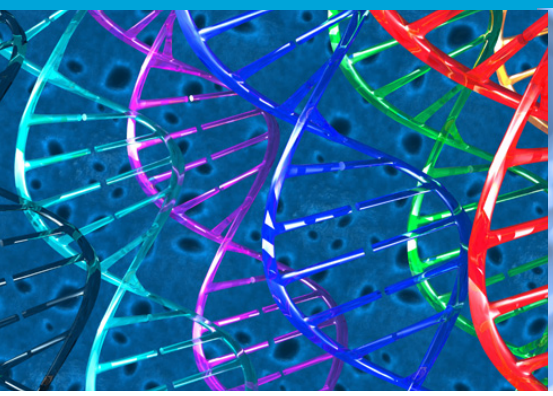
HUNTON& WILLIAMS

# Pharmaceutical, Chemical and Biotech Year in Review 2012



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## Introduction:

If you pose the question to the average patent practitioner in the chemical, pharmaceutical or life science areas to highlight the most significant developments of 2012, you are very likely to hear about two things — (1) the blockbuster cases such as *Myriad*[1] and *Prometheus*,[2] which are redefining previously well-entrenched doctrines in the area of statutory subject matter of biological molecules and diagnostics/personal medicine and (2) the continued implementation of the America Invents Act.[3]

Little noticed, however, has been the increase in Federal Circuit decisions on anticipation and obviousness affecting chemical, pharmaceutical and biotech inventions in 2012, which has far exceeded the number of cases decided in recent years. Of greatest concern is that, whether intentional or not, the court in several cases has significantly blurred the line between anticipation and obviousness, opting to deny applicants the ability to rely on a teaching away or secondary considerations even in situations lacking the precision that precedent required for a finding of anticipation.[4] The court has also established new doctrine in the area of "lead compounds," apparently holding that only compounds disclosed as having the same utility as the claimed compounds can serve as lead compounds, even where the claim under review is silent as to utility. The result is a body of law assembled over the past year that often seems to disregard precedent and interject much confusion into the law.

In the area of reexaminations, the court *en banc* reversed its earlier panel decision and held that intervening rights for reexamined claims cannot be applied where an applicant never amended the claim.

Finally, in the area of written description, the court seems to have created a new test for supporting negative limitations in a claim, holding that the disclosure must provide a reason for excluding a component.

[1] *Association for Molecular Pathology v. USPTO*, 689 F.3d 1303, 103 U.S.P.Q.2d. 1681 (Fed. Cir. 2012)

[2] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 101 U.S.P.Q.2d 1961 (2012)

[3] Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (codified as amended in scattered sections of 35 U.S.C.

[4] Robert M. Schulman, "Is Obviousness the new Anticipation?" Law 360 (Oct. 2,2012)

## Cases relating to statutory subject matter under Section 101

### Prometheus — *Replacing the Bright Line Rule for Patent-Eligibility with a New, Blurrier "Additional Elements" Rule*

In *Bilski,*[5] the United States Supreme Court warned us a claim might meet the machine-or-transformation ("MOT") test yet still not be statutory, or it might fail to meet the test and still be statutory. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 101 U.S.P.Q.2d 1961 (Fed. S Cir. 2012), the Court wasted no time in giving us an example of the former, holding that even though Prometheus's claims met the MOT test, they did not meet the patent-eligibility requirement of Section 101.

The claim at issue in *Prometheus* recited "[a] method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder …" The claim recited "(a) administering a drug providing 6-thioguanine to a subject … and (b) determining the level of 6-thioguanine in said subject …" The claim further recited "wherein the level of 6-thioguanine less than [a predefined level] indicates a need to increase the amount of said drug subsequently administered to said subject" and "wherein the level of 6-thioguanine greater than [a predefined level] indicates a need to decrease the amount of said drug subsequently administered to said subject." 132 S. Ct. at 1295 (internal quotation marks omitted).

The case arrived at the Supreme Court following a remand to the U.S. Court of Appeals for the Federal Circuit to reconsider its earlier decision holding the claims to be patent-eligible under the MOT test. On remand, the Federal Circuit affirmed its earlier decision, again relying on the MOT test and holding that "methods of treatment … are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition."[6]

The Supreme Court struck down the claim as patent-ineligible, holding that the claim was directed to a natural principle. The Court ruled that merely reciting the correlation between the metabolites produced and the need to adjust the amount

[5] *Bilski v. Kappos*, 130 S. Ct. 3218, 95 U.S.P.Q.2d. 1001 (2010)

[6] *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1356, 97 U.S.P.Q.2d. 1097, 1104 (Fed. Cir. 2010)

of drug subsequently administered was not enough to satisfy Section 101. Rather, to be patent-eligible, a claim must include additional elements or steps that integrate the natural principle into the invention such that it is practically applied. *Id*. at 1296-97. Thus, satisfying *Bilski*'s MOT test is not enough. Instead, the Court announced a new "additional features" test for assessing patent-eligibility:

> If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. *Id*. at 1297.

Put another way, the question is whether the claims recite "significantly more" than just the natural laws on which they rely. Because Prometheus's claim did not recite "significantly more" than the natural law, it was invalid: "[S]imply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." *Id*. at 1300. The claims simply "tell doctors to apply the law somehow when treating their patients." *Id*.

The Court contrasted Prometheus's claim to a "typical" patent claim to a new drug or new use of a known drug, explaining that the steps in Prometheus's claim "add nothing of significance to the natural laws themselves" and "do not confine their reach to particular applications of those laws." *Id*. at 1302. The Court also dismissed the notion that Sections 102 and 103 are sufficient to address its concerns, observing, "to shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do." *Id*. at 1304.

*Prometheus* signals a major shift in Section 101 jurisprudence, and the courts and PTO are responding. Shortly after *Prometheus* was handed down, the PTO issued interim subject matter eligibility guidelines,[7] which set forth "three essential inquiries" in assessing patent eligibility: (1) Is the claimed invention directed to a process? (2) If yes, does the claim focus on use of a natural principle? (3) If yes, is the claim more than a law of nature plus the general instruction to simply "apply it" (e.g., does it include additional elements/steps that integrate the natural principle into the invention such that the natural principle is practically applied)? If no, the claim is not patent-eligible and should be rejected.[8] The PTO has also passed the word along to its examiners to give particularly close scrutiny to medical diagnostic claims — like those at issue in *Prometheus* — and any other claim that merely recites a correlation.

***Federal Circuit Reaffirms Patent-Eligibility of Isolated DNA; But Supreme Court Will Have the Last Word***

As we reported in last year's "Year in Review,"[9] in *Association for Molecular Pathology v. USPTO* (Fed. Cir. 2011),[10] a split panel of the Federal Circuit held that Myriad's patent claims on the BRCA1 and BRCA2 genes and methods of screening a patient's predisposition to breast cancer using those genes were patent-eligible under Section 101. In the wake of *Prometheus*, however, the Supreme Court granted AMP's motion to vacate and remand the Federal Circuit's *Myriad* decision for further consideration in view of *Prometheus*. On remand, the Federal Circuit issued an opinion remarkably similar to its initial opinion.

In *Association for Molecular Pathology v. USPTO*, 689 F.3d 1303, 103 U.S.P.Q.2d, 1681 (Fed. Cir. 2012) the Federal Circuit unanimously affirmed the patent-eligibility of isolated cDNA claims. But the panel was split, as in the first opinion, on whether isolated gene sequences are patent-eligible. Writing for the majority, Judge Lourie held that isolated DNA sequences, whether cDNA or not, are patent-eligible subject matter under Section 101 because they are "markedly different" from the DNA found in nature. While the isolated sequences may share the same informational properties as the native sequences, human intervention in isolating the DNA imparts it a distinctive chemical identity from that possessed by native DNA. 689 F.3d at 1328-29.

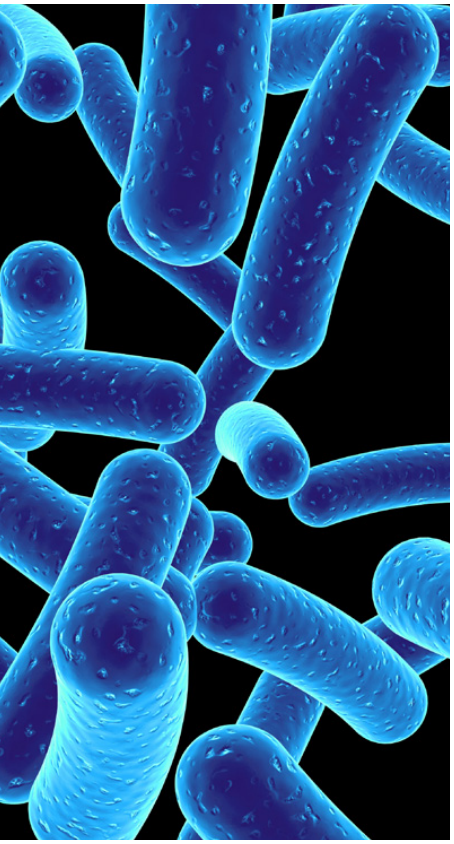
In her concurring opinion, Judge Moore cited precedent, the USPTO's longstanding policy of granting gene patents and the lack of congressional action to change the law as reasons for siding with Judge Lourie. *Id*. at 1337-48. She also restated her previously articulated concerns about upsetting the

[7] USPTO, 2012 *Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature* (2012), http://www.uspto.gov/patents/law/exam/2012_interim_guidance.pdf.

[8] *Id*. at 2.

[9] Robert M. Schulman, Jeff B. Vockrodt & David A. Kelly, "Pharmaceutical, Chemical & Biotech Year in Review 2011" (2012).

[10] 653 F.3d 1329, 99 U.S.P.Q.2.d. 1398 (Fed. Cir. 2011)



"settled expectations of the biotechnology industry" vis-à-vis gene patents. *Id*. at 1344.

Dissenting in part, Judge Bryson reiterated his objections to allowing patents for purified or isolated versions of naturally occurring elements. He compared the isolation of a gene to the snapping of a leaf from a tree, extracting a kidney from a host and "extracting a slab of marble from the earth." *Id*. at 1352-1353 n.4. Citing *Prometheus* in support of his opinion, he reasoned that, since the isolated DNA sequences are essentially identical to the naturally occurring sequences, there is not insufficient inventive contribution to justify patent protection. *Id*. at 1355.

The court next turned to Myriad's method claims, which were divided into two groups: claims directed to methods of "comparing" or "analyzing" the *BRCA* sequences of a patient against the normal *BRCA* gene sequence, and a claim directed to a method of screening potential cancer therapeutics. The court reiterated its pre-*Prometheus* decision invalidating the "comparing" and "analyzing" method claims, while upholding the patent eligibility of the screening method. *Id*. at 1334-36. Notably, the screening method claim was spared because it required growing man-made "transformed cells" in the presence and absence of a potential cancer therapeutic, an inherently transformative step involving the manipulation of the cells and their growth medium. *Id*. at 1336-37.

Many in the biotech community breathed a sigh of relief when the Federal Circuit reaffirmed its earlier decision holding gene patents are patent-eligible. That relief, however, was short lived. On November 30, 2012, the Supreme Court granted *certiorari* in the case.[11] Many commentators — the authors included — predict that the Court will overrule the Federal Circuit decision, and hold that isolated segments of DNA are patent-ineligible "products of nature," not human-made inventions. The implications of such a decision would be hard to overstate. Such implications will be detailed in a future "Year in Review" should the Supreme Court, as feared, strike down isolated DNA claims. In the interim, patent applicants should continue pursuing claims directed to isolated cDNA sequences, shorter fragments of the conserved regions of genes, and other nucleic acid sequences that are structurally distinct from the native chromosomal sequence.

## Cases relating to obviousness and anticipation

***Federal Circuit expands doctrine of anticipation to cover situations where the prior art merely proposes a claimed pharmaceutical method without knowing if it will even work.***

In *In re Montgomery*, 677 F.3d 1375, 102 U.S.P.Q.2d 1881 (Fed. Cir. 2012), the court reviewed the patentability of a claim reciting "[a] method for the treatment or prevention of stroke or its recurrence," comprising "***administering, to a patient diagnosed as in need of such treatment or prevention***, an inhibitor of the renin angiotensin system," such as ramipril.

Montgomery appealed the affirmance by the Patent Office Board of Appeals and Interferences ("the Board") of the primary examiner's rejection of the claims as being anticipated by several references, all of which, according to the Board, "describe the administration of ramipril to subjects at risk of stroke," although none actually showed effectiveness. The question as framed by the court was whether a showing of effectiveness was necessary for inherent anticipation of Montgomery's method.

The only reference ultimately relied upon by the Federal Circuit described the design of a larger trial of ramipril to prevent myocardial infarction, stroke or cardiovascular death for a group of patients at high risk for cardiovascular events such as myocardial infarction and stroke. Although the study ultimately found that patients receiving ramipril had a statistically significant reduction in the risk of stroke, these results were irrelevant to an anticipation analysis because they were not published until after Montgomery's priority date. The only actual administration of ramipril reported in the reference used a dose of ramipril below the therapeutic dose as part of an initial patient "randomization" carried out before the actual trial.

The Board rejected Montgomery's argument that none of the references demonstrated that ramipril actually treats or prevents stroke, noting that ramipril inherently treats or prevents stroke, and "[i]t matters not that those of ordinary skill heretofore may not have recognized these inherent characteristics." Finding that "there is no question here that treating stroke-prone

[11] *Ass'n for Molecular Pathology v. USPTO*, 689 F.3d 1303, 103 U.S.P.Q.2d 1681 (Fed. Cir. 2012), *cert. granted sub nom. 'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (Nov. 30, 2012) (No. 12-398).

patients with ramipril does in fact inevitably treat or prevent stroke," *id*. at 1381, the Federal Circuit affirmed the Board's rejection based on inherent anticipation. Referring to its decision in *Bristol-Myers Squibb,*[12] the court noted that "[w]e have repeatedly held that '[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.' [246 F.3d at 1376] As we stated in *Cruciferous Sprout*, 301 F.3d at 1350, '[i]t matters not that those of ordinary skill heretofore may not have recognized the[ ] inherent characteristics of the [prior art].' "

There are several interesting takeaways from this case.

First, the claim specifically limits the treated population to stroke patients yet the prior art proposed use of the drug not only for stroke but also for myocardial infarction or cardiovascular death. In addition, ramipril was already known for treating high blood pressure. The problem with rejecting the claim as anticipated is that it would preclude a showing by Montgomery, for example, that the proposed research plan was not necessarily predictive of effectiveness. Two examples come to mind — (1) Montgomery shows that other drugs that reduce blood pressure do not reduce the risk of stroke or (2) Montgomery shows that the drug is not effective for treating other uses proposed by the prior art, such as myocardial infarction. Either showing would cast doubt on whether a person skilled in the art would have harbored a reasonable expectation of success at the time of the invention that ramipril would treat strokes, yet by finding unpatentability based on anticipation, the court essentially has foreclosed such a showing. For these reasons it would make more sense to reject the claims based on obviousness, which can be rebutted.

Second, the cases relied upon by the court such as *Cruciferous*,[13] *King*[14] and *Schering*[15] were all distinguishable. For example, in both *King* and *Cruciferous*, a process was already being carried out exactly as claimed, and the applicant merely observed an additional, but previously unappreciated, result of that process.

