a physiologic pH and osmolality by use of buffer and tonicity components would have been simple and well-known modifications." 643 F.3d at 1371. The court further noted that Ratcliff discloses that SCD can be used as an effective sole preservative for an ophthalmic solution.

This case presents yet another example of prior art both suggesting and teaching away from the invention. The court here acknowledged the teaching away in Stockel but concluded that it was "undercut" by the force of the rest of its disclosure. To the extent it was a close call, the court seemed to resolve the doubt against Allergan because the Ratcliff reference included an example using SCD as the sole preservative. The problem with this is that Ratcliff was primarily directed to mouthwashes and only had a single prophetic example of the use of SCD in an ophthalmic preparation with no details about the other claim limitations. Accordingly, it appears here that the court gave more weight to an example that was prophetic and silent on eye irritation than it gave to a teaching away that presumably was based on an actual observation of eye irritation when SCD was used as the sole preservative. It is hard to believe that the statutory arbiter of obviousness, one of ordinary skill in the art, would let a prophetic example trump an actual observation.

The fact that it was known in the art that the use of two formulations separately was therapeutically effective does not suggest that they would be compatible and effective if combined into a single solution.

The court next assessed the obviousness of the four "related patents" directed to an aqueous solution including brimonidine in an amount effective to provide a therapeutic

benefit, CMC as a solubility-enhancing component, and a chloride such as SCD as a preservative. The district court found that one of ordinary skill in the art would not have turned to CMC as a solubility enhancer. On appeal, Apotex argued that the claims read on a combination of two Allergan products: Alphagan® (brimonidine) and Refresh Tears®, which "is a non-medicated eyedrop adjusted to a pH of 7.2 to 7.9," including "SCD as a preservative and CMC as a viscosity agent." In holding that it would not have been obvious to combine the two formulations, the court found that "[t]wo ingredients might be therapeutically effective when used separately as part of an overall treatment regimen, yet be incompatible or ineffective when combined in a single solution." *Id*. at 1374.

The fact that prior art teaches that CMC solubilizes cyclodextrins and "most of the drugs tested" does not make the use of CMC to solubilize brimonidine obvious, absent expert testimony or other evidence.

Apotex also appealed the district court's holding that the prior art (1994 and 1997 articles by Loftsson) do not disclose or suggest the use of CMC to solubilize any α-2 adrenergic agonist, let alone brimonidine. The Loftsson articles "tested the effect of polymeric solubility enhancers, including CMC, on the water solubility of cyclodextrin–drug complexes." While acknowledging the Loftsson articles did not discuss use of CMC with brimonidine or even the generic class of α-2-adrenergic agonists, Apotex relied on Loftsson's general "statement that 'the addition of a very small amount of [CMC] resulted in a significant increase in the aqueous solubility of "most of the drugs tested.'" This, according to Apotex, made it obvious to use CMC to solubilize brimonidine. The court rejected this argument, holding that "Apotex provided no expert testimony or other evidence to support that proposition, and the generalization made by counsel on appeal does not undermine the district court's contrary determination following the trial." *Id*.

Despite prior art showing that the active agent was stable for 120 hours in the presence of a strong antioxidant such as hydrogen peroxide, court accepts expert testimony that those skilled in the art would have concluded that strong antioxidants such as claimed SCD would break down the active agent.

Finally, Apotex challenged the district court's holding that one skilled in the art would not have combined Refresh Tears® and Alphagan® because of concerns that SCD would oxidize brimonidine. Despite Apotex's citation of a reference showing that brimonidine was stable for 120 hours even when exposed to hydrogen peroxide (a stronger oxidant than SCD), the district court dismissed such reference as teaching nothing about the oxidative stability of brimonidine in a formulation such as Allergan's Purite® which " 'needs to be shelf-stable for two years.' " On appeal, the Federal Circuit acknowledged Apotex's argument that the district court improperly imported a two-year shelf-stability limitation into the claims and used that limitation to avoid the teachings of the prior art. Nonetheless, the court found persuasive the testimony of Allergan's expert that Purite® was known as a strong oxidant, which would have made one skilled in the art extremely hesitant, if not directed away, from formulating brimonidine with a chlorite compound such as Purite®. The court held that "[w]hile we recognize that hydrogen peroxide may be a stronger oxidant than the SCD in Purite®, the fact that Allergan touted Purite® as being less reactive than hydrogen peroxide does not establish that one skilled in the art would not have expected SCD to oxidize brimonidine." *Id*. at 1375.

The part of this case that is the most difficult to understand is why the oxidation effect of SCD on brimonidine crossed the proverbial "teaching away" line in the context of one set of claims, but the irritation effect of SCD being used as the sole preservative did not with another set of claims. Indeed, the prior art relied upon to negate the teaching away in the former situation was arguably stronger than that relied upon in the latter situation. In the former situation, the expectation that brimonidine would break down in the presence of SCD oxidant was based on expert testimony, and the evidence used to repudiate that expectation was based on an actual observation showing that an oxidant stronger than SCD did not break it down. By contrast, the expectation that eye irritation

would result from the use of SCD as the sole preservative in an ophthalmic solution was based on an actual observation, whereas the evidence used to repudiate that expectation was based on a prophetic example. For some reason, the court seems ill-equipped to give proper weight to conflicting evidence in those instances where the art provides both a teaching away, and a suggestion of, the invention.

The process for preventing formation of nitrosamines on tobacco plants by providing an airflow free of combustion gases and preventing an anaerobic condition not obvious where prior art did not establish nexus between airflow and activation of enzymes leading to TSNA formation.

In *Star Scientific, Inc. v. R.J. Reynolds Tobacco Company*, 655 F.3d 1364, 99 U.S.P.Q.2d 1924 (Fed. Cir. 2011), the court reviewed the obviousness of Star's claims reciting a process of substantially preventing formation of nitrosamines in harvested tobacco plants. The process claimed drying the plants in a "controlled environment" comprising "air free of combustion exhaust gases and an airflow sufficient to substantially prevent an anaerobic condition around the vicinity of the plant portion." The "controlled environment" includes "controlling at least one of humidity, temperature, and airflow."

Reynolds argued that the claims were obvious in view of a combination of two prior art references, Tohno and Wiernik. Wiernik recognized that tobacco-specific nitrosamines (TSNAs) form from high humidity, optimal temperature, and oxygen deficiency (anoxia). Tohno taught that increased airflow helps avoid an oxygen-deficient condition and results in faster curing and less malodor. On appeal, the court noted that that Wiernik taught only that nitrites leading to TSNA production ***may*** be produced under the right conditions of humidity, temperature and anoxia when nutrients are made available to microorganisms through cell death. The court further noted that Tohno does not mention TSNAs and critically does not provide a link between the oxygen levels (inherent in increasing airflow) and activation of the enzymes leading to TSNA formation. Such "speculative and tentative disclosure of what 'might' or 'may' lead to nitrite and TSNA production does not sufficiently direct or instruct one of skill in this art." 655 F.3d at 1376. The court thus found that there was no "motivation to combine an article on remedying a foul odor in tobacco with a summary of studies about TSNA formation." *Id*. The court also found that even if combined, the references fail to teach the recited step of curing with "air free of combustion gases." *Id*.

Long-felt need is established by fact that industry had sought to reduce TSNA levels in tobacco for decades and unexpected results are established by interest shown by other tobacco companies.

The court found secondary considerations supporting nonobviousness, including a substantial need in the industry for curing methods that minimized or eliminated the formation of TSNAs. The court noted that the record "showed decades of unsuccessful attempts at reducing TSNA levels to the extent achieved by" the patents. *Id*. The record also evinced unexpected results that met a long-felt industry need, as evidenced by great interest in the invention by other tobacco companies when the inventor presented the invention at a conference. Finally, the court cited to licensing royalties paid to patentee as further evidence that the invention had achieved considerable market acceptance and commercial success.

It appears it was really a combination of two facts that carried the day for Star. First, although the prior art reported formation of TSNAs under an anoxic condition, the court was clearly troubled by the fact that the art said only that TSNAs "may" form. Second, while the secondary reference clearly taught the desirability of an airflow for faster curing and for preventing malodor, it did not establish a nexus between airflow and deactivation of the enzymes leading to TSNA formation.

In several cases decided over the course of 2011, the court appears to be signaling to the United States Patent and Trademark Office Board of Appeals and Interferences ("Board") that it is going to look at its factual findings and legal conclusions with greater scrutiny.

Court remands case back to...the Board, based on the Board's erroneous... erroneous derivation of a ratio between a paddle method value and a basket method value for controlled release and application of that ratio to the prior art.

In *In re Kao*, 639 F.3d 1057, 98 U.S.P.Q.2d 1799 (Fed. Cir. 2011), the court reviewed the decision by the Board affirming the examiner's obviousness rejections of the claims in three applications owned by Endo Pharmaceuticals and directed to controlled-release tablets containing the opioid narcotic oxymorphone.

The first application claims a controlled release tablet comprising oxymorphone or its salt with a 12-hour dosing interval. Kao claimed its controlled-release aspect in terms of a USP paddle method such that, under the recited conditions, about 15 percent to about 50 percent of the drug is released from the tablet after one hour. The primary reference disclosed all the recited limitations with the exception of the claimed dissolution rate. The Board relied on an example ("Formula 6") differing from the claims in its use of oxycodone instead of oxymorphone and in its use of the USP basket method, not the claimed USP paddle method. Because the reference identifies oxymorphone as a preferred opioid, the Board concluded that it would have been obvious to replace the oxycodone in Formula 6 with oxymorphone. The Board also cited Endo's own declaration against it as establishing a correlation of 1.3 between the basket and paddle methods. Applying that correlation to Formula 6, the Board concluded that Formula 6 satisfied the claimed dissolution profile and that substitution of oxymorphone for oxycodone in Formula 6 would result in an oxymorphone controlled-release pill with a dissolution profile as claimed.

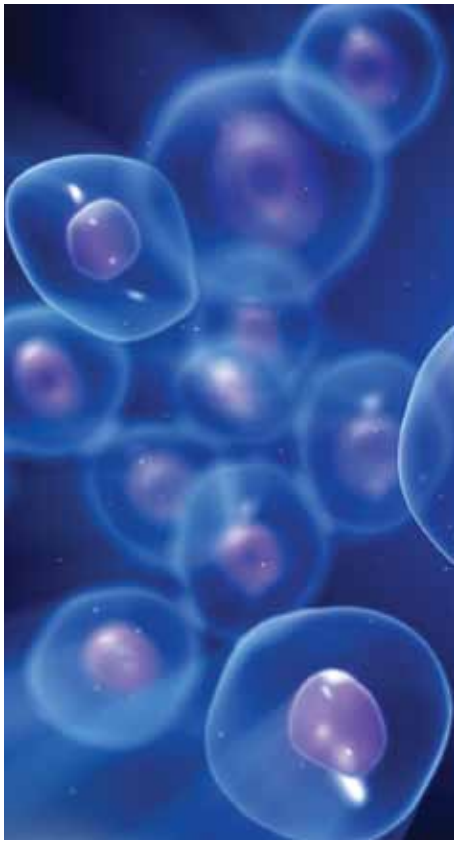
On appeal, the court found that it was error for the Board to derive a 1.3 ratio between the basket and paddle dissolution methods based on a single example reported in Endo's declaration. The court noted that "the declarant responsible for the exhibit expressly stated that there is no general correlation between the Basket and Paddle Methods and cited prior art literature that supported this conclusion." 639 F.3d at 1067. Thus, "[t]he Board's own conjecture does not supply the requisite substantial *evidence* to support the rejections." *Id*. The court therefore vacated and remanded "so that the Board can consider whether, under the proper analysis, the evidence of record is sufficient to maintain an obviousness rejection." *Id*.

Court remands to Board on question of showing of unexpected results to determine whether a nexus exists between some aspect of the claim not already in the prior art, such as dissolution rates, as against prior-art dissolution rates.

The court also reviewed the Board's holding that Endo failed to show unexpected results. The Board acknowledged Endo's evidence that it obtained unexpected multiple peaks in oxymorphone blood concentration, but concluded that such evidence related to Endo's specific commercial embodiment and therefore was not commensurate with the claim scope. On review, the court noted that Endo's expert declaration demonstrated that the claimed extended-release formulations of oxymorphone cause multiple peaks in oxymorphone blood concentration independent of any specific excipient. The court held that "[b]ecause the Board ignored the evidence of record and relied instead upon its own conjecture, its treatment of Endo's argument regarding unexpected results was improper." *Id*. at 1069. The court directed the Board, on remand, to

> determine whether there is a nexus between the unexpected in vivo concentration profile and aspects of the claimed invention not already present in the prior art. More specifically, for the unexpected *in vivo* concentration profile of the applicant's product to have substantial weight, there must be a nexus to some aspect of the claim not already in the prior art, such as the claimed range of dissolution rates, as against other unclaimed prior art dissolution rates.

Id. This case is somewhat puzzling. Other than reciting the oxymorphone or its salt as the active, and generically reciting an excipient, the rest of the claim is completely functional, relating to its release profile. Accordingly, if compared to an



immediate- release oxymorphone, the point of novelty is the purely functional-release profile. On the other hand, if compared to Formula 6 in the primary reference, the only difference is the use of oxymorphone rather than oxycodone and possibly the release profile. In other words, the point of novelty over the prior art appears to be a purely functional recitation divorced from any structural requirements. The court was probably right in its remand requiring a focus on what is actually novel structurally. It is also interesting that the examiner and the Board did not require more structure under either the enablement or written description requirements. A legitimate question to ask is whether it should really be necessary for an applicant to show a nexus between unexpected results and the point of novelty of the invention, given that it is the "invention as a whole" that must be unobvious under § 103.

Court remands case back to Board on issue of commercial success to determine whether the commercial success resulted from the merits of the claimed invention as opposed to the prior art or other extrinsic factors.

The court also reviewed the Board's holding that Endo's evidence of commercial success, based on its commercial product Opana® ER, was not commensurate with the scope of the claims. On review, the court noted that while an applicant need not sell every conceivable embodiment of the claims in order to rely upon evidence of commercial success, here "the record is nearly silent on whether the commercial success was caused by the merits of the invention as distinct from the prior art." *Id*. The court concluded that "if it is not established that the claimed and novel range for a controlled release oxymorphone formulation causes commercial success where the prior art range would not, then it will be difficult to show the required nexus." *Id*. The court thus remanded the case to the Board to "make a factual determination as to whether the commercial success of the embodying product resulted from the merits of the claimed invention as opposed to the prior art or other extrinsic factors." *Id*. at 1070.

Court remands case back to the Board after Board incorrectly construes prior art reference to support an obviousness rejection.

In *In re Glatt Air Techniques, Inc*., 630 F.3d 1026, 97 U.S.P.Q.2d 1661 (Fed. Cir. 2011), the court reviewed the patentability of Glatt's reexamined patent directed to improved Wurster coater's used for coating particles such as pharmaceuticals without undesired agglomeration causing blockage of the apparatus. Glatt claimed the invention as an improvement using "Jepson format," by reciting prior Wurster coaters in the preamble and reciting the improvement as a "shielding means" for preventing particles from prematurely entering a coating spray nozzle. The Board found that the secondary reference teaches shielding the coating spray nozzle with an air wall and therefore concluded that Glatt's invention was obvious.

On appeal, the court agreed with the Board that both the secondary reference and the claimed shield include an air source located below the coating spray nozzle to circulate the particles in the apparatus into the spray of coating material. However, the court disagreed with the Board's conclusion that such air sources served as a shield, finding instead that while the secondary reference "teaches a way to *remedy* the blockage caused by particle agglomeration using bursts of air," the invention by contrast "*prevents* the agglomeration from occurring in the first place." 630 F.3d at 1030. Because the secondary reference does not teach shielding, the court concluded that the Board lacked substantial evidence to make a proper *prima facie* case of obviousness.

An applicant need not sell every conceivable embodiment encompassed by the claims to rely on commercial success. Rather, the evidence should be considered so long as what was sold was within the scope of the claims.

The court also found that the PTO's requirement that Glatt submit commercial success evidence from multiple embodiments "is not consistent with our precedent." *Id*. The court found it "unlikely that a company would sell a product containing multiple, redundant embodiments of a patented invention." *Id*. Accordingly,

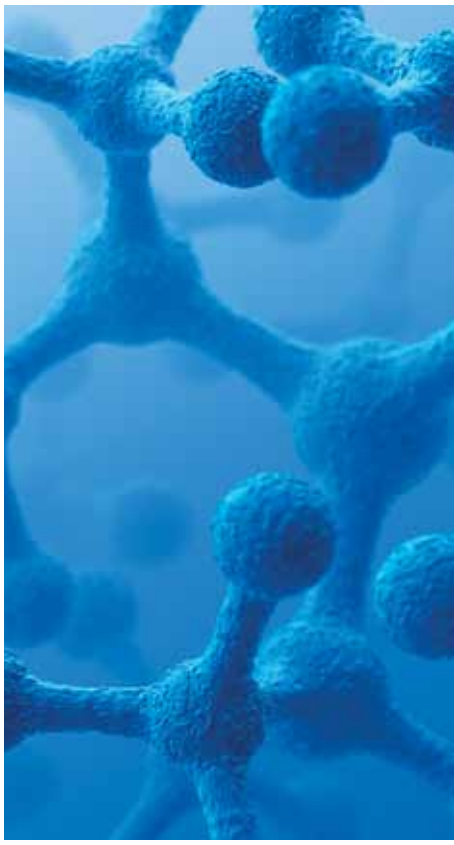
"[t]he fact that Glatt's commercial products only contain one type of shielding means does not make its commercial success evidence irrelevant. Under the PTO's logic, there would never be commercial success evidence for a claim that covers more than one embodiment." *Id*. The court found that an applicant need not sell every conceivable embodiment of the claims in order to rely upon evidence of commercial success. Rather, commercial success evidence should be considered so long as what was sold was within the scope of the claims.

The significance of this holding lies not so much in the specific facts as to what the prior art taught, which admittedly would only be of interest to those involved, but rather in the fact that the Federal Circuit overturned conclusions of fact reached by the Board as not being supported by substantial evidence. Combined with *In re Kao*, discussed above, and *In re Stepan Co*., discussed later, these cases may signal that the carte blanche approach exercised by the court for years following the decision in *In re Zurko*,[23] where the court almost never overturned a finding of fact, may be under review.[24]

Despite teaching in prior art that the identified mutation is "a clinically insignificant polymorphism unrelated to a disease state," court finds that claimed method of diagnosing an iron disorder based on presence of such mutation to be anticipated by that prior art.

In *Billups-Rothenberg, Inc. v. Associated Regional and University Pathologists, Inc.*, 642 F.3d 1031, 98 U.S.P.Q.2d 1578 (Fed. Cir. 2011), the court reviewed both parent and CIP applications of Billups and found the first case invalid for failure to comply with the written description (discussed in next section) and the second CIP case invalid for anticipation, largely based on the court's much stricter requirements for a patent application than for a prior art reference cited against a patent application.

The patents under review relate to a genetic test for Type I hereditary hemochromatosis, an iron disorder characterized by excessive iron absorption by the body. The claims recite detection of one or both of two distinct mutations in the high iron or "*HFE* gene, known as C282Y and S65C." 642 F.3d at 1033. In reviewing Billups's CIP claims reciting the specific sequence and location of the mutation, the Federal Circuit agreed with the district court that such claims were anticipated. The prior art disclosed the genetic sequence of the S65C mutation and described a genetic assay for detecting one or more of the C282Y, H63D, and S65C mutations. On appeal, Billups acknowledged that the S65C mutation disclosed by the prior art falls within its claim but disputed whether the prior art taught the use of such mutation for diagnosing an iron disorder. In particular, Billups argued that correlating the presence of the mutation with persons suffering from the disease as done by the prior art was not the same thing as teaching use of the mutation to diagnose a predisposition to the disease as claimed by Billups. Billups further argued that, far from correlating the mutation with a hemochromatosis diagnosis, the prior art characterized the mutation as a clinically insignificant polymorphism unrelated to a disease state, citing a prior art passage disclosing that "[t]he presence of the 24d7(T) allele shows no increase in risk of acquiring [hereditary hemachromatosis] and thus may only be a polymorphic variant within the population." *Id*. at 1038.



Despite the prior art's discounting of the utility of the S65C mutation in diagnosing hemochromatosis, the court found that the prior art nonetheless describes two genetic tests for hemochromatosis that involve detection of the S65C mutation as an input for the diagnosis of hemochromatosis. Referring to its precedent, the court noted that "we have held that a 'reference is no less anticipatory if, after disclosing the invention, the reference then disparages it.'" *Id*., at 1038-39 (quoting *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361, 47 U.S.P.Q.2d 1516 (Fed. Cir. 1998)). The court further noted that whether a reference teaches away from the invention is inapplicable to an anticipation analysis. Thus, even though the prior art qualified its disclosure with the observation that the mutation "*may* only be a polymorphic

[23] 258 F.3d 1379, 59 U.S.P.Q.2d 1693 (Fed. Cir. 2001).

[24] See also *In re Klein*, 647 F.3d 1343, 98 U.S.P.Q.2d 1991 (Fed. Cir. 2011), where the court likewise reversed the Board's finding of fact regarding whether the five cited references were analogous art.

variant," the prior art nonetheless discloses using the S65C mutation when diagnosing hemochromatosis. The court thus held that the prior art discloses a diagnostic test for hemochromatosis that included identification of the S65C mutation, and, therefore, anticipates the claims.

This case represents yet another data point demonstrating this court's inability to handle prior art that both suggests and teaches away from the invention. The basic problem here is that, even absent a teaching away, the prior art at best merely taught that the mutation was observed in patients suffering from hemochromatosis, not that the presence of the mutation was an indication of a predisposition to the disease state. This is as sound science as observing an obese person drinking a diet cola and thereby concluding that it was the diet cola that was the cause of the obesity. The court's attempt to rely on the doctrine that a teaching away cannot negate an anticipatory teaching was also specious. The fact was that the prior art did not establish the correlation between the presence of the mutation and the disease in the first instance, so there was not an anticipation even without the teaching away. Finally, the court mischaracterized the precedent cited. In *Celeritas*, the so called disparagement was not a statement of inoperability as here; it was merely a statement that another embodiment was not optimal. *Id*. at 1039 (quoting *Celeritas*, 150 F.3d at 1361 ("[t]he fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed")).

Written Description

Because the specification disclosed neither the exact location nor sequence of the mutation useful for diagnosing hemochromatosis when it filed its patent application, the claimed diagnosis method using such mutation lacked written description.

In *Billups-Rothenberg, Inc. v. Associated Regional and University Pathologists, Inc.*, 642 F.3d 1031, 98 U.S.P.Q.2d 1578 (Fed. Cir. 2011), the court also reviewed Billups's parent application and found it invalid for failure to comply with the written description requirement.

When Billups claimed methods of detecting mutations responsible for hemochromatosis in the first patent, it had not yet identified any disease-causing mutations. What Billups did disclose is that hemochromatosis is a disease caused by a gene linked to the major histocompatibility complex ("MHC"). Billups claimed the method in terms of detecting a mutation in a gene encoding a nonclassical MHC class I heavy chain and detecting a mutation in said gene, which mutation (1) results in the reduced ability of said heavy chain to associate with a β2 microglobulin and (2) identifies said individual as having or being predisposed to having hemochromatosis.

The district court found that Billups's claim failed to satisfy the written description requirement. On appeal, Billups argued that its disclosure of the mutation's general location somewhere "'within less than a 300 base pair region of a defined exon of a well studied multi-gene family,'" combined with the knowledge that existed at the time of filing the patent, established possession of the invention. Noting that Billups disclosed neither the exact location nor sequence of the mutation useful for diagnosing hemochromatosis when it filed its patent application, the Federal Circuit affirmed. The court rejected Billups's reliance on knowledge outside the patent, including the subsequent discovery of the C282Y mutation, holding that "[g]iven the lack of knowledge of sequences for the hemochromatosis gene and its mutations in the field, the limited extent and content of the prior art, and the immaturity and unpredictability of the science when the [patent] was filed, Billups cannot satisfy the written description requirement merely through references to later-acquired knowledge." 642 F.3d at 1037.

Because Billups failed to provide a "representative number of species falling within the scope of the genus," the court next assessed, under *Ariad*,[25] whether Billups showed "'structural features common to the members of the genus.'" *Id*. Here, the court found that the "patent does not identify even a single species that satisfies the claims." The court rejected Billups's argument that

[25] *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350, 94 U.S.P.Q.2d 1161 (Fed. Cir. 2010).

the patent's correlation of function with the general location of the C282Y mutation, combined with the knowledge of a person of ordinary skill in the art in the field at the time of filing, satisfied the written description requirement by localizing the mutation to a 300 base pair region. "The disclosure of the general location'is too imprecise to constitute structural features necessary to meet the written description requirement.'" *Id*.