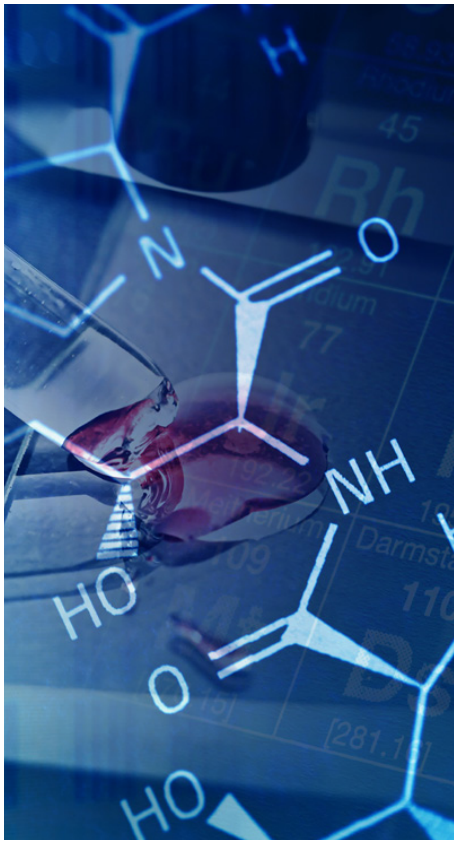
Finally, the case is difficult to reconcile with the court's earlier *In re '318 Litigation* decision, where the court held that a method of treating Alzheimer's was not enabled because it was based on an unproved hypothesis, even though that hypothesis proved to be correct:

> Thus, at the end of the day, the specification, even read in the light of the knowledge of those skilled in the art, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis. That is not sufficient. *See Rasmusson v. SmithKline Beecham Corp*., 413 F.3d 1318, 1325 (Fed. Cir. 2005) ("If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to 'inventions' consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the 'inventor' would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis.")[16]

***Federal Circuit expands doctrine of anticipation to cover a range within a range absent a showing of criticality.***

In *ClearValue, Inc. v. Pearl River Polymers, Inc*., 668 F.3d 1340, 101 U.S.P.Q.2d 1773 (Fed. Cir. 2012), the court reviewed the validity of a claim, reciting "[a] process for clarification of water of *raw alkalinity* ***less than or equal to 50 ppm*** by chemical treatment" comprising adding and blending with the water both a particular high molecular weight aluminum chlorohydrate ("ACH") polymer and a particular high molecular weight quaternized ammonium polymer ("DADMAC") "in an amount sufficient to form a flocculated suspension in the water and to remove turbidity from the water." The district court found that ClearValue's patent was both valid and infringed.

On appeal, the Federal Circuit reviewed whether ClearValue's claims were anticipated over prior art generally teaching treatment of water with an alkalinity of 150 ppm or less and providing a specific example showing the same combination of DADMAC and ACH to clarify water, but with an alkalinity of between 60 and 70




[12] *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 58 U.S.P.Q.2d 1508 (Fed. Cir. 2001).

[13] *In re* Cruciferous Sprout Litig., 301 F.3d 1343, 64 U.S.P.Q.2d 1202 (Fed. Cir. 2002).

[14] *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 95 U.S.P.Q.2d 1833 (Fed. Cir. 2010).

[15] *Schering Corp. v. Geneva Pharm., Inc.,* 339 F.3d 1373, 67 U.S.P.Q.2d 1664 (Fed. Cir. 2003).

[16] *In re* '318 Patent Infringement Litig., 583 F.3d 1317, 92 U.S.P.Q.2d 1385 (Fed. Cir. 2009).

ppm. ClearValue argued that the prior art's teaching of clarifying water with alkalinity of 150 ppm or less is too broad to anticipate the 50 ppm or less limitation of its claim.

The question thus addressed by the court was whether a prior art disclosure of a genus of less than 150 ppm anticipated a claim setting forth a species of less than 50 ppm. ClearValue cited *Atofina v. Great Lakes Chemical Corp*.[17] for the proposition that a broader genus does not anticipate a narrower species. The court in *Atofina* found that a temperature range of 100° to 500° C in the prior art did not anticipate a claimed range of 330° to 450° C in a method of synthesizing difluoromethane:

> Here, the prior art, JP 51-82250, discloses a temperature range of 100 to 500 °C which is broader than and fully encompasses the specific temperature range claimed in the '514 patent of 330 to 450 °C. Given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim.[18]

Interestingly, although the *Atofina* decision cited the lack of "sufficient specificity" as its rationale, the panel in *ClearValue* went in a completely different direction, relying on the fact that "[Atofina's] patent states that 'only a narrow temperature range enables' the process to operate as claimed, and that problems occur when operating the reaction either below 330 °C or above 400 °C." 668 F.3d at 1344. The court thus concluded that "[i]n *Atofina*, the evidence showed that one of ordinary skill would have expected the synthesis process to operate differently outside the claimed temperature range, which the patentee described as 'critical' to enable the process to operate effectively." *Id*. at 1345. By contrast,

> ClearValue has not argued that the 50 ppm limitation in claim 1 is "critical," or that the claimed method works differently at different points within the prior art range of 150 ppm or less. Nor does ClearValue argue that the Hassick reference fails to teach one of ordinary skill in the art how to use the claimed invention, i.e., that Hassick is not enabled to the extent required to practice claim 1 of the '690 patent. *Id*.

There are several very disturbing aspects to the court's holding.

First, the most applicable precedent, *Atofina*, said nothing in its holding about the claimed range being critical to enable the invention to operate as claimed but rather simply relied on the fact that the prior art range was so much broader than the claimed range. Accordingly, why would ClearValue have made such an argument?

Second, to the extent the new coin of the realm for avoiding anticipation of a narrower species in view of a broader prior art genus is intrinsic evidence of criticality of the narrower range, then ClearValue seems to meet that test as well as Atofina did. In particular, the patent at issue in *ClearValue* indeed did disclose a critical difference between its claimed range of under 50 versus the prior art range of under 150:

> It is well-known that significantly greater chemical dosages are needed for clarification of water with low alkalinity than for clarification of water with high alkalinity. (… Water having a high alkalinity can be defined as water with alkalinity of greater than 60 ppm.) … [W]ater having a low alkalinity and a low turbidity is very difficult to clean.[19]

So in fact, there was a criticality set forth in ClearValue's specification relating to carrying out the process with water having an alkalinity under 50, and the prior art fell squarely in the definition of those systems having alkalinity higher than 60, which were expected to be treatable by the process. Perhaps it was ClearValue's purported failure to argue this criticality that distinguishes this case, though this would be rather harsh given that this is a doctrine created by this panel on the fly.

Finally, in addition to establishing a new test for anticipation of a range within a range that goes well beyond what was established by precedent such as *Atofina*, this case also now conflates well-entrenched differences between obviousness and anticipation. In particular, when a claim is obvious over the prior art, it is well established that one can rely on a teaching away or secondary considerations such as unexpected results. On the other hand, when a claim is anticipated, a teaching away or an

[17] 441 F.3d 991, 78 U.S.P.Q.2d 1417 (Fed. Cir. 2006).

[18] 441 F.3d at 999.

[19] U.S. Patent No. 6,120,690 col.5 ll.4-6, 9-10, 13-14 (filed Aug. 12, 1998).

unexpected result is legally irrelevant. By this holding, the court creates a new hybrid animal, where one looks to factors relevant to obviousness, such as criticality of a claimed range, to determine whether a claim is anticipated.

So in essence, this court now wants you to rebut anticipation by providing it with evidence, such as criticality, which it heretofore held was irrelevant to anticipation!

***Federal Circuit expands doctrine of anticipation to cover selection of multiple components from multiple listings.***

In *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC,* 683 F.3d 1356, 103 U.S.P.Q.2d 1130 (Fed. Cir. 2012), the court reviewed the validity of Wrigley's claim directed to a gum including as flavor components menthol and a N-2,3-trimethyl-2-isopropyl butanamide, which goes by the trade name "WS-23." The district court concluded that the gum was anticipated by Shahidi, U.S. Patent No. 5,688,491. On appeal, Wrigley argued (1) that while Shahidi discloses all the claim limitations, it does not disclose them in the combination recited and (2) that Shahidi would not have enabled a person of ordinary skill in the art to derive the claimed combination without undue experimentation.

The Shahidi reference broadly disclosed oral compositions including toothpastes, mouth rinses, liquid dentifrices, lozenges and gums containing copper bis-glycinate. The compositions include both essential and nonessential components.

**Essential Components:**

- Xylitol
- Copper bis-glycinate
- Pharmaceutically acceptable carriers including mouthwashes, toothpastes, tooth powders, prophylaxis pastes, lozenges, chewing gums

**Optional Components**

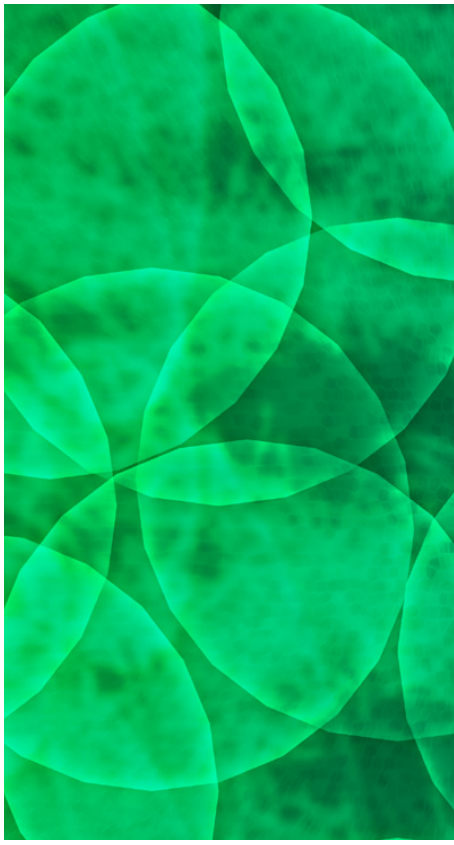
- Water
- A cooling agent or combination of cooling agents including all those described in five different patents, and three preferred compounds identified as WS-3, WS-23 and TK-10
- A water-soluble fluoride compound
- A humectant
- An abrasive polishing material
- A surfactant, including anionic, cationic, zwitterionic and nonionic surfactants
- Thickening agents if a toothpaste
- Antimicrobial agents
- Buffering agents
- Non-cationic water-insoluble agents
- A flavoring agent, including as "the most suitable" 23 different agents, one of which is menthol
- Coloring agents
- Sweeteners
- Ethyl alcohol

On review, the court concluded that "[t]his is not a case in which the prior art reference merely discloses a genus and the claim at issue recites a species of that genus" and where the issue of anticipation therefore "turns on whether the genus was of such a defined and limited class that one of ordinary skill in the art could 'at once envisage' each member of the genus," 683 F.3d at 1361, citing *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*[20] Rather, in this case

> Shahidi envisions using WS-23 and menthol in a single product. While Shahidi discloses a number of different combinations of cooling and flavoring elements, one of them is the combination of menthol, which Shahidi identifies as one of the "most suitable" flavoring agents, with WS-23, which Shahidi identifies along with WS-3 as among a group of three "particularly preferred cooling agents." Based on the disclosure of the combination of those components, we agree with the district court that Shahidi anticipates [the claim].

*Id*. The court noted that "the number of categories and components in Shahidi" was not "so large that the combination of WS-23 and menthol would not be immediately apparent to one of ordinary skill in the art." *Id*. The court found in particular that "Shahidi specifically discloses the use of both WS-23 and menthol in chewing gum." *Id*. at 1362. Relying on the fact that the patent under review had as its objective the obtaining of a cooling flavor composition that will contribute a long-lasting cooling sensation, the court noted that "the Shahidi reference clearly identifies the combination of WS-23 … and menthol …" *Id*.

There are two somewhat questionable aspects to the court's logic. First, the court appears to have relied on the fact that the Wrigley patent was seeking a cooling flavor agent as the basis for selecting such agent in the prior art Shahidi reference. ("Given the objective of the [Wrigley] patent, to obtain 'a cooling flavor composition that will



[20] 471 F.3d 1369, 1376, 81 U.S.P.Q.2d 1324, 1328 (Fed. Cir. 2006).

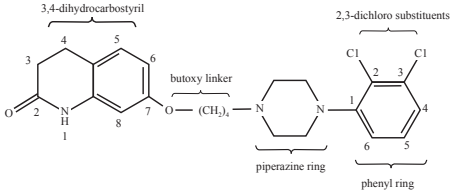
contribute a long-lasting cooling sensation' and a chewing gum with a 'clean, high-quality flavor … with a good cooling effect,' the Shahidi reference clearly identifies the combination of WS-23 … and menthol …" *Id*.). In other words, the court impermissibly relied on Wrigley's own specification to support selection of a cooling agent and a flavoring agent.

Second, though the court was technically correct when it noted that the prior art characterized menthol as one of the "most suitable" for use in the invention, the court conveniently omitted from its discussion that all the other listed flavoring agents (more than 20 others) were similarly characterized as being the "most suitable."

Thus, in *Wrigley*, one had to choose to use (a) a gum (1/6); (b) one of the optional components (1/2); (c) the particular combination of cooling agent and flavoring agent (1/14)(1/14); (d) WS-23 as the cooling agent (1/3); and (e) menthol as the flavoring agent (1/23), for a total likelihood of 1 out of 162,288 possible combinations. This, according to the Federal Circuit, was "immediately apparent." Selecting specific combinations of components, where each component itself has to be selected from a separate list of optional components, has generally not been viewed as anticipatory.[21]

***Court holds that "lead compounds" selected from the prior art must have the same utility as the claimed compound, even if that utility is not recited in the claim.***

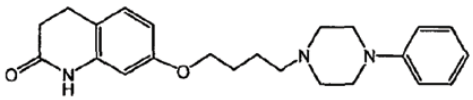
In *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 102 U.S.P.Q.2d 1729 (Fed. Cir. 2012), the court reviewed the validity of claims covering the commercial product ABILIFY, which goes by the chemical name aripiprazole. The claimed compound is of the formula:




There were three pieces of prior art reviewed by the court that provide good insight into both how the court selects a "lead compound" from a large list of prior art compounds as well as how the court assesses the obviousness of a claimed compound in view of the selected lead compound.

Initially, the Federal Circuit found "no error" in the district court's restatement of the law as to the obviousness of compounds as involving "the hypothetical person of skill in the art's identification of a lead compound, structural differences between the proposed lead compound and the claimed invention, motivation or teachings in the prior art to make the necessary changes to arrive at the claimed invention, and whether the person of skill in the art would have a reasonable expectation of success in making such structural changes."

The first of the prior art lead compounds cited by defendant as rendering the claims obvious is 7-[4-(4-phenylpiperazinyl)-butoxy]-3,4-dihydrocarbostyril, which has the following chemical structure:



This "unsubstituted butoxy" differs from the claimed compound in that it does not include the two chlorine atoms on the phenyl ring. Although the unsubstituted butoxy compound was just one of literally trillions of compounds encompassed by the prior art patent, the prior art patent specifically tested it and claimed it in methods for producing an antihistamine effect.

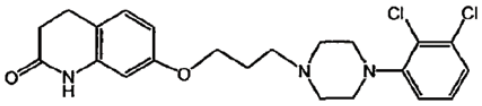
The district court rejected defendant's proposed unsubstituted butoxy as a lead compound and instead concluded that two compounds — clozapine and risperidone — would have been considered viable lead compounds because "[t]hese were the only marketed antipsychotic compounds at the time the present inventors began their work. They were the natural and obvious lead compounds whose structures one would have considered to modify to obtain improved antipsychotic compounds." 678 F.3d at 1293. By contrast, "[a]t the relevant time, there were no carbostyril compounds that were marketed as antipsychotics or were publicly known to have potent antipsychotic activity with minimal side effects. Carbostyrils were thus not plausible lead compounds, except in retrospect …" *Id*. The Federal Circuit agreed, noting that "the claims of the prior art … patent explicitly disclose the unsubstituted butoxy as producing an antihistaminic effect" and that "[t]his clear teaching controls over the far

[21] *See, e.g., Akzo N.V. v. U.S. Int'l Trade Comm'n,* 808 F.2d 1471, 1480, 1 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1986) (no anticipation where the prior art "would have required [patentee] randomly to pick and choose among a number of different polyamides, a plurality of solvents, and a range of inherent viscosities").

more nebulous disclosure that the trillions of carbostyril compounds encompassed by the … patent 'have antihistaminic and central nervous controlling effects.' " *Id*. (citation omitted).