While it is often the case that it is possible with hindsight to see what the patentee could have done differently to avoid the negative outcome of a case, the *Billups* case is one where there appears to have been no way out. When Billups filed early, before it identified the mutation, its claims were invalid for lack of written description. By the time Billups specifically identified the sequence and location of the mutation and correlated it with the iron disorder, there was anticipatory prior art that, at best, only disclosed the presence of the mutation in those with the disease without having determined the nexus between the gene and diagnosis of the disease. The fundamental problem here, for which there is no solution, is that so long as this court applies a markedly lower requirement for the disclosure required for anticipatory prior art versus the disclosure necessary for adequate written description, those in the pharmaceutical industry will always run the risk that their inventive efforts will be undermined by half-baked and speculative prior art. The court should realize that obviousness is assessed through the eyes of one of ordinary skill in the art, whereas enablement and written description are assessed by a person skilled in the art. By plain meaning, one of ordinary skill in the art should be of lower knowledge than the generic skilled practitioner. Under this court's jurisprudence, however, one of ordinary skill in the art is a veritable genius and a person skilled in the art is of hampered discernment.

Largely applying an enablement analysis, the court finds that an application claiming a completely human anti-TFN-α antibody with a list of properties does not find written description support in an application disclosing mouse and mouse/human chimeric antibodies.

In *Centocor Ortho Biotech, Inc. v. Abbott Laboratories*, 636 F.3d 1341, 97 U.S.P.Q.2d 1870 (Fed. Cir. 2011), the court reviewed whether Centocor's claims directed to human tumor necrosis factor-α ("TNF-α") antibodies to treat arthritis, found written description support under § 112, ¶ 1. Centocor's disclosure described mouse antibodies and chimeric mouse/human antibodies. Centocor prepared the chimeric antibodies by substituting a human constant region for the mouse constant region while leaving intact the mouse variable region, which is responsible for the antibodies activity. At issue was whether the disclosure of the antigen, the mouse antibody and the mouse/human chimeric antibody provided written description for a fully-human antibody.

The court framed the issue as whether the application provides written description for an antibody to human TNF-α with (1) a human constant region, (2) a human variable region, (3) high affinity for human TNF-α, (4) neutralizing activity, and (5) the ability to bind to TNF-α in the same place as Centocor's A2 mouse antibody. For its part, Abbott pointed out that far from disclosing any fully-human antibody or even a single human variable region, Centocor merely disclosed tools that might be used in an attempt to make the claimed invention. In response, Centocor argued that it went beyond what the PTO's Written Description Training Materials[26] and *Noelle v. Lederman*[27] require by describing the antibodies not only by their binding affinity for TNF-α, but also by specifying that they competitively inhibit binding of the A2 mouse antibody to TNF-α. Centocor also argued that the written description requirement demands neither actual reduction to practice nor working examples to claim an invention.

The court found that "very little in [the patent] supports that Centocor possessed a high affinity, neutralizing, A2 specific antibody that also contained a human variable region." 636 F.3d at 1349. The court noted that the single mouse variable region of the antibody described by Centocor is very different structurally from the human variable region and "does not serve as a stepping stone to identifying a human variable region within the scope of the claims." *Id*. In support of its finding, however, the court proceeded

[26] U.S.P.T.O., Written Description Training Materials (1st rev. 2008), available at http://www.uspto.gov/web/menu/written.pdf [hereinafter Training Materials].

[27] 355 F.3d 1343, 69 U.S.P.Q.2d 1508 (Fed. Cir. 2004).

to conduct an analysis using the language typically reserved for enablement. For example, the court cited the testimony of Abbott's expert that (1) "the disclosure of the mouse sequence information does not teach one of ordinary skill in the art[28] ***how to make and use*** a fully human antibody" (emphasis added) and (2) the references cited in Centocor's patent addressing the "phage display" technique for generating human antibodies "describe only very general library technologies that could be used to make …human antibodies but they do not teach ***how to isolate or use such antibodies***." *Id*. at 1350 (emphasis added). However, while the court was all too willing to consider enablement criteria when it viewed those criteria as pointing away from written description, the court was equally zealous in its refusal to consider enablement criteria when those criteria supported written description: "The fact that a fully-human antibody could be made does not suffice to show that the inventors of the…patent possessed such an antibody."[29]

Interestingly, while the court framed its analysis in terms of enablement, it stated its conclusions in terms of written description, holding that

> while the patent broadly claims a class of antibodies that contain human variable regions, the specification does not describe a single antibody that satisfies the claim limitations…It does not disclose any relevant identifying characteristics for such fully-human antibodies or even a single human variable region…Nor does it disclose any relationship between the human TNF-α protein, the known mouse variable region that satisfies the critical claim limitations, and potential human variable regions that will satisfy the claim limitations…There is nothing in the specification that conveys to one of skill in the art that Centocor possessed fully-human antibodies or human variable regions that fall within the boundaries of the asserted claims.
>
> *Id*. at 1350-51 (internal citations omitted). At bottom, [according to the court,] the asserted claims constitute a wish list of properties that a fully-human, therapeutic TNF-α antibody should have: high affinity, neutralizing activity, and the ability to bind in the same place as the mouse A2 antibody. [However,] at best [the specification] describes a plan for making fully-human antibodies and then identifying those that satisfy the claim limitations. But a "mere wish or plan" for obtaining the claimed invention is not sufficient.

The court holds that in addition to fully describing the antigen, a written description of an antibody requires that its generation be "so routine that possessing the protein places the applicant in possession of an antibody."

Centocor cited *Noelle*[30] and the PTO's Written Description Training Materials[31] in support of its view that fully disclosing the human TNF-α protein provides adequate written description for any antibody that binds to human TNF-α. The court rejected such reliance as "based on an unduly broad characterization of the guidelines and our precedent." *Id*. Regarding the PTO guidelines, the court found that while "some antibodies to a well-characterized protein may be adequately described even when they are functionally claimed and not actually produced[,]…this reasoning might not apply to obtaining *human* antibodies to a *human* protein." (emphasis added) *Id*. at 1351 n4. The court held that "an applicant can claim an antibody to novel protein X without describing the antibody when (1) the applicant fully discloses the novel protein and (2) generating the claimed antibody is so routine that possessing the protein places the applicant in possession of an antibody." *Id*. at 1351-52. The court also distinguished its holding in *Noelle*, that "[w]hile our precedent suggests that written description

[28] In addition to blurring the line between written description and enablement by carrying out a written description analysis using enablement criteria of how to make and how to use, the court demonstrates a further lack of understanding of the statute by interjecting the standard of "one of ordinary skill in the art," which is the standard by which obviousness is adjudged, rather than the standard of "a person skilled in the art," which is the reference point of Section 112.

[29] *Id*. This statement would have been less troublesome if the court had qualified it by stating that the fact that a fully human antibody could be made does not suffice to show that the inventors of the patent possessed the fully-human antibody ***having all the claimed characteristics***. However, by using the phrase "such an antibody," the court was clearly indicating that the ability to make a particular antibody does not demonstrate possession of the same antibody.

[30] 355 F.3d at 1349.

[31] Training Materials, *supra* note 23, at 46.

for certain antibody claims can be satisfied by disclosing a well-characterized antigen, that reasoning applies to disclosure of newly characterized antigens where creation of the claimed antibodies is routine." *Id*. at 1352. Here, "Centocor simply failed to support its contention that generating fully-human antibodies with the claimed properties would be straightforward for a person of ordinary skill in the art given the state of human antibody technology in 1994." *Id*.

At bottom, two things are apparent from this case. First, the court seems to be creating a super-enablement requirement for antibodies by holding that when the applicant fully discloses the novel protein X without describing the antibody, possession of the antibody for written description purposes is demonstrated when "generating the claimed antibody is ***so routine*** that possessing the protein places the applicant in possession of an antibody." *Id*. (emphasis added). So whereas normal enablement requires a lack of "undue experimentation," the enablement criteria used by this court for written description of biotech inventions requires something more, that it be "so routine." Here, it seems the court could have disposed of this case in a far more straightforward manner, either by relying on straight enablement or by noting that in this case, unlike *Noelle*, the patentee may not have actually identified an antigen which would elicit an A2 specific antibody as required by the claim.

Second, the "reasoning" the court applies in this case perfectly demonstrates why it would seem more logical to rely on enablement than written description in such cases. Note how the court toggles between written description language (distinguishing characteristics, etc.) and enablement language (does not teach how to make and use). The roller coaster starts with written description language ("the single mouse variable region of the antibody described by Centocor is very different structurally from the human variable region"), and the analysis then morphs to enablement language ("the disclosure…does not teach "***how to make and use*** a fully human antibody," *Id*. at 1349 n.2 (emphasis added), and the references "do not teach ***how to isolate or use such antibodies***" *Id*. at 1350 (emphasis added)). The analysis using enablement criteria completed, the court then morphs back to written description language. *Id*. at 1351 (holding that the specification "does not disclose any relevant identifying characteristics for such fully-human antibodies or even a single human variable region."). Then, when criticizing the PTO for following the court's own precedent in *Noelle*, the court goes back to enablement criteria. *Id*. at 1352 ("While our precedent suggests that written description for certain antibody claims can be satisfied by disclosing a well-characterized antigen, that reasoning applies to disclosure of newly characterized antigens where creation of the claimed antibodies is routine.").

The underlying problem here is that the court is advancing irreconcilable doctrines. On the one hand, the court requires disclosure of "relevant identifying characteristics" that permit an applicant to distinguish the invention. On the other hand, the court in precedents such as *Noelle* held that disclosure of an antigen is sufficient description for the corresponding antibody. But the question must be asked: how does describing an antigen at all provide "relevant identifying characteristics" for the corresponding antibody, which is structurally unrelated? The essential problem is that the court has boxed itself into a doctrine that makes no sense in the context of biological macromolecules, which often defy description in conventional molecular terms. The solution to the problem is obvious–go back to the doctrine that the court conveniently disregarded when it decided *Eli Lilly v. Regents of the University of California*[32] That doctrine, as stated in *In re Smith*,[33], says that "[w]here the claim is an original claim, the underlying concept of insuring disclosure as of the filing date is satisfied, and the description requirement has likewise been held to be satisfied." That way, if a claim is literally supported or substantially supported by an original filing, there is no written description issue. At that point, it becomes an enablement inquiry using the *Wands* factors.[34] Given the requirements set forth in the claim for the antibody, such as its specificity for the A2 epitope, it may very well be the case that

[32] 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997).

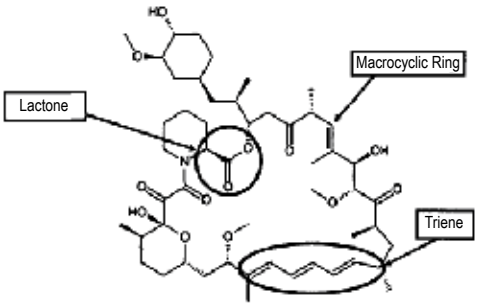
[33] 481 F.2d 910, 914, 178 U.S.P.Q.2d 620 (C.C.P.A. 1973) (citing *In re DiLeone*, 436 F.2d 1404, 168 U.S.P.Q. 592 (C.C.P.A. 1971).

[34] *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988).

the claim here would not pass enablement muster. However, until the court recognizes that its written description paradigm does not work in the context of biological molecules, we will continue to have cases, such as *Johnson & Johnson*, discussed next, which confound the written description and enablement doctrines. We will also continue to have cases where those in the biological sciences have to satisfy a higher standard of super-enablement (the "so routine" standard) as opposed to those in all other areas ("undue experimentation").

Claims directed to stents including rapamycin or lactone analogs of rapamycin lack written description, even where the prior art disclosed some species of the claimed lactone analogs, in view of the specification's failure to disclose any analogs and the unpredictability of the state of the art.

In *Boston Scientific Corporation v. Johnson & Johnson*, 647 F.3d 1353, 99 U.S.P.Q.2d 1001 (Fed. Cir. 2011), the court reviewed whether Johnson & Johnson's claims directed to drug-eluting coronary stents used in the treatment of coronary artery disease satisfy the written description requirement. The patents claim drug-eluting stents comprising either rapamycin, lactone analogs of rapamycin, or triene analogs of rapamycin. Some of the patents recited that the drug was present in an amount effective to inhibit neointimal proliferation. The molecule is depicted as follows:



The specification disclosed prior art describing dozens of rapamycin analogs containing the same macrocyclic ring, including the compound "everolimus" which is both a macrocyclic lactone and triene analog of rapamycin. It also is the compound used by the accused infringer, Boston Scientific Corporation ("BSC").