Even if one accepts the court's conclusion that the only use disclosed by the prior art patent for the unsubstituted butoxy compound was as an antihistamine, it is rather curious that this was the basis for disqualifying the compound as a so-called "lead compound." Otsuka's claims were all product claims. Accordingly, in selecting a lead compound from the prior art, shouldn't any compound that has been characterized and tested be fair game even if that compound has a different use than the claimed compound? Indeed, it is interesting to ask the following question — if Otsuka had claimed ***exactly*** the same compound using exactly the same words but disclosed its utility as an antihistamine, might that compound have been found to be obvious based on use of the unsubstituted butoxy antihistamine of the prior art patent as the lead compound? And if the court would so hold, then doesn't such holding contradict both *Tyco*[22] (that one should not read uses into product claims) as well as *Dillon*[23] (that a composition is obvious even if one would have modified it for a use different from that discovered by the applicant)?

The second so-called lead compound is likewise from prior art generally disclosing carbostyril derivatives. The defendant proposed as a lead compound "2,3-dichloro propoxy" of the formula:

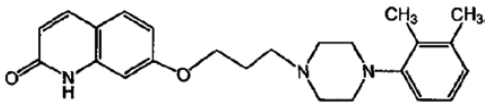



This compound differs from the claimed compound in that it includes a propoxy linker rather than a butoxy linker. The prior art teaches that its carbostyril derivatives "can be used as antihistamines or agents having a regulating action in the central nervous system" and discloses dozens of carbostyril compounds. The 2,3-dichloro propoxy is just one of 96 different compounds disclosed in a single example.

According to the defendants, the district court erred by failing to find that the claimed aripiprazole would have been obvious over the 2,3-dichloro propoxy compound, which was taught by the prior art as having antipsychotic activity. As was the case with the first compound, the court disagreed that the prior art taught antipsychotic activity for the second compound. Although *Pfizer*[24] was not a decision involving a lead compound analysis, the defendants cited *Pfizer* for the proposition that the prior art's generic disclosure including the 2,3-dichloro propoxy compound "is all that is required for obviousness." *Id*. at 1295 (citation omitted). The court disagreed, noting that in *Pfizer* "[t]his court premised its conclusion on findings that the prior art not only provided 'ample motivation to narrow the [prior art] genus of … salt-forming anions … to a few [species],' but also 'predicted the results.' " *Id.* (alterations in original) (citation omitted). In contrast to *Pfizer*, the court concluded that the defendants failed to make an analogous showing and therefore the district court correctly found that one of ordinary skill in the art would not have selected the 2,3-dichloro propoxy compound as a lead compound for further antipsychotic research.

Once again, it is difficult to comprehend why an unclaimed use of a product claim disqualifies as a lead compound a prior art compound having a different use. Further, citation of *Pfizer*, which predates *KSR*,[25] and this court's lead compound approach interject confusion into how one should conduct the analysis.

The final purported lead compound, OPC-4392, has a 2,3-dimethyl substituted phenyl ring, a propoxy linker and a carbostyril ring containing a double bond at the 3,4-position and is of the formula:




As compared to the claimed compound, OPC-4392 substitutes methyl groups for chloro groups on the phenyl ring, includes a butoxy rather than a propoxy linker and has unsaturation on the double ring. The court held that (1) the district court correctly rejected OPC-4392 as a lead compound; and (2) even if correctly selected as a lead compound, the claimed compound was not obvious over OPC-4392.

The court characterized as "selective" defendants' reliance on the prior art as teaching that OPC-4392 was "an anti-psychotic drug" and the fact that OPC-4392

[22] *Tyco Healthcare Grp. LP v. Mutual Pharm. Co., Inc.,* 642 F.3d 1370, 99 U.S.P.Q.2d 1212 (Fed. Cir. 2011).

[23] *In re* Dillon, 919 F.2d 688, 16 U.S.P.Q.2d 1897 (Fed. Cir. 1990) (en banc).

[24] *Pfizer, Inc. v. Apotex, Inc.,* 480 F.3d 1348, 82 U.S.P.Q.2d 1321 (Fed. Cir. 2007).

[25] *KSR Int'l Co. v. Teleflex, Inc.,* 550 U.S. 398, 82 U.S.P.Q.2d 1385 (2007).

proceeded to Phase II clinical trials. The court held that "[i]n light of the totality of the evidence before the district court, we perceive no clear error in the conclusion that OPC-4392 was 'considered a failure insofar as it did not treat the positive symptoms of schizophrenia and was not well-tolerated in modest doses.' " *Id*. at 1296 (citation omitted). Accordingly, the court concluded that "one of ordinary skill in the art would not have selected OPC-4392 as a lead compound for further antipsychotic research." *Id*.

The court further held that even if one would have selected OPC-4392 as a lead compound, defendants failed to prove that the prior art would have directed one to make the various modifications necessary to convert OPC-4392 into the claimed aripiprazole. The court noted that "the Defendants rely in large part on the inventors' and Otsuka's own development efforts in an attempt to prove that aripiprazole would have been obvious," e.g., by arguing that Otsuka's aripiprazole development involved a "short timeline" and only "took a few months." *Id*. The court found that "[t]hose arguments cannot trump the district court's careful fact finding, however. The inventor's own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art." *Id*.

***Because obviousness-type double patenting necessarily focuses on the compounds listed in a claim, it is unnecessary to first select a lead compound in the analysis.***

Finally, the court reviewed an obviousness double patenting rejection comparing the claimed compound having two chlorine atoms on its phenyl ring with the prior art unsubstituted butoxy compound, which does not include the two chlorine atoms. The court discussed the differences between an obviousness analysis and an obviousness-type double patenting analysis, concluding that (1) unlike obviousness, a double patenting analysis "must necessarily focus on the earlier claimed compound over which double patenting has been alleged, lead compound or not," *id*. at 1297; but (2) like obviousness, it is still necessary to identify "some reason that would have led a chemist to modify the earlier compound to make the later compound with a reasonable expectation of success." *Id*.

***Although other prior art disclosed 2,3-dichloro substitutions on phenyl rings, such art failed to tie such substitutions to antipsychotic activity, especially given the unpredictability of minor structural changes on a compound's antipsychotic activity.***

The district court determined that the prior art, including the declaration filed by Otsuka during prosecution, did not teach 2,3-dichloro substitution on the phenyl ring to achieve antipsychotic activity. Although other prior art disclosed 2,3-dichloro substituted compounds, those references "failed to tie that disclosure to any meaningful suggestion of antipsychotic activity." *Id*. at 1299. Finally, the court rejected defendants' reliance on *In re Zickendraht*,[26] a case that affirmed a double patenting rejection of an azodyestuff compound[27] differing from the prior art by further inclusion of a methyl group. There, the court held that "[i]t has not been shown that this difference has any effect on the dyeing characteristics of the compound." The court distinguished *Zickendraht*, holding that "the evidence here not only demonstrates the unpredictability of minor structural changes on a compound's antipsychotic properties, but also indicates that the prior art would not have provided the skilled artisan with a reason to make the necessary structural changes to the unsubstituted butoxy to yield aripiprazole." *Id*.

Again, the interesting observation here is that the court does not even consider whether it would have been obvious to modify the unsubstituted butoxy compound taught ***as an antihistamine*** for the purpose of making ***another antihistamine***.

This case has a couple of interesting takeaways. First, as discussed above, the court seems to now be saying that you have to consider the utility of the claimed compound in selecting lead compounds from the prior art. This makes no sense not only because it contradicts precedent such as *Dillon* but also because it will potentially give rise to anomalous results such as two identical claims receiving different treatment based solely on the use disclosed in the specification, the one reciting the same use being found obvious under a lead compound analysis and the one reciting a different nonobvious use being found patentable. While it might be true that one of ordinary skill in the art seeking a new antipsychotic

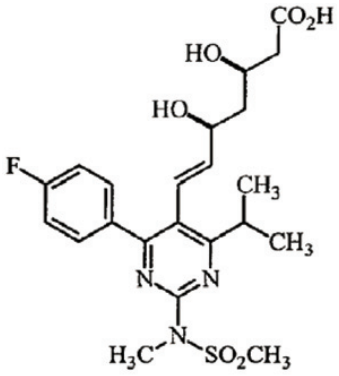
[26] 319 F.2d 225, 138 U.S.P.Q. 22 (C.C.P.A. 1963).

[27] 319 F.2d at 228.

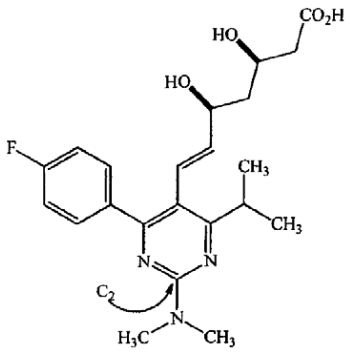
might not chose the antihistamines, one of ordinary skill in the art seeking a new antihistamine would. The second takeaway of this case is that a lead compound analysis is not applicable to an obviousness-type double patenting rejection, which only looks to the compounds set forth in the claims of the patent under review and the patent being cited against it.

***Court rejected obviousness of compound based on "obvious to try" because prior art teaching of desirability of making compound more lipophilic by modifying $-SO_2CH_3$ group to a $-CH_3$ group negated by skepticism relating to such statins and abandonment of general structure by competitors.***

In *In re Rosuvastatin Calcium Patent Litigation*, 703 F.3d 511, 105 U.S.P.Q.2d 1437 (Fed. Cir. 2012), the court reviewed the validity of the drug rosuvastatin, sold commercially as CRESTOR of the formula:




The defendants identified as the closest prior art a "Compound 1b," which has two $-CH_3$ methyl) groups on the amino side chain, instead of one $-CH_3$ and one $-SO_2CH_3$ group as in rosuvastatin. The reference described Compound 1b as an "especially preferred embodiment of the invention" of the following structural formula:




The defendants argued that Compound 1b would be a good "lead compound" for further research and that the change of the $-CH_3$ group to a $-SO_2CH_3$ group would have been obvious because it would make Compound 1b more hydrophilic, a property taught as desirable by numerous publications as increasing liver selectivity. Defendants further argued that because one of ordinary skill in the art knew that the $C_2$ position did not affect the compound's activity, such position would be the logical place to increase hydrophilicity and further, $SO_2$ was a known spacer to achieve this effect.

The district court rejected the defendants' argument that the insertion of a sulfonyl group at position $C_2$ was one of a "finite number of identified, predicable solutions" to existing problems with statins, in the words of *KSR*,[28] and thus that it would have been obvious to make this specific compound and test its properties. Instead, the district court found that this situation was similar to that discussed in *In re O'Farrell*,[29] where the court explained that obviousness is not shown when "what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave general guidance as to the particular form of the claimed invention or how to achieve it."[30]

On appeal the Federal Circuit agreed, holding that "obvious to try" was "negated by the general skepticism concerning pyrimidine-based statins, the fact that other pharmaceutical companies had abandoned this general structure, and the evidence that the prior art taught a preference not for hydrophilic substituents but for lipophilic substituents at the $C_2$ position." 703 F.3d at 518.

***Court finds that claim reciting combination of a known antimigraine drug and known NSAID "for concomitant administration" to a patient requires simultaneous, not sequential, administration and is not obvious over prior art table showing administration of both but not indicating that they are administered simultaneously.***

In *Pozen Inc. v. Par Pharmaceutical, Inc.,* 696 F.3d 1151, 104 U.S.P.Q.2d 1969 (Fed. Cir. 2012), the court reviewed the validity of several patents covering Pozen's migraine drug TREXIMET, which is a combination of the 5-HT agonist such as sumatriptan

[28] *KSR Int'l,* 550 U.S. at 421.

[29] 853 F.2d 894, 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988).

[30] 853 F.2d at 903.

(a known migraine drug) and naproxen (a known nonsteroidal anti-inflammatory drug or "NSAID"). The first two patents recited, respectively, "[a] therapeutic package for dispensing to, or for use in dispensing to, a migraine patient" including the two drugs, and "[a] pharmaceutical composition in unit dosage form, useful in treating a migraine headache patient," including the two drugs. The claims recited the criticality of the combination as follows:

> wherein the respective amounts of said 5-HT agonist and said LA-NSAID in said unit dose are effective, upon concomitant administration to said patient of one or more of said unit doses, to reduce migraine relapse or produce longer lasting efficacy compared to the administration of said 5-HT agonist in the absence of said LA-NSAID or the administration of said LA-NSAID in the absence of said 5-HT agonist ….

The district court upheld the validity of the first two patents, holding that the references did not teach or suggest the simultaneous administration of sumatriptan and naproxen or otherwise disclose that their combination produces a longer-lasting efficacy, reducing migraine relapse, compared to the administration of each alone.

On appeal, Par argued that the district court erred because it failed to apply the term "concomitant administration" to include both simultaneous and sequential administration of the two drugs. The Federal Circuit disagreed, holding that "[w]hen considering the claim language as a whole the term 'unit dose' [found in all the claims] necessarily limits concomitant administration to mean simultaneous administration [thereby excluding sequential administration] because a single drug administration entity cannot be administered in any other fashion." 696 F.3d at 1161.

The court next assessed the obviousness of the claims in view of this construction. The first reference, Parma, disclosed combinations of the two claimed drugs in a table, but there was a factual dispute between the parties as to whether Parma taught simultaneous or sequential administration of the drugs. The district court gave more weight to Pozen's expert, who testified that a person skilled in the art would have interpreted Parma to disclose a sequential administration of various drug combinations. On review, the Federal Circuit noted that Parma provided separate tables disclosing monotherapy treatment and combination therapy treatment. Although the combination therapy table specifically listed the claimed NSAID and sumatriptan combination, the court found that "Parma only specifies the unsatisfactory results of monotherapy treatment in [the monotherapy table]; it does not indicate the relative successes of various combination treatments listed in [the combination table]." *Id*. at 1162. Furthermore, the court found no reversible error in the district court's finding that "Parma does not disclose anything about the combination of 'FANS [NSAIDS] + sumatriptan' in particular reducing migraine relapse or producing longer lasting efficacy, nor does it disclose the dosage of the combination treatment." *Id*. at 1162-63.

***Where prior art shows that the wild-type enzyme works in both prokaryotic and eukaryotic cells, there would have been a reasonable expectation of success that the modified enzyme would likewise work in both types of cells.***

In *In re Droge*, 695 F.3d 1334, 104 U.S.P.Q.2d 1377 (Fed. Cir. 2012), the court reviewed the patentability of Droge's claim covering a method of recombining DNA in a eukaryotic cell using an integrase enzyme ("Int"), which was modified from the wild-type. Int is a vector capable of inserting, deleting or rearranging DNA at a specific location on a target cell's DNA by using recognition sites, referred to as *attB*, *attP*, *attR* and *attL*. The modified wild-type Int claimed was called Int-h and Int-h/218, which facilitate recombination at either the *attB* and *attP* or the *attR* and *attL* recognition sites.

The prior art showed either (1) the use of the wild-type Int in any type of cell host (both bacteria and eukaryotic cells); or (2) use of the modified Int-h and Int-h/218, but only in prokaryotic cells. The prior art did not show use of modified Int in a eukaryotic cell as claimed by Droge. The Board concluded that because "the wild-type integrase works in eukaryotic cells, the ordinary artisan would have had a reasonable expectation of success that [Int-h and Int-h/218] would also function at some level in eukaryotic cells."

On appeal, Droge argued that the use of the modified integrase proteins in *prokaryotic* cells would not lead to expectation that these integrases would also work in *eukaryotic* cells. Droge argued (1) that there was a teaching away from using modified Ints in eukaryotic cells because the prior art taught that their activity decreases in the absence of certain cofactors produced

only by prokaryotic cells; and (2) that the applicant's declaration showed no reasonable expectation of success because the ability of modified integrases to promote recombination in prokaryotic cells was tied to particular cofactors such as IHF and three-dimensional structures associated with prokaryotic cells.