The court first reviewed whether the patents provided adequate written description of the lactone analogs. Appellants argued that it was not necessary to disclose "formulae or structures" or set forth "definitions, examples, or experimental models" of particular macrocyclic lactone analogs because the prior art disclosed the structure, mechanism of action, and biological activity of rapamycin lactone analogs which provided one skilled in the art with a "template" to use for identifying analogs falling within the scope of the claims. 647 F.3d at 1350. Appellants characterized their invention as "a combination of known elements, as opposed to a novel compound," such that appellants "need not list examples" nor was any "comprehensive description" required." *Id*. at 1362 (internal quotations omitted). Appellants also argued that because it established a correlation between structure and function, its functional language in the claim met the written description requirement.

For its part, BSC argued that the specification failed to meet *Eli Lilly's* test requiring, for a chemical genus, "a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *Id*. at 1360 (quoting *Regents of the University of California v. Eli Lilly & Co*., 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) (internal quotations omitted). BSC pointed out "that there are no examples of "macrocyclic lactone analogs" of rapamycin in the patents" and that the patents fail to disclose the structures or features that render a molecule sufficiently similar to rapamycin to classify it as a macrocyclic lactone analog. *Id*. at 1363.

The court agreed with BSC. Citing *Ariad*,[35] the court noted that a patentee can comply with the written description requirement either by (1) disclosing a representative number of species falling within the scope of the genus or (2) providing structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus.

[35] *Ariad Pharm., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1350, 94 U.S.P.Q.2d 1161 (Fed. Cir. 2010).

The court found that the patent contains "virtually no information regarding macrocyclic lactone analogs of rapamycin" and "does not evidence possession of the genus of macrocyclic lactone analogs of rapamycin in the claimed invention to inhibit restenosis." *Id*. at 1364. For example, no experiments are detailed using macrocyclic lactone analogs nor does the specification even indicate performance of any such experiments. While acknowledging that examples are not always required to satisfy the written description requirement, the court found here that the patents give no guidance on how to properly determine whether a compound is a macrocyclic lactone analog of rapamycin besides vaguely indicating they must be structurally similar to rapamycin. The court noted rapamycin's "structural complexity" and the fact that "the universe of potential compounds that are structurally similar to rapamycin and classifiable as macrocyclic lactones is potentially limitless." *Id*. The court further noted that even minor structural changes to rapamycin could have significant and unpredictable effects on functionality. Thus, even though the prior art disclosed some specific species of the claimed macrocyclic lactone analogs, the state of the art was sufficiently unpredictable so as to require a more detailed disclosure.

Appellants cannot rely on functional language directed to rapamycin lactone analogs to satisfy the written description requirement because they failed to establish a correlation between structure and function.

Finally, the court rejected the appellants' argument that the functional language directed to analogs met the written description requirement in view of knowledge in the art of (1) the structure and mechanism of action of rapamycin, and (2) the correlation between the structural elements of rapamycin and its mechanism of action and biological activity. The court found that the articles and declaration relied upon by appellants as purportedly establishing such correlation were undermined by the patents themselves, which explicitly stated that the precise mechanism of rapamycin is still under active investigation. The court noted that "when the four corners of the specification directly contradict information that the patentee alleges is 'well-known' to a person of skill at the effective filing date," *id*. at 1366, patentee does not demonstrate possession of the invention.

The court drew similar conclusions for the later patent claiming "rapamycin or a macrocyclic triene analog thereof," finding that such technology was "still in its infancy," and that, once again, appellants failed to disclose even a single triene analog. As with the lactones, the appellants' specifications likewise admitted that the molecular events responsible for the actions of rapamycin "are still being elucidated." *Id*. at 1368. Accordingly, appellants could not rely on an established relationship between structure and function.

If there is nothing else that one can glean from this case, as well as *Ariad*[36] and *University of Rochester*,[37] it is this simple truism of Federal Circuit jurisprudence: even though examples are not an absolute requirement for satisfying written description, do not file an application claiming a broad genus of molecules, whether they be biological or small molecules, without providing even a single example in the specification. It was fatal to appellants here, as it was to the parties in the cases referenced above, that they lacked such examples. Furthermore, we have seen in the past how the court has used a patentee's statement of uncertainty regarding mode of action against that patentee when carrying out a written description analysis.

If one were to make a criticism of the case, it would be along the lines expressed by Judge Gajarsa in his concurrence, where he argued that, while agreeing with the ultimate holding of invalidity, he would have found it on enablement grounds rather than written description grounds:

> The majority focuses solely on the written description aspect of whether the therapeutic agent's analogs were adequately described and ignores that in nearly all of the asserted claims, the agents must effectively inhibit neointimal proliferation. Because undue experimentation was required to practice the 1997 patents, the district

[36] *Id*.

[37] *Univ. of Rochester v. G.D. Searle & Co*. 358 F.3d 916, 69 U.S.P.Q.2d 1886 (Fed.Cir.2004).

> court's grant of summary judgment of invalidity should have been affirmed on enablement grounds.

Id. at 1369 (Gajarsa, J., concurring). Judge Gajarsa noted that "[t]he majority's opinion further extends the written description requirement into the realm of enablement," *id*., and that "[a]pplying the enablement requirement would help to clear the thicket of jurisprudence regarding § 112 ¶ 1. . . . . [I]n this case, the enablement analysis is simpler and more appropriate." *Id*. As we stated in our discussion of *Centocor*, the better rule would be to simply find written description satisfied for claims literally supported by the specification and then launch into the *Wands* factors. This would, using Judge Gajarsa's words, "clear the thicket" and ensure that inventions in chemistry and molecular biology were not subject to a super-enablement requirement.

With the benefit of hindsight, which as the cliché goes, is always 20/20, it would have made a lot more sense for patentees not only to disclose but also to claim stents, including the rapamycin analogs that were known at the time of filing. Because BSC used one such known analog, it would have infringed the patent and the claim presumably would have been both enabled and adequately described.

A claim reciting an "airflow sufficient to substantially prevent an anaerobic condition" in a tobacco–curing process finds written description support in an earlier application disclosing a minimum airflow of at least 28,000 Cubic Feet per Minute ("CFM") even though later application broadened airflow rate to include approximately 25,000 CFM.

In *Star Scientific, Inc. v. R.J. Reynolds Tobacco Company*, 655 F.3d 1364, 99 U.S.P.Q.2d 1924 (Fed. Cir. 2011), the court reviewed whether Star's original provisional application filing provided written description support for Star's claim reciting a process for curing tobacco leaves "in a controlled environment" comprising "air free of combustion exhaust gases and an airflow sufficient to substantially prevent an anaerobic condition." Because the later non-provisional application included a new example calling for "air flow of approximately 25,000 CFM," but the provisional application disclosed a minimum airflow of "at least 28,000 CFM," the district court concluded that the 25,000 CFM airflow rate in the non-provisional application was new matter. The district court thus concluded that the claim encompassed an airflow (25,000 CFM) not supported by the original provisional filing.

On appeal, the Federal Circuit referred to the provisional application's written description that the minimum airflow "may be about 28,000 CFM at 1 static pressure in a typical curing barn," but that the "minimum flow of air may vary according to conditions and may be determined on a routine basis." 655 F.3d at 1372. The court further noted that claim 3 of the provisional application covers a "flow . . . sufficient to prevent an anaerobic condition" around the curing tobacco. The court thus held that,

> [b]ecause the provisional application teaches one of ordinary skill that a minimum air flow "may vary," one of ordinary skill would know that the conditions in a curing barn could demand an air flow of 25,000 CFM. The district court's reliance on specifically disclosed air flow rates improperly narrowed the scope of the provisional application based on an added example in the later-filed non-provisional application that discloses a process for curing using an "air flow of approximately 25,000 CFM."

Id. What is interesting about this case is that Star was essentially able to obtain through the back door what it could never have obtained through the front door, given this court's recent strict jurisprudence on written description. Picture the following scenario, which could have just as easily played out in this case: Star files a provisional application with the exact same disclosure setting forth a minimum flow rate of 28,000 CFM but, instead of claiming the flow rate functionally in terms of preventing an anaerobic condition, Star specifically sets forth a minimum flow rate of 28,000 CFM in its claim (and still includes its functional dependent claim). Then Star files its regular application including its newly added disclosure of a flow rate of approximately 25,000 CFM and likewise presents a claim now setting forth

a minimum 25,000 CFM flow rate. There is little doubt in such a scenario that if Star tried to obtain benefit of its provisional disclosing at least 28,000 CFM to provide support for a claim to at least 25,000 CFM, the court would have denied that benefit. Practically speaking, however, this is the result that occurred in this case "through the back door" by use of functional language.

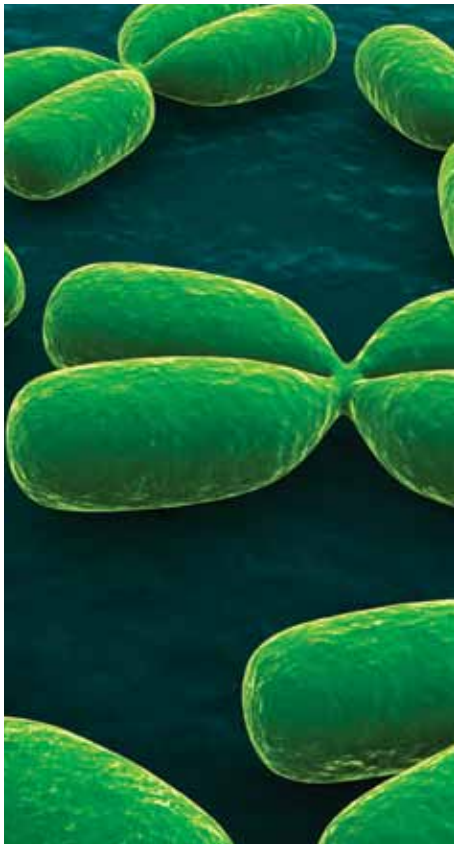
Best mode

Where the claims of a regular application can claim the benefit of a provisional application, applicant need not disclose its best mode in the regular application even if (1) an applicant invents a new best mode between the provisional filing and the regular filing and (2) adds new matter to the regular filing.

In *Star Scientific, Inc. v. R.J. Reynolds Tobacco Company*, 655 F.3d 1364, 99 U.S.P.Q.2d 1924 (Fed. Cir. 2011), the court addressed on appeal whether Star had complied with the best mode requirement when it filed its regular application. Finding that Star had both added new matter between its provisional and non-provisional filings and had failed to disclose a best mode it had developed between those filings, the district court held that Star violated the best mode requirement. On appeal, the Federal Circuit reversed, finding it dispositive that despite the added subject matter, Star's claims found support in the original provisional filing. The interesting thing about this case is that while the court had previously found in the *Transco* case[38] that it was not necessary to renew best mode in a straight continuation or divisional that added no new matter, the court had not previously extended such doctrine to CIPs or other cases where new matter was added, such as between a provisional and non-provisional application. Accordingly, without a lot of fanfare it would now appear that so long as the claims in a later application are entitled to benefit of an earlier application, there is no need to include the best mode in that new application even if (1) the application includes new matter and (2) the applicant developed its best mode between the first and second filings.

Federal Circuit affirms invalidity based upon failure to disclose best mode; victory for advocates of full and fair disclosure short-lived, given Congress's subsequent elimination of best mode defense in litigation.

In *Wellman, Inc. v. Eastman Chemical Co*., 642 F.3d 1355, 98 U.S.P.Q.2d 1505 (Fed. Cir. 2011), the Federal Circuit affirmed the district court's s grant of summary judgment of invalidity for failure to disclose the best mode. The technology at issue in *Wellman* related to polyethylene terephthalate ("PET") resins for use in plastic beverage containers, which are "slow crystallizing" in that they possess a significantly higher heating crystallization exotherm peak temperature ("TCH") as compared with conventional PET resins.