In affirming the Board, the Federal Circuit pointed to evidence showing that the modified integrases have increased affinity for core binding sites in the *att* regions, even in the absence of the prokaryotic IHF. The court also concluded that there would have been a reasonable expectation of success in view of a separate publication that directly contradicted applicant's declaration by teaching (1) that Int-h "sponsors reduced but significant levels" of recombination in the absence of the IHF and (2) that even in the absence of IHF, Int-h recombines supercoiled prokaryotic and nonsupercoiled eukaryotic DNA identically. 695 F.3d at 1338.

This case raises once again the issue of how to handle prior art that both suggests and teaches away from the invention. In last year's "Year in Review," we commented that sometimes the court seems ill equipped to properly assess the relevant merit of facially contradictory references.[31] Certainly an advocate in possession of such facially contradictory references should ensure that evidence is put in the record explaining to the relevant tribunal, whether the PTO Board or a federal court, why the teaching away is stronger than another contrary reference.

***As is the case with obviousness under §103, obviousness-type double patenting requires assessing the claimed subject matter "as a whole," and not merely the differences between the claims at issue, while excluding common features from consideration.***

In *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 689 F.3d 1368, 104 U.S.P.Q.2d 1134 (Fed. Cir. 2012), the court reviewed Lilly's claims directed to "antifolates," and in particular to "pemetrexed," intended to treat cancer by inhibiting one or more of the folate-specific enzymes necessary for DNA synthesis. Lilly had two earlier patents, one claiming a structurally related compound and another claiming an intermediate used to prepare the compound claimed in the later patent.

The court first addressed the appropriate legal standard applicable in a double patenting analysis. Teva argued that the correct analysis involves only the *differences* between the claims at issue, so that any features held in common between the claims would be excluded from consideration. The court disagreed, holding that

> just as §103(a) requires asking whether the claimed subject matter "as a whole" would have been obvious to one of skill in the art, so too must the subject matter of the [later patent claims] be considered "as a whole" to determine whether the [claims of the earlier patent] would have made those claims obvious for purposes of obviousness-type double patenting.

689 F.3d at 1377.

***Where a prior art compound provides many opportunities for modification with no expectation that the one pursued by the applicant would be successful, the modification is not obvious.***

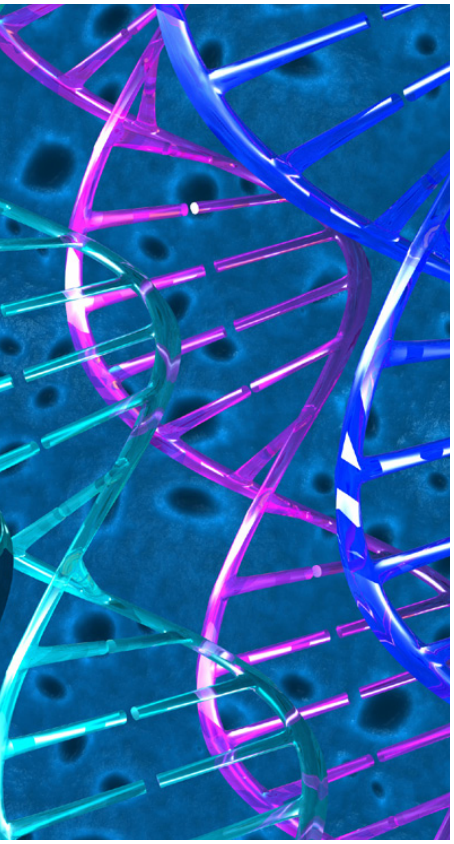
On the merits, the court found that the claimed compound was not obvious over the related compound of the first patent because a

> complicated compound such as the [compound of the first patent] provides many opportunities for modification, but the district court did not find that substituting a phenyl group into the aryl position was the one, among all the possibilities, that would have been successfully pursued. Thus, absent any motivation to derive pemetrexed from the [compound of the first patent] or reason to expect success in doing so, the district court correctly concluded that the asserted claims were not invalid for obviousness-type double patenting …

*Id*. at 1378. As for the second patent, Teva argued that because the intermediate claimed in Lilly's prior patent is used to make the later-claimed pemetrexed, and because Lilly disclosed that use in the prior patent's specification, the later-claimed pemetrexed is obvious over the earlier-claimed intermediate, citing precedent-such as *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.*[32] In *Sun*, the court found that Lilly's later patent claiming a method of treating cancer using gemcitabine was invalid under the doctrine of obviousness-type double patenting in view of Lilly's earlier

[31] Robert M. Schulman, Jeff B. Vockrodt & David A. Kelly, "Pharmaceutical, Chemical & Biotech Year in Review 2011" 15 (2012).

[32] 611 F.3d 1381, 95 U.S.P.Q.2d 1797 (Fed. Cir. 2010).



patent claiming the gemcitabine itself. 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."[33]

However, the court refused to extend *Sun*'s holding to the situation here. The court noted that "[a]s a general rule, obviousness-type double patenting determinations turn on a comparison between a patentee's earlier and later claims, with the earlier patent's written description considered only to the extent necessary to construe its claims." *Id*. at 1378-79. The court distinguished *Sun* and related cases on the grounds that "the claims held to be patentably indistinct [there] had in common the same compound or composition — that is, each subsequently patented 'use' constituted a, or the, disclosed use for the previously claimed substance." *Id*. at 1380. By contrast, the asserted claims of Lilly's patent in suit "do not recite a *use* of the *same compound*, but a *different compound* altogether." *Id*.

If one accepts the premise as enunciated by the court that obviousness-type double patenting rejections turn on a comparison of later and earlier claims, without resort to the specification except where necessary to construe a term in the claims, then this case certainly makes sense. What still does not make sense, however, is that the court conveniently disregarded this rule in *Sun,* where resort to the specification was not necessary to construe the meaning of the earlier claim directed to gemcitabine but the court, citing the disclosed use of gemcitabine for treating cancer in the specification, invalidated a later claim directed to a method of treating cancer using gemcitabine. One certainly cannot fault Teva for making the logical argument that if a claim to a compound brings in the uses disclosed in the specification, then a claim to an intermediate likewise brings in the uses disclosed for that intermediate in the specification, which is to make a final product of the claim. For some reason, however, this court makes a distinction that while a use can be brought in, the result of that use, a new compound, cannot.

***Where dependent claim recites an amount of active of 0.0001% to 5%, the "therapeutically effective amount" recited in the independent claim must include at least that range even if the functional limitation requiring "mast cell stabilization" in the independent claim is not met for that entire range.***

In *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 103 U.S.P.Q.2d 1737 (Fed. Cir. 2012), the court reviewed whether Alcon's claims covering the antiallergy eye drop PATANOL were obvious. The claims under review recite a method for treating allergic eye disease in humans comprising stabilizing conjunctival mast cells by topically administering a composition comprising a therapeutically effective amount of olopatadine.

Olopatadine was known in the prior art as an effective antihistamine, but not for treatment of human eyes or for stabilizing mast cells. The only prior art showing the use of olopatadine in eyes was as an antihistamine to treat guinea pig eyes. Even in the context of guinea pig eyes, however, the court found the prior art taught that the compound was ineffective as a mast cell stabilizer. The district court concluded that that method was nonobvious, finding that (1) the prior art taught away from use of the compound as a mast cell stabilizer; and (2) the use of the compound in guinea pig eyes would not have suggested its use in human eyes. The district court also found that Alcon demonstrated commercial success and unexpected results.

On appeal, the Federal Circuit began its obviousness analysis by first construing the meaning of the phrase "a therapeutically effective amount" of olopatadine for treating allergic eye diseases by stabilizing mast cells. Using the specific range recited in dependent claim 2 as "a starting point," the court found that "if claim 2 covers the range from 0.0001% w/v-5% w/v, claim 1 must cover at least that range," noting that "[i]t is axiomatic that a dependent claim cannot be broader than the claim from which it depends." 687 F.3d at 1367. Alcon sought a narrower construction, arguing that not all formulations falling within the range recited in claim 2 are operative to stabilize mast cells and, therefore, the "therapeutically effective amount" term of claim 1 imposes a narrower range than recited in claim 2. The court rejected this argument, stating that "[t]his is not how patent law works. When you claim a concentration range of 0.0001%-5% w/v (as claim 2), you can't simply disavow the invalid portion and keep the valid portion of the claim." *Id*. at 1368. Accordingly, the court held that it was the entire claimed range of 0.0001%-5% w/v olopatadine that should be compared to the disclosure of the prior art. *Id*.

[33] 611 F.3d at 1387.

This is a case that could have just as easily been upheld or invalidated on other grounds. For example, if the court had given weight to the "therapeutically effective amount" limitation in claim 1, then the range in claim 2, by definition as a dependent claim, should be construed as including only amounts that are therapeutically effective. There is somewhat of a "tail wagging the dog" aspect to the court's use of the dependent claim as the starting point for claim construction here. Perhaps it would have been cleaner had the court simply held the claim to be indefinite on the grounds that the range in claim 2 is inconsistent with the functionality of claim 1.

***Because the motivation for modifying a prior art teaching need not be the same as the motivation articulated by the patent, the use of a prior art ocular formulation with guinea pigs as an antihistamine renders obvious the use of the same formulation with humans as a mast cell stabilizer.***

The court next compared the recited therapeutically effective amount of 0.0001%-5% for mast cell stabilization with the prior art 0.0001% to 0.01% antihistamine formulation used to treat eye allergies in guinea pigs and noted that such ranges overlap. *Id*. The court further concluded that guinea pig models are predictive of both antihistaminic activity and topical ocular availability in humans. *Id*. The Federal Circuit disagreed with the district court's reliance on the prior art's teaching away from the use of the compound to stabilize mast cells, holding that "[t]he district court's error stemmed from its refusal to look at any motivation beyond that articulated by the patent … Here, the motivation to adapt [the prior art's] formulation for human use is that it is an effective antihistamine in guinea pigs and that animal models are … predictive of antihistaminic efficacy in humans." *Id*. at 1368-69. The court thus found that, "even if for a different purpose," the disclosure of overlapping concentrations in the prior art rendered the claimed method obvious. *Id*. at 1369.

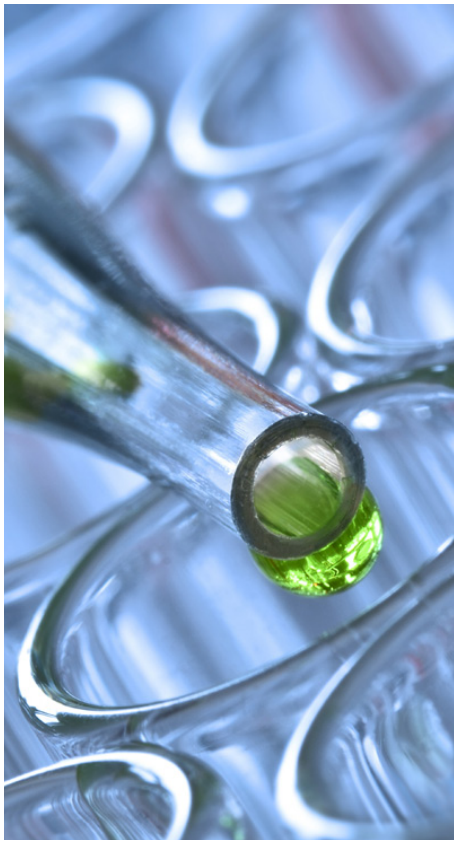
Adopting a stance that what is sauce for the goose is sauce for the gander, the court rejected Alcon's argument that one of ordinary skill in the art would not have harbored a reasonable expectation of success that olopatadine would be safe for use in the human eye, noting that just like the prior art, Alcon's own patent did not actually test the compound in a human eye but rather relied on *in vitro* tests with human mast cells. *Id*.

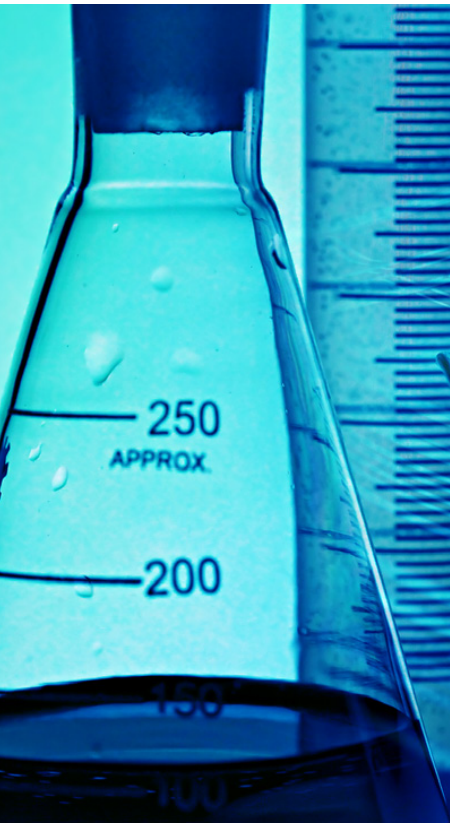
The court also rejected Alcon's argument that the court was improperly relying on the doctrine of inherency, normally relegated to anticipation rejections, in its obviousness analysis. In particular, the court found that the recited step of "stabilizing conjunctival mast cells" "is not an additional requirement imposed by the claims …, but rather a property necessarily present in the [claimed invention]," *id*. (second alteration in original) (citation omitted), because the patent itself teaches that such mast cell stabilization occurs at the recited concentrations. Noting that the prior art "expressly discloses using olopatadine eye drops to treat eye allergies at concentrations that overlap with those in [the claims]," *id*., the court held that the "stabilizing conjunctival mast cells" limitation was met by the prior art.

***It would not have been obvious to increase the highest prior art concentration of active component from 0.01% by an order of magnitude to the claimed concentration of 0.1% given concerns in the prior art that the compound might become biphasic at such increased concentration.***

Finally, the court found that the claims reciting the 0.1% composition were not obvious. Apotex argued that because Kamei's testing showed that antihistaminic efficacy increased as olopatadine concentration increased from 0.0001% to 0.01%, it would be logical to try a 0.1% formulation. Apotex also relied on a secondary reference disclosing treatment of allergies using a class of chemical compounds that includes olopatadine and an example teaching an ophthalmic solution containing 0.1% of a different active compound. Apotex argued that a skilled artisan would simply modify this 0.1% w/v formulation by substituting olopatadine for the other active compound at the same concentration.

The court noted that the 0.01% olopatadine concentration of the prior art was "substantially lower" than the claimed 0.1% and agreed with the district court that "a person of ordinary skill in the art would not have a reasonable expectation of success for increasing the highest dosage used in Kamei by an order of magnitude." *Id*. The court further agreed that in view of concerns that olopatadine might be biphasic at the increased concentration, one of ordinary skill in the art would not have tried a formulation with 10 times more olopatadine than the highest dosage used in Kamei. *Id*. at 1370-71. The court also rejected






Apotex's substitution argument because "a person of ordinary skill in the art would have known that one could not simply substitute one active ingredient for another without adjusting the concentration." *Id*. at 1371. Lastly, the court was convinced as to Alcon's evidence of commercial success. *Id*.

This case reaffirms the principle that if it is obvious to modify the prior art for any reason, then such modification is obvious even if that reason is different from that for which the patentee made the modification. In this case, therefore, because it would have been obvious to treat a human eye with olopatadine at the claimed concentration for use as an antihistamine, it was irrelevant that such method also stabilized mast cells. Alcon's claimed range not only encompassed the entirety of the prior art range but in addition the lowest point of Alcon's range corresponded exactly to the lowest point of the prior art range. Alcon could not succesfully argue that there was a difference in effect between its larger range and the prior art's narrower range.

This case presents an interesting contrast with *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc.* (Fed. Cir. 2012), discussed *infra*. There, the prior art disclosed compounds that could be used as antihistamines and as antipsychotics. In reviewing the validity of Otsuka's compound claims in a patent disclosing their use as antipsychotics, the court rejected Sandoz's attempts to rely on several specifically identified and characterized antihistamines as lead compounds, limiting itself instead to lead antipsychotic compounds (even though the antihistamines were structurally closer). So for the present time, we seem to have an incongruity in the Federal Circuit jurisprudence, perhaps unintended, where you are limited to the use of a claimed compound when selecting a lead compound from the prior art, but where you are not limited to the use of the claimed compound in an obviousness analysis once a prior art compound has been selected.

***An obvious formulation cannot become nonobvious simply by administering it to a patient and claiming the resulting property, otherwise any formulation, no matter how obvious, would become patentable merely by testing and claiming an inherent property.***

In *Santarus, Inc. v. Par Pharmaceutical, Inc.*, 694 F.3d 1344, 104 U.S.P.Q.2d 1641 (Fed. Cir. 2012), the court reviewed the validity and enforceability of Santarus's patent directed to Zegerid PPI, a benzimidazole proton pump inhibitor (PPI) that inhibits gastric acid secretion and helps prevent and treat stomach acid-related diseases and disorders. The prior art had required enteric coatings on PPIs in view of their acid sensitivity, which reduced their bioavailability. By contrast, the claimed formulation provided no such coating but instead combined the PPI with a bicarbonate salt of a Group IA metal for oral administration as an aqueous solution or suspension as a single dose.

As some of the claims were entitled to an earlier filing date and others to a later date, the court conducted two separate analyses.

As for the claims entitled only to the later date, the court reviewed the validity of the claims in view of Santarus's own prior art, the '737 patent, which discloses formulating an aqueous suspension with a buffering agent, such as a bicarbonate salt of a Group 1A metal, which, when dissolved in aqueous solution, is suitable for enteral administration. The '737 patent teaches that the omeprazole does *not* need to be enterically coated. On appeal, Santarus argued that its claims distinguished the '737 patent in that (1) they require an uncoated PPI and buffer in specific amounts and ratios not disclosed in the prior art; (2) they achieve the desired results using only 1000 mg to 2000 mg of sodium bicarbonate; and (3) they achieve specific blood serum concentration levels not disclosed in the prior art.

The court found that the '737 discloses broad ranges for the amounts of omeprazole and sodium bicarbonate that overlap with claimed ratios, as well as the sodium bicarbonate concentration of from about 1000 mg to about 2000 mg. As for the recited blood concentrations, the court found that "[t]he initial blood serum concentration resulting from administering a PPI dosage is an inherent property of the formulation, and an obvious formulation cannot become nonobvious simply by administering it to a patient and claiming the resulting serum concentrations." 694 F.3d at 1354. Holding otherwise, according to the court, "would allow any formulation — no matter how obvious — to become patentable merely by testing and claiming an inherent property." *Id*. Here, the court found that "[t]here is no dispute that the blood serum concentrations claimed … are expected in light of the dosages." *Id*.

It is hard not to develop a certain amount of discomfort whenever reading an opinion that relies on inherency as part of an

obviousness rationale. By definition, if one has to select among a number of variables (such as the ratios and sodium bicarbonate ranges of the prior art), then the results one achieves are not the necessary, i.e., inherent, result. Despite this unfortunate and confusing choice of language, it is evident from the opinion that the court in fact based its conclusions regarding the serum concentration on a secondary reference that taught that such levels were achievable with formulations of the type claimed.

This case, as well as the *Alcon* case, discussed immediately before, both emphasized the same principle, namely, that if a formulation is otherwise obvious, it is not made unobvious by reciting a property that would be necessarily possessed by the formulation.

***A teaching that a particular embodiment is a "second best choice" is not a teaching away.***

With respect to claims encompassing powders that can be combined with an aqueous medium then orally administered, the court found no such teaching away. Rather, the court found that the prior art teaches that "*uncoated omeprazole formulations* containing a sodium bicarbonate buffer could be used as an alternative to enteric coating in order to protect omeprazole from degrading in the stomach." *Id*. at 1355 (citation omitted). While the prior art characterized such formulation as a "second best choice," the court noted that it was nonetheless a viable alternative. The court rejected Santarus's argument that a characterization of an embodiment as less preferred amounted to a teaching away. *Id*. at 1356.

***Where the prior art teaches using significantly greater amounts of buffer than claimed, the formulation is nonobvious despite the fact that the prior art discloses the claimed ratio of sodium bicarbonate to PPI.***

As for certain dependent claims reciting specific amounts of buffering agent, the court found such claims nonobvious, noting that Pilbrant discloses using significantly greater amounts of buffer than claimed. The court rejected Par's argument that because the prior art teaches the claimed ratio of sodium bicarbonate to PPI, it would have been obvious to reduce the total amount of sodium bicarbonate buffer disclosed in those references. The court concluded that nothing in the prior art indicates that it was the ratio of buffering agent to PPI, as opposed to the total amount of buffer consumed, that was the key to preventing the stomach from being too acidic. *Id*. at 1356-57.

***Motivation to combine two references directed to ultrahigh molecular weight polyethylene not negated by fact that one is directed to artificial joints and the other to films or sheets because neither reference limits the structure to which the material is applicable.***

In *In re Hyon*, 679 F.3d 1363, 102 U.S.P.Q.2d 1889 (Fed. Cir. 2012), the court reviewed the patentability of Hyon's claims directed to an ultrahigh molecular weight polyethylene ("UHMWPE") molded article for artificial joints and a method of preparing the same. The method recites the steps of (a) crosslinking an ultrahigh molecular weight polyethylene block with high-energy radiation; (b) heating the crosslinked block up to a compression deformable temperature below the … melting point of the UHMWPE; (c) subjecting the heated block to pressure; and then (d) cooling the block.

During prosecution, the examiner found that the primary reference meets the claims except for the step of crosslinking the UHMWPE prior to compression, but found a secondary reference disclosing crosslinking the UHMWPE prior to compression. The examiner concluded, and the Board agreed, that it would have been obvious to modify the method of the primary reference to carry out the crosslinking prior to compression, given the secondary reference's teaching that crosslinking prior to compression deformation results in improved transparency, an increased melting point and excellent dimensional stability.

On appeal, Hyon argued that one of ordinary skill in the art would not be motivated to combine the references because the first is directed to artificial joints whereas the second is directed to films or sheets, which Hyon characterized as "fundamentally different material technologies." The Federal Circuit disagreed, noting that both "pertain to UHMWPE" and "[n]either reference limits the structure of the UHMWPE product that can be made; artificial joints … and sheets … are simply embodiments of the polyethylene made by each process." 679 F.3d at 1366.

***Because the secondary reference linked pre-compression crosslinking to improved polymeric properties, the Board did not improperly rely on an arbitrary selection by incorporating such feature into the primary reference.***

The court also rejected Hyon's argument that the Board improperly relied on the arbitrary selection of a single feature (pre-compression crosslinking) from the secondary reference while ignoring the other features, holding that "it is clear that the examiner and the Board selected the pre-compression crosslinking step because [the secondary reference] indicated that pre-compression crosslinking was responsible for the improved properties." *Id*. at 1367. Thus, rather than excluding other parts of the reference necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art as argued by Hyon, "[t]he Board merely selected an element emphasized by the reference, relying on the reference's suggestion that the selected element was responsible for the improved properties." *Id*.

***Because there was no known relationship between the drug's pharmacokinetic value ("PK") and its therapeutic efficacy, the fact that it was obvious to make an extended-release formulation having the same PK value as the known immediate release formulation does not suggest that the extended-release formulation would likewise have therapeutic efficacy.***

In *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 676 F.3d 1063, 102 U.S.P.Q.2d 1760 (Fed. Cir. 2012), the court reviewed the validity of two Cephalon patents covering the drug AMRIX, one covering a modified-release dosage form of skeletal muscle relaxants and the other covering a method of relieving muscle spasms with such dosage form. A single dose of Amrix releases the drug cyclobenzaprine hydrochloride in the body during a 24-hour period.

The district court found that it would have been obvious to a person having ordinary skill in the art to target extended-release pharmacokinetic ("PK") values "mirroring" — in other words, bioequivalent to — those of the immediate-release cyclobenzaprine formulation. On review, however, the Federal Circuit noted that, in addition to achieving bioequivalence in the extended release formulation, the district court was also required to consider the asserted claims' limitation requiring therapeutic effectiveness. 676 F.3d at 1069. Here, because there was no known relationship between the drug's PK values and therapeutic efficacy, the court concluded that "skilled artisans could not predict whether any particular PK profile, including a bioequivalent one, would produce a therapeutically effective formulation." *Id*. at 1070.

Defendants argued and the district court agreed that despite the lack of a known relationship between PK profile and therapeutic efficacy, a skilled artisan would nonetheless have reasonably expected that achievement of the desired PK profile would also result in a therapeutically effective formulation. The Federal Circuit, however, found an "inherent contradiction" in the idea that one of ordinary skill would simultaneously not know the PK/PD relationship but nonetheless assume that the immediate-release and extended-release PK profiles produce the same therapeutic effect: "Because all experts and parties agree, however, that skilled artisans did *not* know the PK/PD relationship even for the immediate-release formulation, there was no way to match the dosage for the extended-release formulation to achieve a known therapeutic effect." *Id*. Citing *KSR*,[34] the court noted that this was not the pursuit of known options from a finite number of identified predictable solutions, but rather more akin to merely throwing metaphorical darts at a board in hopes of arriving at a successful result where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. *Id*.

***FDA guidelines setting forth a goal for the release profiles of extended-release formulations do not by themselves render formulations meeting those goals obvious.***

The Federal Circuit also rejected the district court's reliance on an FDA guidance document directing that extended-release formulations having the same AUC and Cmax as an already-approved immediate-release formulation should also be bioequivalent, holding that "[t]he document provides little support for an obviousness finding here, because, in the absence of a known PK/PD relationship for cyclobenzaprine, there is no evidence that a skilled artisan would have targeted bioequivalence in the first instance." *Id*. at 1074. The court noted that "[o]ne judge of our court has observed that the FDA's publishing of approval requirements for extended-release formulations does not necessarily render obvious a drug that meets those requirements, because 'knowledge of the goal does not render its achievement obvious.' " *Id*. (citation omitted).

[34] *KSR Int'l,* 550 U.S. at 421.

***Objective considerations of nonobviousness must be considered in the initial assessment of obviousness, and not as a rebuttal after a finding of prima facie obviousness.***

The court next addressed what it perceived as confusion relating to the allocation of burdens in obviousness defenses. The court cited *Stratoflex*[35] for the proposition that all objective evidence should be considered before reaching an obviousness conclusion. The court acknowledged that other panels spoke of first establishing "prima facie" obviousness, which the patentee must then rebut. The court cautioned, however, that those cases should not be interpreted as establishing a formal burden-shifting framework that permits a fact finder to reach a conclusion of obviousness before considering all relevant evidence, including evidence of objective considerations. *Id*. at 1076. This would conflict with *Stratoflex*'s directive that objective considerations are to be considered as part of all the evidence, not just when the decision maker remains in doubt after reviewing the art. Considering the objective evidence in its entirety in light of the actual burden imposed upon a patentee and a patent challenger, the court found that "evidence of a longfelt need for an extended-release formulation and the failure of others to formulate one strongly support a conclusion of nonobviousness." *Id*. at 1080.

***Evidence that others who failed to make the invention took a materially different approach to the problem is strongly probative of nonobviousness, which is not negated where the failing party had a goal in addition to the common goal to create a therapeutically effective extended-release product.***

As for failure of others, the court found that "evidence of ALZA's failure to develop an extended-release formulation strongly supports a nonobviousness finding." *Id*. at 1081. The court noted that ALZA and Cephalon took "materially different" approaches, whereby ALZA failed to develop a therapeutically effective product but Cephalon succeeded. *Id*. at 1082. The court cited precedent to the effect that others going in different ways is strong evidence that the inventor's way would not have been obvious. The court also rejected the district court's conclusion that because ALZA had the additional goal of reducing side effects, ALZA's failure was not probative of nonobviousness because it was not directed to the problem that Cephalon's patents purport to solve. Rather, the court found that such evidence was probative because "Cephalon and ALZA did share a central common goal: to create a therapeutically effective product …. The district court was not required to disregard Cephalon and ALZA's common goal simply because ALZA had an *additional* goal not encompassed by the patents in suit." *Id*. The court noted that failure of others or long-felt need are particularly probative of nonobviousness "[w]here, as here, the obviousness determination turns on whether one of ordinary skill in the art would have expected that a particular formulation of an extended-release drug would be successful …." *Id*. at 1083.

***In the absence of a definition in the specification or a clear disavowal in the specification or prosecution history, the court will not import safety and efficacy standards from the specification into the "perfusion" recited in the claims.***

In *Aventis Pharma S.A. v. Hospira, Inc*., 675 F.3d 1324, 102 U.S.P.Q.2d 1445 (Fed. Cir. 2012), the court reviewed the validity of Aventis's claims directed to (1) a perfusion containing docetaxel, less than 35 ml/l of ethanol and less than 35 ml/l of polysorbate and which was capable of being injected without anaphylactic or alcohol intoxication manifestations being associated therewith; and (2) a composition comprising docetaxel dissolved in a polysorbate surfactant, essentially free or free of ethanol.

The court first reviewed the district court's construction of the term "perfusion" to mean "an injectable solution containing the active pharmaceutical ingredient and an aqueous infusion fluid." Sanofi argued that the court construe "perfusion" to further require that it be effective for treatment, safe and stable (i.e., not precipitate) for at least eight hours. The court disagreed, holding that "[n]either the claims, the specification, nor the prosecution history suggest that the claimed perfusion must satisfy certain safety or efficacy standards." 675 F.3d at 1330. The court referred to the standard for narrowing a claim beyond its plain and ordinary meaning as a "stringent" one occurring only when 1) a patentee sets out a definition and acts as its own lexicographer; or 2) the patentee disavows the full scope of a claim term either in the specification or during prosecution. *Id*. (citation omitted). Here, the court found that "nothing in the specification indicates that a minimum stability of eight hours is an essential feature of the claimed perfusion or

[35] *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39, 218 U.S.P.Q. 871, 879 (Fed. Cir. 1983).

an advantage of the perfusion over the prior art." *Id*. at 1331. Because Sanofi conceded that its claimed perfusion would be obvious over the cited prior art under the district court's construction, the court affirmed the invalidity of that claim.

***A claim directed to a method of preserving hepatocytes involving multiple freezing steps found nonobvious in view of art showing a single freezing step and expectation in art that additional freezing steps would cause further cell damage.***

In *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 101 U.S.P.Q.2d 1153 (Fed. Cir. 2012), the court reviewed whether the district court properly found that Celsis was likely to prevail against CellzDirect, now Life Technologies Corporation ("LTC"), on the issue of the nonobviousness of the claims. The claims at issue relate to methods for preparing multi-cryopreserved hepatocytes where hepatocytes were first frozen and thawed, then subject to density gradient fractionation to separate viable hepatocytes from nonviable hepatocytes, followed by recovery of the viable hepatocytes and cryopreserving the recovered viable hepatocytes to form the desired hepatocyte formulation.

The issue on appeal was whether the district court erred in finding Celsis likely to succeed on nonobviousness in view of an article analyzing whether single-cryopreserved hepatocytes can replace fresh hepatocytes as laboratory models, by comparing fresh versus (single) cryopreserved human, monkey and dog hepatocytes.

The court acknowledged that the invention is in an art well known for its unpredictability. Further, despite the crowded nature of the art, there was not one reference to multi-cryopreservation. To the contrary, the record shows that the prior art taught away from multiple freezings in view of the severe damage caused by even a single round of freezing. The court accepted Celsis's argument that a person of ordinary skill would expect a second freezing on those damaged cells to kill even more cells than the first freezing. Combined with the fact that the article cited by LTC carried out only one round of freezing, the court concluded that it "has not seen LTC identify any teaching, suggestion, or motivation in the … article that multiple rounds of freezing would somehow increase rather than decrease cell viability." 664 F.3d at 928.

The basic problem that LTC had here is that if a freezing step is known to damage cells, then certainly repeating such step would, if anything, be expected to kill even more cells.