At the time Wellman filed its patent application, it had commercialized a slow-crystallizing PET resin called Ti818, which contained carbon black N990 as a heat-up rate additive. However, Wellman failed to disclose the recipe for Ti818, or any other specific PET resin recipes, in its application. Instead, the application provided ranges of concentrations for categorized lists of possible ingredients. The district court found the patents invalid for failure to comply with the best mode requirement, concluding that the inventors viewed Ti818 as the best mode of practicing the invention at the time of filing, yet the patents did not disclose Ti818 sufficiently to enable one of ordinary skill in the art to identify it. The court further concluded that the inventors actively concealed Ti818 by disclosing "preferred" ranges for certain ingredients that do not encompass the actual concentrations of those ingredients in the Ti818 formula.

On review, the court first referred to its two-pronged test for best mode: (1) does the inventor subjectively believe there was a best mode for practicing the invention and (2) if so, does the application objectively disclose that best mode, or has the inventor effectively "concealed" it from the public? 642 F.3d at 1360. With respect to the first prong, the Federal Circuit agreed with the district court's finding that an inventor believed that the Ti818 formula was the best mode of carrying out the claimed invention. As for the second prong, the Federal Circuit agreed that Wellman effectively

[38] *Transco Prods., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 U.S.P.Q.2d 1077 (Fed. Cir. 1994).

concealed the best mode from the public by failing to disclose the recipe for Ti818 and describing preferred concentration ranges and particle sizes that excluded those used in Ti818. "By masking what at least one inventor considered the best of these slow-crystallizing resins, Wellman effectively concealed its recipe for Ti818." *Id*. at 1365. In addition, the court found that Wellman's failure to disclose its use of carbon black on the grounds that it was a trade secret constituted an intentional concealment of the best mode. *Id*. Moreover, the court found the fact that some of the ingredients for Ti818 fell outside the disclosed preferred ranges actually led away from the Ti818 recipe. *Id*. at 1364.

Less than four months after *Wellman* was decided, Congress enacted the America Invents Act,[39] which, among other things, all but abolishes the best mode requirement by eliminating it as a defense in patent litigation. While disclosing the best mode is still technically a requirement under the patent laws, the absence of any practical mechanism for enforcing compliance has left many to wonder what vitality, if any, the best mode requirement will still retain. Accordingly, the patent holder here may hold the dubious distinction of being the last patentee to have its patent invalidated for failure to comply with the best mode requirement.

Indefiniteness

Because a person skilled in the art possesses an adequate understanding to manipulate the variables such as humidity, temperature and flow relating to the claimed "controlled environment," such phrase is not indefinite merely because the claim does not recite specific numbers for those variables.

In *Star Scientific, Inc. v. R.J. Reynolds Tobacco Company*, 655 F.3d 1364, 99 U.S.P.Q.2d 1924 (Fed. Cir. 2011), the court reviewed the district court's holding that the phrase "controlled environment" in Star's claim was indefinite. The district court construed the claim term "controlled environment" to mean "controlling one or more of humidity, temperature and airflow in the curing barn, in a manner different from conventional curing, in order to substantially prevent the formation of TSNAs." 655 F.3d at 1373 (citation omitted). In reversing the district court's finding of indefiniteness, the Federal Circuit faulted the jury's assumption that the term was indefinite merely because the patents do not give exact numbers measuring humidity, temperature, and airflow in a conventional curing barn. Contrary to the jury, the court found "that a person of skill in the art of tobacco curing would possess adequate understanding to manipulate these variables to create a controlled environment." *Id*. at 1374. The court found that "because conventional curing varies depending on the conditions for each cure, specific numerical values are not needed for one skilled in the art to implement conventional curing." *Id*. The court concluded from the record that tobacco curing variables are well known in the tobacco industry such that the term "controlled environment" falls well within the bounds of ordinary skill in the art. Thus, this term is not insolubly ambiguous and is not indefinite. *Id*.

Inequitable Conduct

Federal Circuit overhauls inequitable conduct standard; "tightens" standards for finding both materiality and deceptive intent.

In *Therasense, Inc. v. Becton Dickinson & Co*., 649 F.3d 1276, 99 U.S.P.Q.2d 1065 (Fed. Cir. 2011) (*en banc*), in a much anticipated decision, the Federal Circuit sitting *en banc* completely overhauled the doctrine of inequitable conduct.

Therasense sued Becton Dickinson ("BD") for infringing Therasense's claims directed to a test strip with an electrochemical sensor for testing whole blood ***without a protective membrane*** over the electrode. BD alleged inequitable conduct arising from Therasense's failure to inform the PTO that it characterized the teachings of a reference to the European Patent Office ("EPO") in a manner that contradicted the way it characterized the teachings of the same reference to the PTO. In particular, in the U.S., Therasense distinguished its claimed membrane-less system from the prior art by filing a declaration averring that the prior art required a membrane when treating whole

[39] Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (to be codified in scattered sections of 35 U.S.C.).

blood. By contrast, in Europe, Therasense allegedly stated the opposite regarding the same reference, i.e., that it did not require a membrane when testing whole blood. Both the district court and the Federal Circuit in its initial review found that Therasense's failure to advise the PTO of these allegedly inconsistent positions constituted inequitable conduct.

Materiality and deceptive intent must be proven separately by clear and convincing evidence; the "sliding scale" approach to materiality and intent employed by previous courts rejected.

On *en banc* review, the Federal Circuit, in a 6-1-4 decision, vacated the district court decision. Condemning the "proliferation of inequitable conduct charges," *id*. at 1291, in recent years that "has plagued not only the courts but also the entire patent system," *id*. at 1289, the court scrapped the old test for inequitable conduct and replaced it with a much stricter test. Specifically, the court "tighten[ed] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." *Id*. at 1290. Under *Therasense*, these elements must be proven separately by clear and convincing evidence.

The court affirmatively rejected the use of a "sliding scale" approach to the materiality and intent requirements for establishing inequitable conduct. Under this previous approach, a particularly strong showing of materiality might be enough to make up for a weak showing of intent to deceive — and vice versa. Emphasizing that materiality and intent are two separate and unrelated requirements, the court held that no matter how strong the evidence of materiality might be, a district court may not infer intent solely from materiality. *Id*.

Court rejects materiality standard proposed by PTO under Rule 56; adopts instead a stricter, "but-for" standard, which asks whether a reasonable patent examiner would have allowed the claims in the face of the reference.

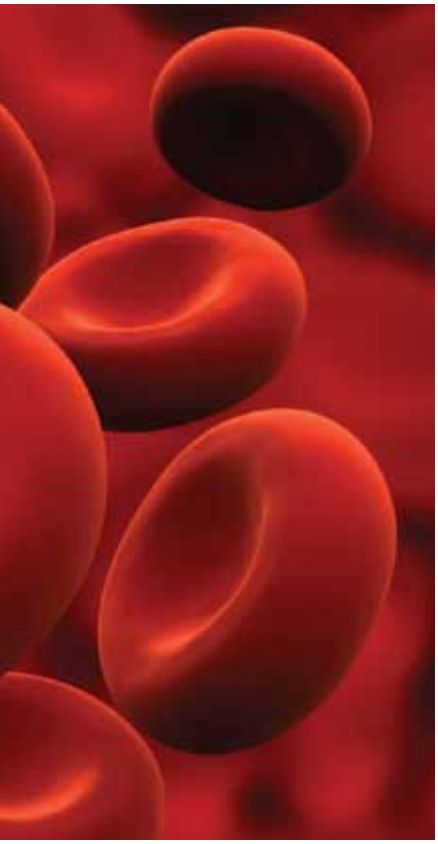
Addressing the materiality element, the court held that the new standard "is but-for materiality," which requires determining "whether the PTO would have allowed the claim if it had been aware of the undisclosed reference." *Id*. at 1291. In making this determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction. *Id*. at 1291-92. In so holding, the court expressly refused to adopt the lower standard of materiality set forth in PTO Rule 56, which it felt would "inevitably result in patent prosecutors continuing the existing practice of disclosing too much prior art of marginal relevance and patent litigators continuing to charge inequitable conduct in nearly every case as a litigation strategy." *Id*. at 1295.

Affirmative acts of egregious misconduct exempted from the "but-for" standard of materiality.

The court carved out an important exception to "but-for" materiality, for "affirmative acts of egregious misconduct" by the patentee, which originates from the "unclean hands" doctrine. *Id*. at 1292. If a court finds such behavior, for example the willful filing of a false affidavit, materiality is assumed. "[M]ere nondisclosure of prior art references to the PTO [or] failure to mention prior art references in an affidavit," however, does not constitute affirmative egregious misconduct. *Id*. at 1292-93. Claims "based on such omissions require proof of but-for-materiality." *Id*. at 1293.

Deceptive intent must be the single most reasonable inference to be drawn from the evidence.

As for the intent element, the court reiterated that the requisite intent for inequitable conduct is "specific intent to deceive"—gross negligence is not enough. *Id*. at 1290. Specific intent requires more than "that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO." *Id*. Rather, deceptive intent "must be the single most reasonable inference able to be drawn from the evidence." *Id*. (citation omitted). Thus, if "there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Id*. at 1290-91. Moreover, the absence of a good-faith explanation for withholding a material reference does not, by itself, prove deceptive intent. Indeed, a patentee need not provide a good faith explanation unless and until the accused infringer establishes "a threshold level of



intent to deceive by clear and convincing evidence." *Id*. at 1291 (citation omitted).

Even after materiality and intent are proven, courts must still weigh the equities to determine whether a finding of inequitable conduct is appropriate in the specific case.

Finally, once both materiality and intent have been proven, the court must then carefully weigh the equities to determine whether the conduct was so egregious as to warrant nullifying the entire patent—what the *Therasense* majority called "the 'atomic bomb' of patent law." *Id*. at 1288. Moreover, as the court explained, "the taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family." *Id*.

Applying these newly-minted principles to the facts at hand, the Federal Circuit vacated the district court's finding of inequitable conduct and remanded the case for the district court. On remand, the district court must "determine whether the PTO would not have granted the patent but for [Therasense's] failure to disclose the EPO briefs," *id*. at 1296, and "whether there is clear and convincing evidence demonstrating that [the applicants] knew of the EPO briefs, knew of their materiality, and made the conscious decision not to disclose them in order to deceive the PTO." *Id*.

The Federal Circuit's decision in *Therasense* has implications for both patent prosecutors and litigators. For prosecutors, gone are the days of disclosing all documents even remotely relevant for fear that doing otherwise would risk a charge of inequitable conduct. One of the articulated concerns of the *Therasense* court was reducing the cautionary incentive of overdisclosure, which had resulted in a "flood of information" that unduly strains the PTO's examining resources and directly contributes to the backlog. Now, prosecutors should disclose only those documents that a reasonable examiner would possibly consider patentability-defeating. Additionally, the court's exemption of certain affirmative acts from the heightened "but-for" standard of materiality will continue to warrant close review of declarations arguing for patentability.

As for patent litigators, the impact of *Therasense* is already being felt, with district court dismissals of inequitable conduct claims on the rise. Indeed, the authors used *Therasense* to much advantage in a recent litigation, helping secure summary judgment of no inequitable conduct where the defendants' allegations failed to prove but-for materiality and specific intent to deceive.

One interesting question centers around whether cases involving inequitable conduct will require two *Markman* hearings. In particular, because the court directed that its new "but-for" materiality standard was to be assessed by construing the claims using the prosecution standard of broadest reasonable construction, a court looking at both inequitable conduct and infringement/validity could find itself affording the same claim two different constructions.

Priority of Invention

While the preponderance of evidence standard applies in PTO interferences, district court interferences under § 291 and infringement litigation where the parties stipulate to conflicting subject matter, the clear and convincing evidence standard still applies when a party merely alleges priority as an infringement defense.

In *Creative Compounds, LLC v. Starmark Laboratories*, 651 F.3d 1303, 99 U.S.P.Q.2d 1168 (Fed. Cir. 2011), the court reviewed the validity of Starmark's patents directed to formulations, including the amino acid creatine, that increase its bioavailability. Starmark's claims recited (1) creatine salts comprising two molecules of creatine and one molecule of dicarboxylic acid, including a dependent claim reciting malic acid and (2) a process to form the creatine salt. Creative had its own patents reciting (1) a dicreatine malate compound comprising approximately two creatine cations per one malic acid dianion and (2) a method of increasing the production of adenosine triphosphate in a human body that consists of administering the compound to a subject.

As an initial matter, the court addressed Creative's argument that the correct standard of proof of priority of invention as between co-pending interfering patents in a litigation is the preponderance of the

evidence, the junior party bearing the burden of pleading and proving priority. The court disagreed, holding that it has long held that because under 35 U.S.C. § 282, each claim of a patent shall be presumed valid, an accused infringer must prove invalidity by clear and convincing evidence. The court acknowledged that the preponderance of evidence standard applied in district court actions under 35 U.S.C. § 291 (relating to priority determinations between interfering patents), in PTO interferences; and in limited circumstances in an infringement litigation where the parties stipulated to conflicting subject matter. Here, however, "the parties did not identify or agree on common claimed subject matter." 651 F.3d at 1311. Accordingly, the court held "that an accused infringer cannot obtain the benefit of the lower burden of proof that prevails in an interference proceeding simply by alleging, as a defense to infringement, that the asserted patent is invalid based upon a co-pending patent unless common claimed subject matter is first identified and an adjudication of priority is sought." *Id*.

In the absence of testimony explaining its significance, an email speculating that the method of making dicreatine malate "should" be like that of making creatine citrate is not sufficient to establish conception of the method of making dicreatine malate.

On the merits, Creative argued that an email order for "dicreatine malate" demonstrated conception of that compound. The email speculated that the method of making dicreatine malate "should" be like that of making creatine citrate. However, because Creative failed to submit testimony explaining the significance of this email and whether this reference would constitute conception of subject matter within the scope of even a single claim in the patent, the court held that the email failed to establish conception. The court found that "the email fails to reveal knowledge of a process for making dicreatine malate and, to the contrary, merely speculates that the process 'should' be like that for creatine citrate." *Id*. at 1312. Accordingly, "[i]n the absence of expert testimony, Creative has failed to show how this email raises a genuine issue of material fact that a method of making dicreatine malate would have been a matter of routine knowledge among those skilled in the art." *Id*. The court also found that a "bald" assertion that its inventor was "diligent" for the 18 months between conception and reduction to practice was insufficient to establish diligence, which is a required element of a § 102(g) defense. *Id*.

This case illustrates well that a party seeking to demonstrate conception must provide adequate testimony showing that those skilled in the art could have taken the conception and reduced it to practice with routine skill.

PTO Procedure

Where a rejection propounds new facts and rationales — none of which were previously raised by the examiner — mere reliance by the Board on the same type of rejection or the same prior art references relied upon by the examiner is insufficient to avoid a new ground of rejection.

In *In re Stepan Co*., 660 F.3d 1341, 100 U.S.P.Q.2d 1489 (Fed. Cir. 2011), the court considered the question of whether the PTO Board had incorrectly applied a new rejection when affirming the final rejection of the primary examiner. The patent covers polyol-based resin blends and the methods of using them to create closed-cell polyurethane and polyisocyanurate-based foam used, for example, to make thermal insulation boards for the walls of homes and buildings.

In its review of the examiner's final rejection for obviousness, the Board found that the examiner erroneously applied the prior art as a reference under § 102(b) (publications or inventions patented more than one year prior to the date of the application of the patent in question), when it should have applied the reference as prior art under § 102(a) (publications or inventions patented before the invention thereof by the applicant). Because of this error, the examiner never reviewed the declaration that the applicant filed under Rule 131 to show a date of invention earlier than the date of the reference. The Board, however, found the declaration to be deficient because (1) it failed to show that the water content of the catalyst supplied and used prior to the critical date was unchanged; (2) it failed to

account for the source of the water; and (3) it appeared inconsistent with other art.

On appeal, Stepan argued that the Board raised for the first time in its opinion a new ground of rejection to which it never had an opportunity to respond. The court agreed, holding that "[b]y making and relying on new fact findings regarding an issue the examiner did not raise, i.e., the sufficiency of Stepan's declaration to swear behind the . . . reference as § 102(a) prior art, the Board relied on a new ground of rejection." 660 F.3d at 1344. The court further held that "[m]ere reliance by the Board on the same type of rejection or the same prior art references relied upon by the examiner, alone, is insufficient to avoid a new ground of rejection where it propounds new facts and rationales to advance a rejection—none of which were previously raised by the examiner." *Id*. at 1345. The court noted that the "mere fortuity" of Stepan's submission of the declaration without the issue being raised by the examiner "does not permit the Board to reject the declaration as ineffective without designating its decision as a new ground of rejection." *Id*. Finally, looking at the plain language of the Board's own rules, the court rejected the Board's argument that Stepan was obligated to file a Request for Rehearing first. *Id*.

Reexamination/Reissue

Court holds that intervening rights may apply to reexamined claims even if those claims are not amended during the reexamination proceeding, based on arguments made during reexamination.

In *Marine Polymer Technologies, Inc. v. HemCon, Inc*., 659 F.3d 1084, 100 U.S.P.Q.2d 1257 (Fed. Cir. 2011), rev'd, 2012 WL 858700 (Fed. Cir. Mar. 15, 2012) (*en banc*), the court held that the arguments made by a patent owner during a reexamination changed the scope of the claims even though such claims were not amended during the reexamination. In so holding, the court vacated the district court's judgment of infringement.

Marine Polymer's patent claims a "biocompatible" poly-β-1->4-N-acetylglucosamine used as an anticoagulant biopolymer. Marine Polymer also claimed levels of biocompatibility of 0, 1 or 2, as measured using specific biocompatibility tests described in the specification as (1) an elution test, (2) an implantation test, (3) an intracutaneous injection test, and (4) a systemic injection test. Certain dependent claims recited the biocompatibility giving rise to an "elution test score" of 0, 1 or 2, respectively.

Defendant HemCon, in hopes of invalidating the claims over the prior art, argued that the claims should be construed broadly as encompassing (1) a polymer from certain algal sources or (2) a polymer "suitable for biomedical applications." Marine Polymer argued a narrower construction that would have avoided the prior art. The district court rejected both proposed constructions and concluded that "biocompatible" meant "polymers . . . with low variability, high purity, and no detectable biological reactivity as determined by biocompatibility tests." Based on this construction, the district court held that HemCon infringed the claims.

HemCon requested reexamination and convinced the PTO to accept a broader construction of the claims than had been accepted by the district court, i.e., that "biocompatibility" means "low variability, high purity, and little or no detectable reactivity as determined by cytotoxicity elution assays having a test score of 0, 1, or 2." The examiner construed the claim broadly to avoid "creating the situation where [the dependent claims] would be improper for failing to further limit the claims from which they depend." In view of this broad construction, the examiner rejected the claims in view of the prior art. Marine Polymer's response was to eliminate the claim differentiation issue by deleting the dependent claims reciting a non-zero bioreactivity and arguing a narrower construction of "biocompatible" that excluded the prior art that, according to Marine Polymer, exhibited severe bioreactivity problems. The examiner found this convincing and Marine Polymer's independent claim issued without amendment.

On appeal from the district court, the Federal Circuit agreed with HemCon that the issuance of the reexamination certificate

changed the scope of the independent claim even though Marine Polymer never amended the claim. And this change gave rise to intervening rights. The court framed the issue not in terms of whether the claim was amended, but rather whether the scope of the claim was substantively changed during the reexamination proceeding. The court acknowledged that "[a]lthough we have not directly addressed whether arguments made to the PTO during reexamination can amend the scope of the claims for purposes of intervening rights doctrine, we have consistently held that arguments made to the PTO during reexamination can create an estoppel or disavowal and thereby change the scope of the claims even when the language of the claims did not change." 659 F.3d at 1091. The court remarked, "[w]e see no reason why this rule, giving effect to disclaimer of claim scope during reexamination or reissue, should not also apply in the context of intervening rights." *Id*. at 1092.

In so holding, the court rejected Marine Polymer's argument that the reexamination did not result in any change in the district court's construction. Instead, the court concluded that "the district court erred in construing the claims to require 'no detectable biological reactivity." because the specification teaches that the polymer can be biocompatible if the polymer exhibits "mild reactivity." *Id*. Thus, it was only after canceling the inconsistent dependent claims that Marine Polymer was able to convince the examiner to adopt the district court's construction. Marine Polymer therefore effectively amended the claims through argument to the PTO, thereby giving rise to intervening rights.

Judge Lourie in his dissent pointed to statutory language suggesting that intervening rights apply in the context of reexaminations only to amended or new claims.

Glaringly absent from both parties' arguments was any discussion of the fact that the standard for claim construction during litigation is different from the broadest reasonable construction standard applicable to PTO proceedings such as reexaminations. Indeed, one could argue that the cancellation carried out by Marine Polymer during the reexamination was nothing more than its attempt to get the same construction of the claim under the broader PTO standard as it had obtained under the narrower litigation standard at the district court. If such were indeed the case, then in reality there was not a narrowing, especially when one considers that intervening rights are relevant only in the context of infringement proceedings before district courts. Accordingly, the better rule would be to not penalize the patent holder unless the litigation construction of a claim before reexamination is different from the litigation construction of that claim after reexamination.

On *en banc* review, the Federal Circuit reversed the panel decision and held that intervening rights did not apply for an unamended claim, relying primarily on the plain language of the statute. It will be interesting to see whether intervening rights apply where a district court (1) looks at an unamended claim both before and after reexamination and (2) the construction of that claim changes in view of the reexamination prosecution.[40]

Reissue claims that replaced "ceramic composite" for "solid solution" of the original patent did not run afoul of the recapture rule because the amendment did not broaden the scope of the properly construed claims of the original patent.

In *AIA Engineering v. Magotteaux International*, 657 F.3d 1264, 100 U.S.P.Q.2d 1089 (Fed. Cir. 2011), the court reviewed whether replacement of the phrase "solid solution" with "ceramic composition" during prosecution of a reissue application was violative of the rule against recapture. Finding that such reissue amendment did not broaden the scope of the claim when it was properly construed, the Federal Circuit reversed the district court's holding that the patentee had violated the recapture rule.

The court noted that "the recapture rule prevents a patentee from regaining subject matter deliberately surrendered during the prosecution of the original patent." 657 F.3d

[40] On March 15, 2012, the Federal Circuit issued a divided *en banc* ruling that "intervening rights do not apply to claims that have not been amended and are not new." Marine Polymer v. Hemcon, Appeal No. 2010-1548 slip op. at 4 (Fed. Cir. 2012) (en banc).

at 1272. The test for recapture is whether the patentee surrendered the recaptured subject matter (1) by pursuing "reissue claims [that] are broader in scope than the original patent claims" (2) when "the broader aspects of the reissue claims relate to subject matter surrendered in the original prosecution," and (3) when the reissue claims were not "materially narrowed in other respects" to avoid the recapture rule. *Id*. In reversing the district court, the Federal Circuit emphasized the need to properly construe the original patent claims in determining whether broadening has occurred.

Here, Magotteaux amended its claim directed to a composite including a ceramic pad to recite such pad as consisting of a homogeneous "ceramic composite" rather than a homogenous "solid solution." Noting that a "solid solution" was broader than a "ceramic composite" and that such term was added to secure patentability without narrowing in other respects, AIA Engineering argued that the reissue patent had violated the recapture rule. However, the court agreed with Magotteaux that when both terms were properly construed, no broadening had occurred. The court explained that the only mention of "solid solution" in the specification stated that "'inserts' in the 'composite wear component' are 'made of a ceramic material, itself *composite*, consisting of a *solid solution* or homogeneous phase of 20 to 80% of Al_2O_3 and 80 to 20% of ZrO_2.'" Because the ordinary meaning of solid solution means a uniform crystalline structure, while a composite is a mixture of two materials that retain their own distinct crystalline structures, "rigidly confining 'solid solution' to its ordinary meaning gives rise to a contradiction in terms." *Id*. at 1276. The court remarked, "We strive, where possible, to avoid nonsensical results in construing claim language," *id*., and thus concluded that solid solution is equivalent to ceramic composite. Further, the court found no serious dispute that the only method described in the patent results in a composite material and not a solid solution. Because broadening of the claims in this aspect had not occurred, the court reversed the district court's finding of recapture.

FDA Extension

A patent term extension for FDA delays applies to the patent as a whole including all of its claims, not just to the individual claims that specifically cover the approved drug.

In *Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc*., 655 F.3d 1291, 99 U.S.P.Q.2d 1713 (Fed. Cir. 2011), Novartis argued that because Genetics Institute (GI) itself identified only certain of its claims as covering its commercial ReFacto® product in its patent term extension application under § 156(d)(1), the extension does not apply to the claims that GI did not identify as covering the commercial product. The court rejected Novartis's contention that patent term extensions apply on a claim-by-claim basis to only those claims that cover the commercial product, holding that "[t]he text of subsection (b), which sets forth 'the rights derived from *any patent the term of which is extended* under this section,' . . . is equally clear that § 156 applies to the term of the patent, not individual claim(s)." 655 F.3d at 1300. The court did note, however, that even though the patent as a whole is extended, "its effect may be limited to certain of its claims." *Id*. at 1301. Finally, the court rejected Novartis's argument that no patent extended under § 156 can form the basis of a § 291 interfering patents action, holding that "[t] he statutory text does not suggest that rights afforded by § 156 are so limited." *Id*.