***A claim requiring an aluminum coating on steel not anticipated by a general disclosure of paint coatings, which does not define a "definite and limited class" of coatings that would permit a person skilled in the art to "at once envisage" aluminum.***

In *ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 105 U.S.P.Q.2d 1211 (Fed. Cir. 2012), the court reviewed the district court's finding of anticipation and noninfringement for ArcelorMittal's ("AM's") claims directed to an aluminum-coated steel and specifically "a hot-rolled steel sheet coated with an aluminum or aluminum alloy coating," comprising a list of components wherein "the steel sheet has a very high mechanical resistance after thermal treatment and the aluminum or aluminum alloy coating provides a high resistance to corrosion of the steel sheet."

AM appealed the district court's holding of anticipation, arguing that the cited art disclosed neither coating the steel sheet before thermal treatment nor coating the steel sheet with aluminum or an aluminum alloy. Although the prior art does not expressly disclose either precoating or particular coating compositions, the court found that there was a sufficient teaching of precoating based on the prior art's statements that "it is advisable to protect heat treated finished parts with coatings" and that "[i]t is possible to coat this new heat treated boron steel after degreasing as with conventional steels." 700 F.3d at 1322-23 (alteration in original) (citation omitted).

However, the court found no basis for the conclusion that the prior art disclosed coating with aluminum or aluminum alloy. The district court had relied on the principle enunciated in *In re Petering*,[36] that when a prior art reference discloses a "definite and limited class" of suitable members within a general formula, it may be read to disclose each member of that class. Here, the Federal Circuit

[36] 301 F.2d 676, 681, 133 U.S.P.Q. 275, 279-80 (C.C.P.A. 1962).

found that the district court was in error in finding that the prior art inherently discloses aluminum as one of a very small class of metals suitable for use in coating boron steel, holding instead that the prior art fails to even refer to metal coatings. Indeed, the only coatings disclosed by the prior art related to paint coatings. This does not provide a "definite and limited class" of coatings for steel sheet sufficiently narrow that one of ordinary skill in the art would "at once envisage" each member of this limited class as required by the holding in *Petering*. *Id*. at 1323.

***Because both the hot forging of the secondary reference and the hot stamping of the primary reference solve the same problem of preventing oxidation and carburization, it would have been obvious that the benefit imparted by hot forging of the secondary reference would be equally applicable to the hot stamped aluminum layer of the primary reference.***

As for the obviousness of coating the steel with aluminum, the parties disputed whether the secondary reference's teaching of coating steel with aluminum during ***hot forging*** suggested coating steel with aluminum during ***hot stamping***. Because both references sought to solve the same problem (prevention of oxidation and carburization), defendant argued that it would have been obvious that the benefits imparted by the aluminum layer to the forged steel of the secondary reference would be equally applicable to the stamped steel of the primary reference because it was "no more than the application of known solutions to equivalent problems in an analogous context." *Id*. at 1324. AM countered that hot forging described in the secondary reference was so different from the hot stamping of the primary reference that there would be no motivation to combine. The court construed AM as arguing that the references were not from analogous arts and therefore would not be combined, which was a question of fact that was for the jury to resolve. The court further concluded that there was a sufficient motivation to combine in view of defendants' expert testimony that a person of ordinary skill in the art would have expected to succeed. *Id*.

***Evidence of commercial success that includes a step in addition to the steps required by the claim must still be considered, though the patentee must show that the success has sufficient nexus to the claimed novel features of the invention.***

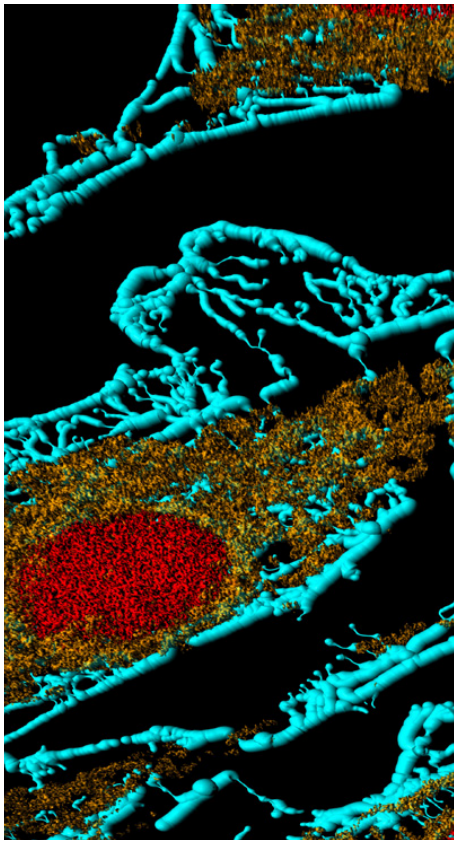
Finally, the court assessed whether AM's evidence of commercial success was sufficient to rebut the prima facie obviousness. The Federal Circuit found that the district court construed the term "hot-rolled steel sheet" too narrowly so as to exclude performance of an additional cold-rolling step. Defendants argued that even under this expanded construction, the claim still encompassed a process carried out ***without*** a cold-rolling step. Because all the evidence of AM's commercial success related to the process carried out ***with*** a cold-rolling step, defendants argued that AM had failed to rebut prima facie obviousness, noting that claims that are broad enough to read on obvious subject matter are unpatentable even though they also read on nonobvious subject matter. *Id*. at 1325.

The court rejected this argument, finding that "this is not a situation in which the claims themselves describe distinct alternative embodiments of the invention, and where the obviousness of one embodiment would invalidate the entire claim." *Id*. Rather, even where the additional cold-rolling step is carried out, the claim still requires performance of a hot-rolling step. Under such circumstances,

> our cases make clear that the commercial success of the embodiment with additional unclaimed features is to be considered when evaluating the obviousness of the claim, provided that embodiment's success has a sufficient nexus to the claimed and novel features of the invention …. [W]hether there is a nexus here depends upon a comparison between cold-rolled steel produced by the patented process and cold-rolled steel produced by alternative processes to see if the former achieved material commercial success over and above the latter. *Id.*

***Court finds that a canceled claim that improperly issued was still entitled to a presumption of validity, though the court acknowledged that such prosecution history must still be considered.***

In *Sciele Pharma Inc. v. Lupin Ltd.,* 684 F.3d 1253, 103 U.S.P.Q.2d 1250 (Fed. Cir. 2012), the Federal Circuit reviewed whether the district court properly enjoined Lupin from selling its generic version of FORTAMET, which Lupin launched at risk after expiration of the 30-month stay. The claims under review relate to controlled release metformin compositions including dosage forms with a mean time to maximum plasma concentration (Tmax) of the drug, which occurs at 5.5 to 7.5 hours after oral



administration on a once-a-day basis to human patients, with a preferred narrower Tmax range of 5.5 to 7.0 hours. This case had an interesting twist in that Shionogi canceled the claims reciting the upper limit of 7.5 of the patent in view of prior art but the patent erroneously issued with the broader range.

The court first addressed whether the presumption of validity and the accompanying burden of proof were altered by the facts of the case. Lupin argued that the presumption of validity should not attach because of the erroneous issuance of the canceled claims. The court found the presumption of validity applicable even to the improperly issued claims, but noted that this "does not mean … that we should not consider the prosecution history."

***The ultimate burden of proof to show invalidity, clear and convincing evidence, does not change even if a reference was considered by the PTO; however, the new evidence not previously considered by the PTO may carry more weight.***

Shionogi argued that there should be a heightened presumption of validity because the prior art references relied upon by Lupin were before the Patent Office during prosecution. The court held that "[b]oth parties are wrong. … Whether a reference was previously considered by the PTO, the burden of proof is the same: clear and convincing evidence of invalidity." 684 F.3d at 1260. However, while the ultimate burden of proof does not change, new evidence not considered by the PTO may carry more weight than evidence previously considered by the PTO, and may go further toward sustaining the attacker's unchanging burden.

***KSR analysis is applicable even where the PTO considered the asserted prior art.***

Lupin argued that the claims are obvious over (1) Cheng, which discloses all the limitations of the asserted claims except for the Tmax range of 5.5 to 7.5 hours (Cheng discloses a Tmax of 8 to 12 hours) in view of (2) Timmins, which discloses a Tmax within the claimed range. Lupin further cited the fact that the applicants themselves admitted that it required no more than "routine experimentation" to obtain the claimed pharmacokinetic parameters. For its part, Shionogi argued that the Tmax disclosed by Timmins is a *median* Tmax and not the *mean* Tmax as claimed, such that there is no motivation to combine Cheng with Timmins. The court agreed that Lupin raised a substantial question of validity, noting that "the district court's obviousness analysis was flawed" in that "[i]t failed to correctly apply *KSR*" based on its perception that there was a fundamental factual difference between this case and *KSR,* namely that the references were before the PTO during prosecution. *Id*.

***Because secondary reference teaches benefits of a lower Tmax, it would have been obvious to modify the Tmax of the primary reference.***

The court further noted that "[a]lthough Timmins expressly discloses a median Tmax, it also provides the raw data from which one skilled in the art could compute the range of possible mean Tmax values," based on which "one skilled in the art would understand that the mean Tmax in Timmins must fall between 4.67 and 6.33 hours." *Id*. at 1262. The court found motivation to combine based on Timmins's teaching that a lower Tmax provides the benefit of the desired plasma levels of drug for an extended period of time as well as a reduction in dosing frequency resulting from an earlier extended release: "These benefits would motivate one skilled in the art to modify Cheng to achieve a lower Tmax range." *Id*. Further motivation to pursue the approach in Timmins comes from the fact that lowering the Tmax allows one skilled in the art to approach the drug profile of Glucophage, the industry standard drug.

***An applicant admitting for enablement purposes that one skilled in the art could manipulate a formulation to obtain the pharmacokinetic properties of the invention coupled with the motivation to lower Tmax provided by the secondary reference renders the invention obvious.***

Finally, the court also agreed with Lupin's argument regarding the applicant's admission that one skilled in the art would be able to manipulate the processes and formulations of the prior art to obtain the claimed pharmacokinetic parameters of the present invention. The court rejected Shionogi's argument that this statement applies only to enablement, noting that

> we are hard pressed to understand this distinction. Coupled with the motivation to lower the Tmax, as disclosed in Timmins, the applicant's characterization of the predictability and skill in the art during prosecution provides further evidence that it would have been a routine and obvious design choice to make an extended release dosage form with a lower Tmax. *Id*. at 1263

This case illustrates the pervasive tension between enablement and obviousness in the sense that once the court found motivation to lower Tmax, Shionogi was hard pressed to argue that the means to achieve such lowering would not be obvious.

## Hatch-Waxman

***A claim for infringement under §271(e) does not lack subject jurisdiction merely because a court views the infringement claim as lacking validity on the merits.***

In *AstraZeneca Pharmaceuticals v. Apotex Corporation* 699 F.3d 1370, 101 U.S.P.Q.2d 1675 (Fed. Cir. 2012), the court reviewed whether an ANDA filer could avoid infringement liability under §271(e) by filing a Section (viii) statement indicating that the ANDA filer would not label the drug for uses covered by the patents listed in the Orange Book. The particular drug at issue here was rosuvastatin calcium, which was approved by the FDA for a number of indications, some of which fell and some of which did not fall within the method of use patents listed in the Orange Book.

The court first addressed whether the district court had properly dismissed AstraZeneca's §271(e)(2) infringement claims for lack of subject matter jurisdiction based on the district court's reasoning that §271(e)(2) creates a limited, technical and artificial cause of action where none would otherwise exist, so that in such cases "a district court's jurisdiction turns on whether a plaintiff asserts a valid claim under Section 271(e)(2)." Concluding that AstraZeneca had failed to state a valid §271(e)(2) claim because appellees' ANDAs excluded all methods of using rosuvastatin calcium claimed in the asserted patents, the district court dismissed AstraZeneca's claims. On appeal, the Federal Circuit agreed with AstraZeneca, holding that "[b]y enacting §271(e)(2), Congress thus established a specialized new cause of action for patent infringement. When patentees pursue this route, their claims necessarily arise under an Act of Congress relating to patents," citing *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003).

***Where an ANDA applicant files a Section viii statement indicating that it is not seeking approval for a patented indication, there is no infringement even if such indication has been approved by the FDA, notwithstanding the patentee's fear that doctors and pharmacists would prescribe the drug for the nonapproved indication.***

The court next addressed the district court's conclusion that there can be no infringement of the method of use claims because the accused ANDA did not seek approval for a patented indication. Citing its earlier holding in *Warner-Lambert*, the court held that a patented method of using a drug can only be infringed under §271(e)(2) by filing an ANDA that seeks approval to market the drug for that use. In so holding, the court expressly rejected AstraZeneca's attempt to distinguish *Warner-Lambert*[37] based on the fact that the patent asserted in that case claimed an unapproved or "off-label" use, while AstraZeneca's method of use patents recite FDA-approved uses for rosuvastatin calcium. "[T]hat distinction is irrelevant for purposes of §271(e)(2) … the statute defines the infringing act as filing an ANDA for 'a drug claimed in a patent or the use of which is claimed in a patent' .... And while generic applicants cannot obtain approval for uses beyond those already approved by the FDA, … nothing in the Act requires that an ANDA must encompass every approved indication."

The court next rejected AstraZeneca's argument that Section (viii) statements and restricted generic labeling ignore market realities because even if a generic drug is formally approved only for unpatented uses, pharmacists and doctors will nonetheless substitute the generic for all indications once it becomes available, holding that "AstraZeneca's position would, in practice, vitiate [the statute] by enabling §271(e)(2) infringement claims despite the fact that Appellees' Section (viii) statements and corresponding proposed labeling explicitly and undisputedly carve out all patented indications for rosuvastatin calcium." The court warned that, if otherwise, "a pioneer drug manufacturer [would be allowed] to maintain de facto indefinite exclusivity over a pharmaceutical compound by obtaining serial patents for approved methods of using the compound and then wielding §271(e)(2) 'as a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent.' "

***Patentee's fear that the FDA will ultimately require an ANDA filer's label to include patented uses originally excluded in the ANDA filer's Section (viii) statement does not make patentee's claim sufficiently ripe for adjudication.***

[37] *Warner-Lambert Co. v. Apotex Corp*. 316F.3d 1348, 65 U.S.P.Q.2d 1481, (Fed. Cir. 2003)

Finally, the court rejected AstraZeneca's argument that because the FDA will ultimately require the label of appellee's tablets to include information relating to the uses in the method of use patents, there is an infringement under §271(e). The Federal Circuit agreed with the district court that such a claim was insufficiently ripe for adjudication, finding that nothing in the record indicates that the FDA has required appellees to add further indications, and we see no reason to presume that the FDA will do so in the future. The court further noted that the FDA has tentatively approved several of the appellees' ANDAs without issuing any such requirements. Accordingly, the district court correctly dismissed AstraZeneca's claims as unripe to the extent that they rely on prospective labeling amendments for appellees' generic rosuvastatin calcium because these claims rest on contingent future events that may never occur.

***Where the use approved by the FDA (contraception) differs from the uses recited in the Orange Book-listed patent (gestagenic, antiandrogenic and antialdosterone effects), there is no infringement.***

In *Bayer Schering Pharma A.G. v. Lupin, Ltd.* 676 F.3d 1316, 102 U.S.P.Q.2d 1583 (Fed. Cir. 2012), the court reviewed whether two ANDA filers, Watson and Sandoz, infringed Bayer's claims directed to a method of simultaneously achieving, during premenopause or menopause, a gestagenic effect, antiandrogenic effect and an antialdosterone effect in a female patient in need thereof, comprising administering an amount of dihydrospirorenone to said female patient. Another claim under review recited simultaneously achieving the same effects except that the gestagenic was replaced with a contraceptive effect and, in addition to dihydrospirorenone, an effective amount of an estrogenic compound was also administered.

Watson and Sandoz argued that because their ANDAs related to the use of the generic form of Yasmin only for oral contraception and not for the combination of uses claimed in the patent, they could not be held liable for inducing infringement of that patent. The district court agreed, noting that the FDA had approved the use of Yasmin only for oral contraception, and not for the simultaneous treatment of three conditions, which was the use claimed in the patent.

On review, the Federal Circuit observed that "the issue in these cases is a very narrow one" — whether "the FDA *did* approve the use of Yasmin to obtain all three effects simultaneously in menopausal and premenopausal patients in need of all three effects, and that the defendants' ANDAs seek FDA approval for the same uses." 676 F.3d at 1320-21. Bayer argued that the defendants are liable for inducing infringement because the label instructs the use of the generic drug to obtain the three effects claimed in the patent.

The court disagreed. Citing *Warner-Lambert Co. v. Apotex Corp.,* the court noted that it is not an act of infringement under Section 271(e)(2)(A) to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved. Because the defendants' ANDAs are substantively identical to Bayer's NDA, the use or uses for which the ANDAs seek FDA approval are necessarily the same as the uses for which the FDA has given its approval by granting Bayer's NDA.

***Inclusion in the "Clinical Pharmacology" section of the label of the "uses" claimed in an Orange-Book listed patent does not rise to the level of FDA-approved uses because such inclusion does not recommend or suggest to physicians that the drug is safe for these uses.***

Referring to the FDA-approved label, the court found that it was not the combination of the three effects claimed in the patent that was the basis for approving Yasmin. Rather, the label for Yasmin that was approved by the FDA states in the Indications and Usage section that "Yasmin is indicated for the prevention of pregnancy in women who elect to use an oral contraceptive." The court rejected Bayer's reliance on the "Pharmacodynamics" subsection of the "Clinical Pharmacology" section of the label even though such section mentioned the claimed effects, finding that "while the label mentions potential anti-mineralocorticoid and anti-androgenic activity, it does not do so in any way that recommends or suggests to physicians that the drug is safe and effective for administration to patients for the purposes of inducing these effects." Id. at 1322.

***Because the safe harbor unambiguously applies to submissions under any federal law, provided that the law regulates the manufacture, use or sale of drugs, it is not limited to preapproval ANDA submissions.***

In *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348, 103 U.S.P.Q.2d 1800 (Fed. Cir. 2012), the court reviewed the scope of the safe harbor under 35 U.S.C. §271(e)(1). The asserted claims generally require digestion of an enoxaparin sample with a heparin-degrading enzyme, followed by the use of a separation method to detect the presence of the nonnaturally occurring sugar resulting from the β-eliminative cleavage. The signal corresponding to the nonnaturally occurring sugar can then be used to analyze the test sample based on a comparison with a reference standard.

On appeal, the Federal Circuit reviewed whether Amphastar was likely to succeed on the merits so as to justify the district court's granting of a preliminary injunction. The district court concluded that the safe harbor does not apply to Amphastar's testing because it does not apply when a generic manufacturer continues the infringing activity after obtaining approval, which Amphastar was doing. On appeal Momenta further argued that the FDA safe harbor was unavailable because other acceptable testing methods were available, thus dispensing of Amphastar's need to use the patented method for FDA approval.

In reviewing the language of the safe harbor, the court found that "Congress could not have been clearer in its choice of words: as long as the use of the patented invention is solely for uses 'reasonably related' to developing and submitting information pursuant to 'a Federal law' regulating the manufacture, use, or sale of drugs, it is not 'an act of infringement.' " 686 F.3d at 1354. Accordingly, "[a]lthough the Hatch-Waxman safe harbor provision was enacted in the context of the then-novel ANDA approval process, [the safe harbor] does not reference the portion of the Federal Food, Drug, and Cosmetic Act describing the ANDA requirements." *Id*. The court thereby held that the safe harbor "unambiguously applies to submissions under any federal law, providing that the law 'regulates the manufacture, use, or sale of drugs.' " *Id*.

***Even though not submitted to the FDA, the records maintained qualify as a "submission" subject to the safe harbor under §271(e) because the FDA required retention of such records as well as their availability for FDA inspection upon request for at least one year.***

Momenta also argued that because the information in question was not "submitted" to the FDA as required by the statute but rather was retained by the ANDA holder, the safe harbor did not apply. The court disagreed, noting that although Amphastar made no submissions to the FDA, FDA regulations require that all records associated with a produced batch of drugs be retained for at least one year after the expiration date of the batch and that they be readily available for authorized inspection by the FDA at any time. *Id*. at 1357. The court held that "the requirement to maintain records for FDA inspection satisfies the requirement that the uses be reasonably related to the development and submission of information to the FDA," *id*., despite the fact that the FDA does not in most cases actually inspect the records.

***Court distinguishes between (1) postapproval submissions that may be routinely reported to the FDA, which do not qualify for the safe harbor and (2) postapproval submissions required to maintain FDA approval, which do qualify for the safe harbor.***

Having determined that the records retained by Amphastar amounted to a "submission," the court next found further that they qualified for the safe harbor. The court noted its *Classen* decision,[38] which held that the safe harbor does not extend to "information that may be routinely reported to the FDA, long after marketing approval has been obtained." Here, however,

> the submissions are not "routine submissions" to the FDA, but instead are submissions that are required to maintain FDA approval. … [U]nlike in *Classen* where the patented studies performed were not mandated by the FDA, the information here is not generated voluntarily by the manufacturer but is generated by FDA requirements the manufacturer is obligated under penalty of law to follow. Under such circumstances, the information can be said to have been gathered solely for submission to the FDA and not, as in *Classen*, primarily for non-FDA purposes.

[38] *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1070, 100 U.S.P.Q.2d 1492, 1503 (Fed. Cir. 2011).


*Id*. at 1358. The court thus rejected Momenta's pre-/post-approval distinction.

***Fact that noninfringing alternative testing methods are available does not remove the potentially infringing testing method from the scope of the safe harbor.***

The court also rejected Momenta's argument that Amphastar's testing is not protected because there are FDA-endorsed noninfringing alternatives available, holding that "[t]he safe harbor … does not mandate the use of a noninfringing alternative when one exists. The only limitation in the safe harbor is that the use must be 'reasonably related to the development and submission of information' pursuant to a federal law regulating the 'manufacture, use, or sale of drugs or veterinary biological products.' " *Id*. at 1359. Having found the safe harbor applicable, the court concluded that Momenta failed to demonstrate a likelihood of success on the merits and vacated the injunction.

It is rather hard to understand how this court underwent the metamorphoses from a "submission" reasonably related to approval of a drug to unsubmitted records prepared after such drug is approved in its apparent politically motivated zeal to expand the safe harbor. As Judge Rader noted in his dissent, "this result will render worthless manufacturing test method patents." *Id*. at 1362. As further pointed out by Judge Rader, "Amphastar uses Momenta's patented method in the manufacture of each commercial batch it sells. By definition, its use is not to obtain FDA approval. One can only market a drug that the FDA has already approved." *Id*. at 1368.

***Where second ANDA filer filed Paragraph IV certifications against three patents of the NDA filer and the NDA filer brought suit only on two of them, the second ANDA filer had declaratory judgment jurisdiction against the NDA filer for the third patent despite the NDA filer's covenant not to sue on the third patent.***

In *Dey Pharma, LP v. Sunovion Pharmaceuticals Inc*., 677 F.3d 1158, 102 U.S.P.Q.2d 1710 (Fed. Cir. 2012), the Federal Circuit considered whether Dey had subject matter jurisdiction, as the district court had found, to bring a declaratory judgment action of no infringement against Sunovion. Here, Dey was the second ANDA filer who filed suit against the patent holder and NDA filer (Sunovion) in order to trigger the first ANDA filer's (Breath's) exclusivity period.

The first ANDA filer, Breath, filed an ANDA with Paragraph IV certifications against all three Sunovion patents and later settled its suit against Sunovion. Dey's later-filed ANDA likewise included a Paragraph IV certification against all three patents. In response, however, Sunovion sued Dey on only two of the three patents. This prompted Dey to bring a declaratory judgment action against the third patent. In response, Sunovion provided Dey with a covenant not to sue on the third patent and moved to dismiss the declaratory judgment action for lack of subject-matter jurisdiction. However, the district court held that the covenant not to sue did not defeat declaratory judgment jurisdiction.

On review, the Federal Circuit referred to its earlier *Caraco* decision[39] where "[w]e held there was declaratory jurisdiction "because the NDA holder's actions were 'potentially exclud[ing] non-infringing generic drugs from the market,' " 677 F.3d at 1162, despite the NDA holder's covenant not to sue because only a court judgment of noninfringement or invalidity would trigger Ivax's exclusivity period and accelerate Caraco's market entry." *Id*. The court here found that

> [j]ust as in *Caraco*, the second ANDA filer (Dey) brought a declaratory judgment action over the last-expiring Orange Book patent … after the NDA holder (Sunovion) only sued for infringement of the other Orange Book patents. … And like the second ANDA filer in Caraco, Dey [was] "excluded from selling a non-infringing product" [where the] injury is "fairly traceable" to Sunovion and "redressible by a declaratory judgment that the [third] patent is not infringed."

*Id*. at 1163 (citations omitted). The court rejected Sunovion's argument "that success in the declaratory judgment action alone is insufficient to redress Dey's injury because Dey would still need to succeed in the separate infringement litigation over the other Orange Book patents," noting that "this was also true in *Caraco*." *Id.*

***Because the possibility remains that the first ANDA filer will not launch on the date when it is entitled to do so, the case or controversy requirement of the declaratory judgment act for a second ANDA filer is not necessarily mooted on such launch date.***

[39] *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1292, 86 U.S.P.Q.2d 1289, 1298 (Fed. Cir. 2008).

The court also rejected Sunovion's argument that once Breath is entitled to launch its generic product, there will no longer be a case or controversy necessary to support declaratory judgment jurisdiction: "The problem with Sunovion's view is that its last assumption is incorrect. The district court will not lose jurisdiction simply because the period of possible first generic market entry arrives. Even after Breath is entitled to launch, the possibility remains that Breath will not do so." *Id*. at 1164. The court noted that Breath has not announced plans to launch and "it is well known that the first generic often elects to delay entry for various reasons, including possible payments from the brand-name manufacturer to delay the launch." *Id*.

The court finally rejected Sunovion's argument that, under *Janssen*,[40] "a possible delay in the future of a first Paragraph IV ANDA filer in launching its generic product does not give rise to declaratory judgment jurisdiction." *Id*. at 1165.

> What Sunovion ignores is that there is a difference between finding that a controversy exists to initiate a suit and determining that the controversy has become moot. While Article III requires that "an actual controversy must be extant at all stages of review, not merely at the time the complaint is filed," the question of whether a controversy exists at a later stage of the proceeding is governed by mootness doctrine.

*Id*. The court thus held that the case may proceed until it is rendered moot.

## Written Description

***Because dispensing pharmaceutical products in containers or packages is not a new or unpredictable concept, disclosure in specification of several dosage forms provides written description support for packaged and labeled products with dosage instructions.***

In *Pozen Inc. v. Par Pharmaceutical, Inc*., 696 F.3d 1151, 104 U.S.P.Q.2d 1969 (Fed. Cir. 2012), Par argued that Pozen's claim was invalid under the written description requirement because the original application did not support the limitations "therapeutic package," "finished pharmaceutical container" and "said container further containing or comprising labeling directing the use of said package in the treatment of migraine," all of which Pozen added during prosecution of the patent-in-suit. The Federal Circuit agreed that the specification "discloses several dosage forms, including an oral unit dosage, to teach treating migraines by concomitantly administering therapeutic amounts of sumatriptan and naproxen." 696 F.3d at 1166. The district court concluded that "persons of skill in the art would know these pharmaceutical dosages are administered to a patient in containers or packages with labeling and inserts with dosage instructions," particularly because dispensing "pharmaceutical products in containers or packages is not a new or unpredictable concept."[41] The district court also noted that "[a] person of ordinary skill in the art would know that medications are not simply handed out to patients. Rather, pharmaceutical products, like the claimed tablets, are routinely administered in containers or packages."[42] The Federal Circuit agreed with these conclusions. *Id*. at 1167.

Although as the court noted that there is not an *in haec verba* requirement for compliance with the written description requirement, it is also true that this court has likewise held that obviousness is not the test for compliance with the written description requirement. Here, no one would dispute that putting oral unit dosage forms into containers with labeling is incredibly obvious. Nonetheless, it seems quite a stretch to say that the disclosure of an oral unit dosage provides support for packaging with labels and those who deal regularly with the PTO no doubt appreciate that there are many examiners who would not permit such an amendment. The best explanation here is that Pozen got away with one at the district court, and as written description is a question of fact that the court will only overturn if there is clear error, the Federal Circuit clearly did not find this so offensive that it required reversal.

***While a component need not be "contraindicated" to support a negative claim limitation excluding that component, the specification needs to describe a reason to exclude the negative limitation for there to be written description support.***

In *Santarus, Inc. v. Par Pharmaceutical, Inc*., 694 F.3d 1344, 104 U.S.P.Q.2d 1641 (Fed. Cir. 2012), the court reviewed whether Santarus's claim directed to a method for treating an acid-caused gastrointestinal disorder was adequately described under the

[40] *Janssen Pharmaceutica, N.V. v. Apotex, Inc*., 540 F.3d 1353, 1363, 88 U.S.P.Q.2d 1079, 1087 (Fed. Cir. 2008).

[41] *Pozen Inc. v. Par Pharm., Inc*., 800 F. Supp. 2d 789, 821, 822 (E.D. Tex. 2011).

[42] *d.* at 822.


written description requirement of 35 U.S.C. §112, ¶ 1. The particular question addressed was whether the specification described the claimed combination of nonenteric-coated omeprazole and sodium bicarbonate "*wherein the composition contains no sucralfate*."

Holding that it was necessary for the specification to include evidence demonstrating that sucralfate is "contraindicated," in order to meet the written description requirement, the district court concluded that the specification's statement that the claimed composition is "advantageous" as compared with sucralfate was inadequate. On appeal, Santarus argued that evidence of "contraindication" of sucralfate was unnecessary, citing its expert testimony that a person of ordinary skill in this field would have known the properties and effects of sucralfate, and would have understood from the specification that disadvantages of sucralfate may be avoided by the claimed formulation. Noting that "[n]egative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation," and that "[s]uch written description support need not rise to the level of disclaimer," 694 F.3d at 1351, the Federal Circuit agreed with Santarus. The court went a step further, stating that "it is possible for the patentee to support both the inclusion and exclusion of the same material." *Id*. Here, the court found that the no sucralfate limitation was "adequately supported by statements in the specification expressly listing the disadvantages of using sucralfate." *Id*.

Few would argue that a specification needs to rise to the level of showing that inclusion of a component was "contraindicated" in order to support exclusion of such component in a claim. However, the majority's statement that negative limitations are supported "when the specification describes a reason to exclude the relevant limitation," seems to be imposing a requirement above and beyond the usual test for written description, i.e., that the specification reasonably convey that the inventor had possession of the invention as of the filing date. For example, if the specification explicitly states that an aspect of the invention excludes a particular component, then why need the inventor provide a reason for that exclusion? In her concurrence, Judge Newman referred to the majority's dicta as "a gratuitous fillip," which devises a "new rule that the specification must 'describe a reason' for the claim limitation, or the claims are invalid on written description grounds." *Id*. at 1358. It will be interesting to see if the court treats this "holding" more as dicta or new law.

## Best Mode

***The inquiry for the second prong of a best mode analysis is an objective one focusing on whether the specification discloses sufficient information to practice, i.e., enables the best mode and not on the motivation of the inventor for the nondisclosure.***

In *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 676 F.3d 1063, 102 U.S.P.Q.2d 1760 (Fed. Cir. 2012), the court reviewed Mylan and Par's allegation that Cephalon's specification fails to disclose the best mode because it omits a particular range of dewpoints, the control of which is relevant to the process of making the claimed cyclobenzaprine formulation with a coated bead.