Infringement

For infringement actions under § 271(g) alleging that an infringer carried out a claimed process outside the U.S., the patentee need only show a "substantial likelihood" that the product was made by the patented process and that it made a reasonable effort to determine the process actually used.

In *Creative Compounds, LLC v. Starmark Laboratories*, 651 F.3d 1303, 99 U.S.P.Q.2d 1168 (Fed. Cir. 2011), the court reviewed whether Creative infringed Starmark's claim directed to a process comprising reacting a molar excess of creatine monohydrate and a dicarboxylic acid or a tricarboxylic acid

with heat to form the creatine salt. Starmark alleged infringement under § 271(g) based on Creative's manufacture of the compound in China. Starmark engaged an expert who analyzed Creative's compound and concluded that it was made by Starmark's process. On review, the court noted that

> [w]hile the burden typically rests with the patentee to prove infringement, the law makes exceptions. In actions alleging infringement of a process claim under § 271(g), there is a rebuttable presumption that the imported product was made from the patented process if the court finds: "(1) that a substantial likelihood exists that the product was made by the patented process, and (2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine."

651 F.3d at 1314. Based on Starmark's expert testimony and the fact that Starmark sought discovery on the manufacturing process but Creative failed to produce documentation regarding the process, the court concluded that "the burden of establishing that the product was not made by [the claims] was properly on Creative." *Id*. at 1315. Because Creative offered no argument as to why or how the process employed to create the product does not infringe. the court concluded the district court properly granted summary judgment of noninfringement.

In the absence of an indemnity agreement, letters by a patent holder to the declaratory plaintiff's customers show at most an economic interest rather than an actual controversy between the parties under the Declaratory Judgment Act.

In *Creative Compounds LLC v. Starmark Laboratories*,(Fed. Cir. 2011) the court reviewed whether Starmark properly established declaratory judgment jurisdiction to seek a judgment of invalidity against Creative's patent. The court noted that an action in declaratory judgment requires "adverse legal interests" in the sense that "there be a dispute as to a legal right . . . that the declaratory defendant could have brought or threatened to bring, if not for the fact that the declaratory plaintiff had preempted it." 651 F.3d at 1316. Starmark contended that Creative could have brought both infringement actions and an interference action under § 291 against Starmark. The court disagreed noting (1) that Creative never accused Starmark of infringing its patent and (2) the letters sent by Creative alleging infringement went not to Starmark but to customers of the claimed product. *Id*. To the extent that Starmark contended that customer letters were sufficient, the court found that such contention "rings hollow" because Creative sent the letters to customers of Starmark's predecessor before Starmark was even formed. *Id*. Accordingly, "[i]n the absence of an indemnity agreement between Starmark and one of these 'customers,' Starmark has, at most, only an economic interest in clarifying its customers' rights under Creative's patents. 'Such an economic interest alone . . . cannot form the basis of an "actual controversy" under the Declaratory Judgment Act.'" *Id*. (citation omitted).

Post-approval activity not covered by the exemption under §271.

In *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 100 U.S.P.Q.2d 1492 (Fed. Cir. 2011), Classen charged Biogen and GlaxoSmithKline with direct infringement on the ground that both companies participated in studies evaluating associations between childhood vaccinations and the risk of developing type 1 diabetes to determine whether timing of vaccination influences risk. Classen argued that the district court extended §271(e)(1) beyond its statutory and legislative purpose because there is no issue in this case of submissions for regulatory approval of generic products, or like policy considerations because the vaccines had already been approved by the FDA. The court agreed, holding that "§271(e)(1) provides an exception to the law of infringement in order to expedite development of information for regulatory approval of generic counterparts of patented products. The statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained." 659 F.3d at 1070.

Foreseeability does not require flawless perfection to create an estoppel under the doctrine of equivalents.

In *Duramed Pharms, Inc. v. Paddock Labs., Inc*., 644 F.3d 1376, 99 U.S.P.Q.2d 1388 (Fed. Cir. 2011), the Court outlined the contours of the unforeseeability exception to the *Festo* presumption[41] of estoppel against the assertion of doctrine of equivalents that arises when a claim is amended during prosecution. The dispute in this case was over how much of the claimed equivalent must be suggested by the prior art before that equivalent is deemed foreseeable. The court permitted flexibility in proving foreseeability and thereby reaffirmed the strength of prosecution history estoppel in defeating claims of infringement under the doctrine of equivalents.

The equivalence issue centered around whether Paddock's polyvinyl alcohol ("PVA") moisture barrier coating was the equivalent of Duramed's ethylcellulose coating for the hormone replacement therapy product, Cenestin®. Because Duramed added the ethylcellulose moisture barrier coating limitation during prosecution to overcome a prior art rejection, Duramed had to rebut the *Festo* presumption of estoppel from having made a narrowing amendment. Duramed sought to rebut the estoppel presumption by arguing that the use of PVA as a moisture barrier coating was unforeseeable at the time the amendment was made. Paddock countered by citing numerous instances where PVA was used as a moisture barrier coating in pharmaceutical formulations, albeit not for the specifically claimed conjugated estrogens.

The Federal Circuit agreed with Paddock, noting that "[f]oreseeability does not require flawless perfection to create an estoppel." 644 F.3d at 1381. Referring to the claim preamble reciting "pharmaceutical compositions," the court found that the claim broadly defines the field of invention for purposes of determining whether a particular moisture barrier coating would have been a foreseeable equivalent. The court thus held that "PVA [moisture barrier coatings] need only to have been known in the field of pharmaceutical composition as of the time of Duramed's narrowing amendment," *id*. and rejected Duramed's argument that the PVA had to have been used with the claimed conjugated estrogens.

This case demonstrates an interesting interplay between the foreseeability doctrine discussed above and the doctrine of ensnarement, which holds that a patentee cannot broaden a claim by equivalents if such claim which would read on the prior art. Here, Duramed's argument that forseeability required a suggestion to practice the claimed equivalent would have, in effect, raised the bar on Paddock to show foreseeability to such a level that the showing would have been tantamount to that required to prove ensnarement. The *Duramed* decision rejects this approach and preserves the dichotomy between ensnarement and foreseeability. As a result, patentees who have narrowed their claims during prosecution face a significantly more difficult time in asserting infringement of doctrine of equivalents due to the ease with which a defendant can make the *Festo* presumption stick by countering the patentee's argument that the equivalent would have been unforeseeable.

Claim limitation "having a temperature within 2°C of the predetermined temperature," when read in accordance with the claim as a whole and specification, "will tolerate and correct minor fluctuations outside of the 4°C range."

In *Lexion Medical, LLC v. Northgate Techs., Inc*., 641 F.3d 1352, 98 U.S.P.Q.2d 1388 (Fed. Cir. 2011), the Federal Circuit clarified that it "prefers a claim interpretation that harmonizes the various elements of the claim to define a workable invention." 641 F.3d at 1356. Lexion's invention was a method for heating gas used in endoscopic procedures so that it would not cause unwanted chilling in the patient during surgery. At issue was the step reciting "flowing the gas into the delivering means such that the gas enters the patient humidified and having a temperature *within 2°C of the predetermined temperature* and thus providing the gas." *Id*. at 1354.

[41] *Festo Corp. v. Shoketsu Kinzoku Kogyu Kabushiki Co*., 535 U.S. 722, 62 U.S.P.Q.2d 1705 (2002).

Northgate argued that its Humi-Flow device did not infringe Lexion's patent because it did not always produce a gas having a temperature within 2°C of the predetermined temperature (i.e., body temperature of the patient). The court addressed the issue of whether the method permitted minor fluctuations outside of the 4°C range bracketing the body temperature of the patient. The court began its analysis by recognizing that it "prefers a claim interpretation that harmonizes the various elements of the claim to define a workable invention." *Id*. at 1356. Considering the claim language itself, the court concluded that limitations (b), (c), and (e), read together, "will tolerate and correct minor fluctuations outside of the 4°C range of limitation (e)." *Id*. The court further found that the term "within" limitation (e) did not require "always within" as argued by Northgate. *Id*. at 1357. Under the new interpretation, the Federal Circuit found that the district court properly concluded on summary judgment that Lexion's claims were infringed.

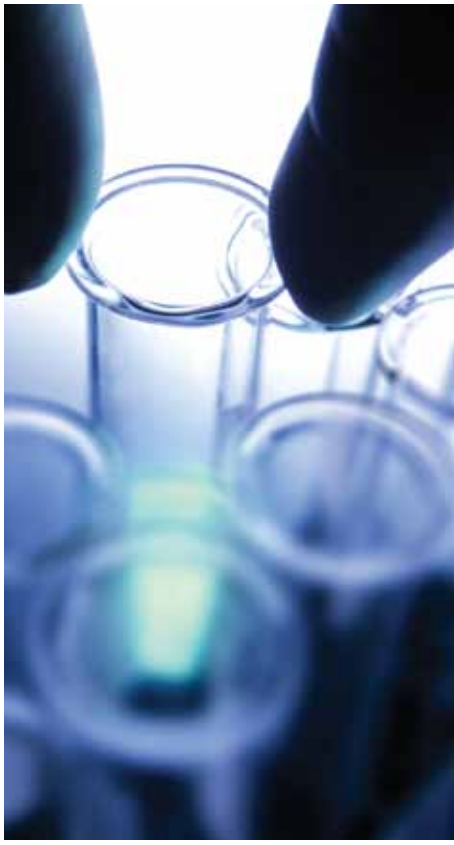
Conclusion

In a perfect world, the patent laws would achieve two goals. First, they would strike the proper balance between (1) properly incentivizing the private sector to invest in the new technologies essential to our advancement as a society by granting exclusivity through a patent while (2) limiting the scope of those patents to prevent overreaching that encompasses the prior art or unduly extends the scope of protection above and beyond what the inventor has actually invented. Second, they would provide a sufficient level of certainty so that those inclined to invest the time and resources in a new invention will know whether the fruits of their efforts will merit meaningful patent protection.

The question of whether the courts are striking the proper balance is one that is going to be highly dependent on one's industry and position in that industry, i.e., brand-name manufacturer versus generic or manufacturer versus troll. For that reason, it is unlikely that one group is likely to successfully persuade the other in the debate. What is not debatable however is that the balance has, with some admitted exceptions, significantly shifted against patent holders, whether in terms of written description, anticipation, obviousness or statutory subject matter. The only area where the shift has gone in favor of the patent holder is in the area of inequitable conduct and, through the legislation, the best mode requirement.

As for providing clarity and certainty to guide decisions by institutions and individual inventors, it is proving more and more difficult to conclude that decisions are based on logic and precedent as opposed to a political agenda, at both the Supreme Court and the Federal Circuit. For this reason, there is much turmoil and uncertainty now regarding whether methods involving personalized medicine can be drafted in a manner that will pass statutory muster. Just when we concluded that claims to isolated genes were safe, the Supreme Court remanded *Myriad* back to the Federal Circuit. On the obviousness front, the Federal Circuit does not seem equipped to weigh conflicting "red light/green light" teachings in a manner that provides any degree of predictability of outcome. In reexaminations, we had intervening rights applied without claim amendment, although that ultimately resolved itself after an en banc review. New law has been forged in the areas of written description for antibodies, for unexpected results, for best mode and for obviousness-type double patenting, none of which could have reasonably been predicted based on precedent. A comment that virtually everyone in this field has heard uttered in response to the question of whether a given patent will or will not survive Federal Circuit review is: "It depends on the panel you get."

In next year's review, we suspect there will be an equal number of surprises to discuss.



Practices

Intellectual Property

Biotechnology

Intellectual Property Litigation

Patent

Contact

rschulman@hunton.com

Washington, DC
202.955.1928
202.778.2201

Education

JD, American University, Washington College of Law, 1983

BS, Biochemical Engineering, Rutgers University, with honors, 1980

Bar Admissions

District of Columbia

Robert M. Schulman

Rob's practice focuses on all phases of patent law in the areas of biotechnology, pharmaceuticals and chemical inventions. His major focus is in the area of patent interferences at the patent office and appellate level, for all types of inventions. He has extensive experience in the area of clearance studies for both established and start-up companies, including analysis of validity, infringement and right-to-use.

Rob's practice includes development of patent portfolios, patent prosecution including application drafting, prosecution of applications and appellate review. He also has practice experience with reissues and re-examinations with a special focus in recombinant plant technology, vaccines and drug delivery technology.

Rob is registered with the US Patent and Trademark Office and is a member of the Court of Appeals for the Federal Circuit and Federal Circuit Inn of Courts.

Rob has taught Interference Practice at Georgetown University Law School since 1992.

Relevant Experience

- Established the firm's chemical and life science patent practice.
- Responsible for compilation of patent case data base of Federal Circuit and Board of Appeals and Interferences decisions starting in 1982.
- Successfully developed intellectual property portfolios for both pharmaceutical and biotech companies from inception to product launch and sale of company.
- Conducted numerous due diligence patent reviews, including validity, infringement and right-to-use studies.
- Engaged by numerous companies to train their counsel in best practices for drafting claims and conducting prosecution and interferences.
- Successfully represented companies in using interferences to invalidate competitor's patents in all technologies but with special focus on biotech, plants, medical devices and pharmaceuticals.
- Successfully represented both junior and senior parties in biotech, chemical mechanical and electrical interferences.
- Successfully represented parties in federal court appeals of interference decisions.
- Successfully worked with trial lawyers in major biotech and pharmaceutical district court litigation.
- Representing substantial number of domestic and foreign chemical, pharmaceutical and biotech companies in the areas of plant biotechnology, vaccines, drug delivery, DNA screening methods, receptor binding, computer DNA analysis, and gas processing, and polymers.
- Obtained numerous commercially significant patents which have been successfully enforced in judicial proceedings.
- Hatch-Waxman experience for patent term extension and immunity from infringement during FDA approval process.

Memberships

- Member, American Intellectual Property Association
- Member, American Bar Association
- Member, Intellectual Property Owner's Association
- Member, Biotechnology Industrial Organization
- Member, Federal Circuit Inn of Courts

Publications

- Co-author, Pharmaceutical, Chemical and Biotech Year in Review 2010, 2011
- Pharmaceutical, Chemical and Biotech Year in Review, 2003-2010
- Co-author, Pharmaceutical, Chemical and Biotech Year in Review 2009, 2010
- Co-author, Pharmaceutical, Chemical and Biotech Year in Review 2008, 2009
- Co-author, Pharmaceutical, Chemical and Biotech Year in Review 2007, 2008
- Co-author, Researchers Beware; Use Of Your Competitor's Patented Inventions In Your Research Is Probably Not Exempt From Infringement, Even Where Such Research Ultimately Generates Data for FDA Submission, *Intellectual Property Today*, March 1, 2004

Events

- Presenter, Developments in Biotechnology, Chemical and Pharmaceutical IP Law, March 8, 2012
- Speaker, Balancing Work and Life; American Intellectual Property Law Association mid-Winter meeting, Las Vegas Nevada; January 2012,
- Speaker, Legislative and Judicial Developments Affecting Patenting of Biotech Inventions in the United States, DeClerq & Partners IP Seminar, Belgium, November 18, 2011
- Speaker, Updates on Case Law Relating to Pharmaceutical Inventions, New Jersey Intellectual Property Law Association, December 8, 2010,
- Speaker, Updates on Case Law Relating to Pharmaceutical Inventions, New Jersey Intellectual Property Law Association, December 7, 2009
- Speaker, Federal Circuit Cases Relating to Patent Interferences, Intellectual Property Owners Meeting, Washington, D.C., November 1, 2008

Awards & Recognition

- Selected for inclusion as a "Best Lawyer," Intellectual Property, *The Best Lawyers in America*, 2010, 2011
- Listed as a top intellectual property attorney, *Virginia Business* magazine, 2010
- Listed as one of 20 top intellectual property attorneys in *Washington Post* Survey, 2010 and 2011
- Listed as a top 25 intellectual property and technology attorney, *Virginia Business* magazine, 2000

Practices

Intellectual Property

Patent

Intellectual Property Litigation

Biotechnology

Contact

jvockrodt@hunton.com

Washington, DC
202.419.2021
202.778.2201

Education

JD, George Washington University Law School, 2005

BS, Chemical Engineering, University of Arizona, 1999

Bar Admissions

District of Columbia

Maryland

Jeff B. Vockrodt

Jeff has counseled clients on global patent procurement and enforcement strategies, represented clients in complex administrative proceedings within the United States Patent & Trademark Office and litigated patents in district court. He has significant experience with patent reexamination due to his representation of both patent owners and third party requesters in reexamination proceedings involving concurrent district court litigation and opposition of foreign counterpart patents.

Prior to his admission to the bar, Jeff served as a patent examiner in the United States Patent & Trademark Office, where he worked on patent applications in the semiconductor manufacturing arts. While serving as a patent examiner, he assisted administrative patent judges at the Board of Appeals and Interferences. He also served as a law clerk for the Office of Unfair Import Investigations within the United States International Trade Commission (ITC), where he assisted staff investigative attorneys at the institution, pre-trial and trial stages of ITC litigation.

Relevant Experience

- Represented numerous patentees and third party requesters in both inter partes and ex parte reexamination proceedings, several of which involved patents that were subject to simultaneous district court litigation or foreign opposition proceedings.
- Represented clients in matters involving complex issues arising from the confluence of district court litigation and reexamination, reissue, and interference proceedings in the United States Patent & Trademark Office.
- Represented clients in complex multi-patent district court litigation, including discovery and pleadings, claim construction hearings, summary judgment briefing and appeal.
- Prepared and prosecuted numerous patent applications in the United States Patent & Trademark Office and directed patent procurement strategy for several patents portfolios each including hundreds of patent applications worldwide.
- Counseled clients in the chemical and pharmaceutical industries on numerous due diligence investigations and licensing transactions involving patent infringement, validity, and freedom to operate issues.

Publications

- Co-author, Pharmaceutical, Chemical and Biotech Year in Review 2009-2011
- Author, Hunton & Williams Reexamination Essentials, 2010

David A. Kelly

David Kelly is a registered patent attorney, who focuses his practice on protecting the intellectual property rights of his clients. In addition to counseling his clients on a diversity of intellectual property issues, David also has extensive patent litigation experience, representing both patent owners and accused infringers, in a wide variety of technologies, including biotechnology, pharmaceutics, medical devices and software-related inventions.

David is admitted to practice before the Federal Circuit, the Eleventh Circuit, all appellate courts of Georgia and Virginia, and the United States Patent and Trademark Office.

Relevant Experience

- Trial counsel for *Fortune* 500 packaging solutions company in patent infringement litigation involving the company's patented perfume packaging technology. Successfully briefed and argued *Markman* issues, obtaining favorable claim construction for all 11 disputed claim terms. Successfully briefed and argued all summary judgment motions, including: (1) obtaining summary judgment that patent claims were novel, non-obvious, definite, and adequately supported; (2) obtaining summary judgment that the patent applicants did not commit inequitable conduct; and (3) successfully defeating all of defendants' motions for summary judgment of non-infringement and invalidity. Awaiting a ruling from the district court on the issue of infringement after a four week bench trial.
- Handling and managing all aspects of complex patent infringement litigations, ranging from pre-filing due diligence, drafting of pleadings, motions, and briefs, conducting fact and expert discovery, briefing and arguing claim construction and dispositive motions, negotiating settlement, drafting of settlement and license agreements, and appeals.
- Trial counsel for pharmaceutical company accused of infringing patents to abuse-resistant opioid products. After successfully defending against the patent owner's attempt to have the case transferred or dismissed, the case was settled on confidential terms favorable to the client on the eve of the summary judgment hearing.
- Trial counsel for owner of patents relating to DNA sequencing technology. Obtained favorable *Markman* ruling, which was affirmed on appeal. Grant of summary judgment against the client was reversed on appeal, and the case is now pending before the district court.
- Trial counsel for leading manufacturer of carpet tiles in a case involving both claims and counterclaims of patent infringement. After a favorable *Markman* ruling, the case was settled on confidential terms favorable to the client.
- Trial counsel on behalf of an industry leader in medical devices accused of infringing medical device patents. After successfully invalidating several of the patent claims, the case was stayed pending re-examination of the asserted patents.
- Appellate counsel for global media and entertainment company accused of infringing patents relating to inventory management systems. Obtained a favorable settlement prior to oral argument before the United States Court of Appeals for the Federal Circuit.
- Pro bono work includes filing a *writ of certiorari* in the United States Supreme Court for an engineer seeking to reinstate his patent for improved automobile engines.
- Counseling clients on a wide range of intellectual property issues.
- Conducting due diligence , freedom-to-operate, validity, and patentability analyses, and preparing formal legal opinions reflecting conclusions of such analyses.
- Preparing and prosecuting patent applications for biotechnology, chemical, and pharmaceutical-related inventions.

Memberships

- Member, Atlanta Bar Association, 2005

Practices

Intellectual Property

Biotechnology

Intellectual Property Litigation

Patent

Contact

dkelly@hunton.com

Atlanta
404.888.4280
404.888.4190

Education

JD, University of California–Davis, 2003

Graduate studies, Microbiology and Immunology, University of North Carolina at Chapel Hill, 2000

BS, Genetics, University of Georgia, 1997

BS, Microbiology, University of Georgia, 1997

Bar Admissions

District of Columbia

Georgia

Virginia

Publications

- Co-author, Pharmaceutical, Chemical and Biotech Year in Review 2007-2011
- Author, “Indefiniteness Invalidations Continue to Rise Sharply in 2008,” 77 Patent, *Trademark & Copyright J*. 676, 2009
- Co-author, “First *Datamize* and Now *Aristocrat* and *Finisar*: Electrical and Software Patent Invalidations For Indefiniteness Sharply on the Rise,” Intellectual Property Owners' Association, Annual Conference, San Diego, September 2008
- Co-author, “Federal Circuit Hits Pharmaceutical Patentees Hard,” *National Law Journal*, August 18, 2008
- Author, “In the Wake of *Datamize* and *Halliburton*: The Recent Spate of Patent Invalidations for Indefiniteness and the Implications for Patent Holders,” 75 *Patent, Trademark & Copyright J*. 1856, 2008
- Co-author, “Recent Trends in Patent Practice: The Federal Circuit's Treatment of Pharmaceuticals,” 442 *Life Sciences Law & Indus*. 1, August 17, 2007
- Co-author, “Is It Harder To Enforce Pharmaceutical Patents?,” *National Law Journal*, August 28, 2006
- Author, "What Constitutes a 'New Use' of a Known Composition and Should a Patentee's Purported Objective Make Any Difference?” 21 *Santa Clara Comp. & High Tech*. L.J. 319, 2005
- Co-author, “The Written Description Requirement,” *National Law Journal*, May 31, 2004
- Author, "The Federal Circuit Transforms the Written Description Requirement Into a Biotech-Specific Hurdle to Obtaining Patent Protection for Biotechnology Patents," 13 *Alb. L.J. Sci. & Tech*. 249, 2003
- Author, “Despite a Recent Eleventh Circuit Decision, Diversity Remains a Compelling Interest in the University Admissions Process,” 17 *BYU J. Pub*. L. 73, 2003

Events

- Presenter, Developments in Biotechnology, Chemical and Pharmaceutical IP Law, March 8, 2012
- Co-author and presenter, To Sue or Not to Sue: Evaluating a Patent Suit, CLE-approved webinar, December 2011
- Author and presenter, U.S. Patent Litigation Basics, November 2011
- Co-author and presenter, Legislative and judicial developments affecting patenting of biotech inventions in the US, November 2011
- Presenter, Effective Brief Writing, Atlanta Bar Association, December 2010
- Presenter, Biologics Price Competition and Innovation Act: Basics of the New Law and Implications for Biologics Companies, September 2010
- Co-author and presenter, Summary of Recent Federal Circuit Case Law in the Chemical, Pharma, and Biotech Arts, November 25, 2009
- Co-presenter, Winning Strategies for Intellectual Property Litigation, CLE-approved seminar at Hunton & Williams, March 2009
- Author and Presenter, A Crash Course in Better Legal Writing, CLE-approved seminar at Hunton & Williams, 2008
- Co-author and presenter, Indefiniteness: The Rise of Another Solid Tool to Defend Against Patent Infringement, CLE-approved seminar at Hunton & Williams, September 2008

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