As for the first prong of the best mode inquiry, i.e., whether at the time the application was filed the inventor subjectively possessed a best mode for practicing the invention, the court found that the inventor indeed preferred particular dewpoints at the time the applications were filed. 676 F.3d at 1085. As for the second prong, i.e., whether the specification objectively discloses sufficient information such that one reasonably skilled in the art could practice the best mode, the court noted that the proper inquiry focuses on the adequacy of the disclosure and not, as urged by Mylan and Par, on the motivation of the inventor for any nondisclosure. *Id*. at 1085-86. The court further found that the district court improperly focused on whether the dewpoints were routine details apparent to one of ordinary skill in the art, when it should have focused instead on whether the optimal dewpoints were enabled despite the specification's failure to disclose them. *Id*. at 1086. Here, because the "harmonization" process known to skilled artisans would produce the optimal dewpoints, the specification need not disclose them to enable skilled artisans to practice the best mode.

While it is clear that the court correctly enunciated the two-pronged test for best mode, the question that comes to mind is whether there is a real difference between the district court's improper inquiry as to whether the omitted disclosure was a "routine detail" apparent to one of ordinary skill in the art versus the Federal Circuit's

inquiry as to whether the omitted disclosure was "enabled" by the specification. It is hard to imagine a fact pattern where a detail characterized as "routine" would not be enabled.

## Infringement

***To meet the "independent dissolution" limitation of the claim relating to a combination drug dosage form, it was not necessary to directly compare the agents individually against the combination product where the patentee demonstrated that one agent dissolved independently of the other.***

In *Pozen Inc. v. Par Pharmaceutical, Inc*., 696 F.3d 1151, 104 U.S.P.Q.2d 1969 (Fed. Cir. 2012), the Federal Circuit reviewed the district court's findings that Par's products meet the "independent dissolution" limitation and the "substantially all" limitation of Pozen's claims.

The parties agreed that "independent dissolution" was properly construed as meaning that dissolution of naproxen and triptan from the multilayer tablet occurs in the same amount of time ±10% as when the same amount of naproxen and triptan are given separately. Appellants contended that because Pozen provided no comparison of the dissolution rates of the accused combination products versus the same amount of naproxen or sumatriptan alone, Pozen failed to establish infringement under the doctrine of equivalents. The court disagreed, holding that "[a]lthough there is no direct evidence comparing the rate of dissolution of the ANDA products to that of the agents individually, no such actual comparison was necessary" because "[u]nder the doctrine of equivalents analysis Pozen need only show that the ANDA products performed the same function in the same way to achieve the same result as the claimed elements" of the patent. 696 F.3d at 1169. Here, the expert testimony shows that "the sumatriptan dissolves completely and independently from the naproxen" and vice versa. *Id*. The court concluded that "logically if the agents dissolve in the same way they would if the other agent was not present, their dissolution takes the same amount of time it would take when given separately." *Id*.

***A claim requiring "substantially all" of a component in a tablet layer was properly construed literally as requiring at least 90% in view of the specification and was further permitted to include as an equivalent a tablet requiring 85% of the component.***

The court next reviewed whether the accused products infringed the claim requirement that "substantially all of said triptan is in the first layer of said tablet and substantially all of said naproxen is in a second, separate layer." The district court construed this phrase as requiring "at least 90%, and preferably greater than 95%, of the total triptan present in the tablet is included within one distinct layer and at least 90%, and preferably greater than 95%, of the naproxen present in the tablet is included within a second distinct layer." The first layer of the accused tablets contain 100% of the tablet's sumatriptan, along with 15% of the tablet's naproxen, with the remaining 85% of the naproxen in the second layer.

Par argued that the claim term "substantially all" was a "fuzzy" quantitative limitation not entitled to equivalents, noting that the word "substantially" was already used to capture amounts as low as 90% when the court construed the claim. Par argued that to further extend the range under the doctrine of equivalents would effectively give Pozen "equivalents of equivalents," which this court refused to do in a similar situation in *Cohesive Technologies, Inc. v. Waters Corp.*[43]

The court noted that "although the claim language itself is a qualitative measure, the claim construction pulls directly from the specification to give the term 'substantially all' a quantitative definition, specifically, 'at least 90%, and preferably greater than 95%,' and this court has previously concluded that the doctrine of equivalents is not foreclosed with respect to claimed ranges." *Id*. at 1170. The court further noted that "in this case, Pozen never stated that 'at least 90%, and preferably greater than 95%' should be an absolute floor. Under the doctrine of equivalents a tablet layer with 85% of the agent can be fairly characterized as an insubstantial change from a tablet layer with 90% of the agent." *Id*. at 1170-71. The court rejected appellants' argument that their products do not achieve separate distinct layers because one of the layers has both agents and concluded that despite the presence of 15% of the naproxen in the first layer, the accused tablets meet the function/way/result test.

Finally, the court rejected appellants' argument that their products are "admixtures," which Pozen specifically

[43] 543 F.3d 1351, 1372, 88 U.S.P.Q.2d 1903, 1916 (Fed. Cir. 2008) (holding that where "a patentee has brought what would otherwise be equivalents of a limitation into the literal scope of the claim, the doctrine of equivalents is unavailable to further broaden the scope of the claim").

disclaimed by stating during prosecution that "[a]mong the dosage forms falling outside the claims are: admixtures; any dosage forms other than tablets; tablets in which one drug is in a core and surrounded by a layer or coating containing the second drug; and tablets containing multiple drug release pellets or microparticles." *Id*. at 1172 (citation omitted). In particular, the court found that "Appellants' ANDA products are not admixtures, i.e. substances with blended or mixed ingredients, because substantially all of the agents are separated and segregated into two distinct layers …." *Id*.

There are a couple of interesting takeaways here. First, where there are the so-called "fuzzy" terms like "about" or "substantially" in a claim, it appears on comparing *Cohesive Technologies* versus the present case that the court will first look to see if there is a specifically enumerated range defined in the specification. If there is not, then one is in the *Cohesive Technologies* situation and the analysis for purposes of both literal infringement and infringement under the doctrine of equivalents is the same. On the other hand, if the specification provides a definitive range for terms like "about" or "substantially," as was the case here, then the court can use that range as the literal infringement range and carry out a separate equivalents analysis, which would permit further extension of that range, based on cases such as *Adams*,[44] where the court held that equivalents are not precluded for claims with specific numerical ranges.

The second interesting takeaway is the court's handling of the estoppel issue. Pozen disclaimed admixtures and the court simply stated as a conclusion that a combination of 85% of one drug and 15% of another drug is not an admixture "as explained above." However, the explanation above was primarily that of the district court finding that the function/way/result test was met with an 85% formulation. So in essence, the court used its own finding of equivalence under the function/way/result test as a rebuttal to file wrapper estoppel on that equivalence. Logically, there must have been some reason that Pozen needed to disclaim admixtures during prosecution of its patent, such as one or more prior art references, but the decision failed to discuss whether this was the case.

***A claim "not requiring" a step cannot be read as prohibiting such step, such that an accused process carrying out the step avoids infringement.***

In *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 101 U.S.P.Q.2d 1153 (Fed. Cir. 2012), the court reviewed whether the district court properly granted a preliminary injunction to Celsis against CellzDirect, now Life Technologies Corporation ("LTC"). The claims at issue relate to methods for preparing multi-cryopreserved hepatocytes.

The first claim under review recited

> A method of producing a desired preparation of multi-cryopreserved hepatocytes … comprising:
>
> (A) subjecting hepatocytes that have been frozen and thawed to *density gradient fractionation* to separate viable hepatocytes from non-viable hepatocytes,
>
> (B) recovering the separated viable hepatocytes, and
>
> (C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes *without requiring a density gradient step* … .

664 F.3d at 924. The second claim under review recited "[a] method of investigating in vitro drug metabolism comprising incubating hepatocytes … in the presence of a xenobiotic, … wherein greater than 70% of the hepatocytes of said preparation are viable *without requiring a density gradient step …*" *Id*.

The district court found that Celsis was likely to succeed in proving that LTC's accused process performs all the steps in the asserted claims. That court found that the accused process performs a density separation that satisfies the "density gradient fractionation" in step (A), because it separates viable from nonviable hepatocytes by density. It also rejected LTC's argument that because LTC carries out the same density separation after both the first thaw step (A) and the second thaw step (C), LTC did not meet the claim language "without requiring a density gradient step" in step (C) of the claim. The Federal Circuit agreed with the district court that "LTC reads 'without requiring' to mean 'prohibiting,' such that the accused process performs an action 'prohibited' by step (C) and therefore does not infringe." *Id*. at 926. It found this reading to be "unnatural" and that " 'without requiring' means simply that the claim does not require the density gradient step." *Id*. at 926-27.

[44] *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 96 U.S.P.Q.2d 1041 (Fed. Cir. 2010).

## Inequitable Conduct

***Patentee's failure to disclose references was not inequitable conduct because negligence, even gross negligence, is insufficient to establish deceptive intent and there were plausible alternative explanations for the failure to disclose the references.***

In *In re Rosuvastatin Calcium Patent Litigation*, 703 F.3d 511, 105 U.S.P.Q.2d 1437 (Fed. Cir. 2012), the defendants argued inequitable conduct in view of the failure of two of Shionogi's in-house patent staff to disclose three documents to the PTO during prosecution of the patent. Defendants further argued Shionogi's disclosure of the three documents in a subsequent reissue application did not cure the inequitable conduct.

The defendants argued that intent to deceive should be inferred from (1) the first agent's possession of one of the references at the time of the filing of the application and her testimony that she knew she had a duty to disclose that reference to the PTO; (2) an internal Shionogi memorandum stating that development information on rosuvastatin must not be leaked to the outside because it is included in the text of that reference; and (3) the second agent's knowledge of that reference, a second reference and an EPO search report combined with his failure to disclose them to the examiner. The district court concluded that deceptive intent was not "the single most reasonable inference to be drawn from the evidence." 703 F.3d at 521.

The Federal Circuit agreed "that clear and convincing evidence did not show that [the two agents] made a deliberate decision to withhold references from the PTO." *Id*. at 522. Citing *Therasense*,[45] the court noted that it had "sought to impart objectivity to the law of inequitable conduct by requiring that 'the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO' … Recognizing the complexity of patent prosecution, negligence — even gross negligence — is insufficient to establish deceptive intent." *Id*. In the final analysis, the court found plausible alternative explanations for Shionogi's failure to disclose the references, including inexperienced agents and an overworked department.

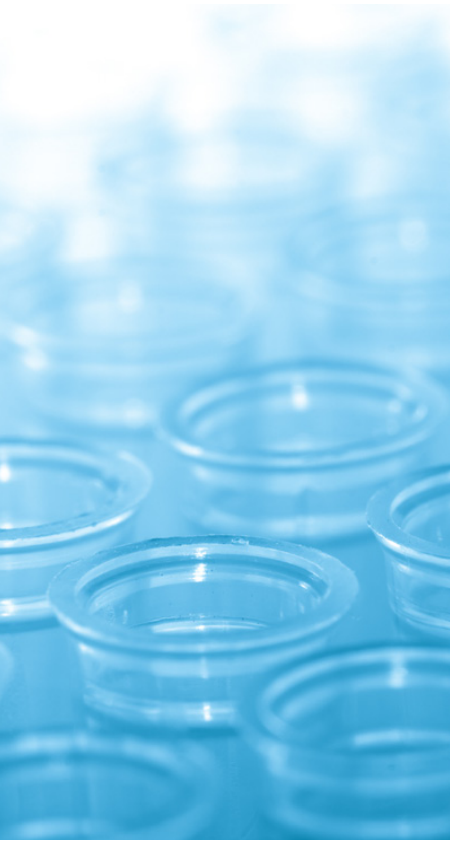
***Despite the district court's finding that the inventor's explanation for failing to disclose his experimental administration of the claimed formulation "strained credibility," there was no specific intent to deceive and thus no inequitable conduct.***

In *Santarus, Inc. v. Par Pharmaceutical, Inc*., 694 F.3d 1344, 104 U.S.P.Q.2d 1641 (Fed. Cir. 2012), the court reviewed whether Santarus engaged in inequitable conduct by failing to inform the PTO that one of the inventors had made the claimed uncoated PPI formulation, administered it to some hospital patients, informed medical colleagues and recorded the medication and its test results in hospital records, before the filing date of his first patent application. The inventor testified that because he was unaware that his experimental administration to patients and his measurement of the effect on stomach acidity required disclosure to the PTO, he had not intentionally withheld information or delayed its disclosure to the PTO. Par also argued that Santarus engaged in inequitable conduct by submitting a misleading declaration that distorted the results of a study carried out by a prior art reference.

Although the district court found that Par had shown materiality of some of this information, and that the explanation by the inventor "strained credibility," the court also found that the evidence was not sufficient to establish by clear and convincing evidence that the inventor acted with an affirmative intent to deceive. On appeal, the Federal Circuit held that "[t]his finding is in accord with *Therasense, Inc. v. Becton, Dickinson & Co.*, where this court explained that '[t]o prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO.' " 694 F.3d at 1349 (citation omitted). The court rejected Par's argument that the district court's remark of "strained credibility" required that the Federal Circuit disbelieve the inventor and hold as the only reasonable inference is that he and his legal representatives acted in bad faith and with intent to deceive. Instead, it accepted Santarus's argument that the district court did not find any testimony false, and that intent to deceive was not established.

***Establishing "but-for materiality" for the withheld references only requires a preponderance of evidence using the "broadest reasonable construction standard" for construing the claims — if claims are invalidated over a withheld reference, there is per se materiality under the but-for test.***

[45] *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290, 99 U.S.P.Q.2d 1065, 1072 (Fed. Cir. 2011).



In *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 102 U.S.P.Q.2d 1445 (Fed. Cir. 2012), the court affirmed the district court's holding of inequitable conduct "although the district court did not have the benefit of our *Therasense* opinion when it rendered its inequitable conduct decision," because the district court "nevertheless found that the withheld references were but-for material to patentability and made distinct intent and materiality findings rather than employing the now-abrogated sliding scale approach." 675 F.3d at 1334.

As for the "materiality" prong, the court noted that "[u]nlike the clear and convincing evidence standard for invalidating a patent in the district court under 35 U.S.C. §§ 102 and 103, the standard for establishing but-for materiality in the inequitable conduct context only requires a preponderance of the evidence," using the "broadest reasonable construction" standard when construing the claims. *Id*. (citation omitted). As a result, the court noted that when a claim is properly invalidated on a deliberately withheld reference, then that reference is necessarily material for purposes of the inequitable conduct inquiry. Indeed, even if the withheld reference is not sufficient to invalidate the claim in district court, the reference may be material if it would have blocked patent issuance under the PTO's different evidentiary standards. Here, because the court affirmed the invalidity of the claims over the withheld prior art, that withheld art was necessarily material.

***Court finds specific intent to deceive in view of inventor's lack of credibility, such as in submitting references that identified the problems with the prior art while withholding those suggesting the solution.***

As for the "intent" prong, the court noted that inequitable conduct requires clear and convincing evidence of a specific intent to deceive the PTO and that "the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence." *Id*. at 1335 (internal quotation marks omitted). On appeal, Sanofi argued that it did not cite the first withheld reference because the resulting perfusions did not demonstrate eight hours of stability and were therefore viewed by the inventors as failures that did not have to be disclosed. The district court, however, found that (1) there were formulations exhibiting longer stability times and (2) the teachings of the withheld reference were one of the "main factors" leading to the claimed formulation. For this reason, the court concluded that the inventor lacked credibility. The district court also noted that Sanofi cited to the reference identifying the problem with the prior art formulation (the anaphylactic reactions associated with Cremophor) while withholding the reference disclosing the solution (the switch from Cremophor to polysorbate 80). *Id*. The Federal Circuit, giving deference to district court credibility determinations, concluded that the district court's factual findings were not "clearly erroneous," affirmed. *Id*. at 1336.

Finally, the court found that Sanofi acted with intent to deceive in withholding a second reference disclosing that better solubility of Taxotere in a polysorbate 80/ethanol, 1:1 excipient system. The court rejected the inventor's testimony that his failure to cite the reference was because he only read an early draft that did not include the relevant disclosure. The court again found that the inventor lacked credibility, citing the fact that (1) the inventor was the project leader who had to approve the reference for publication; (2) the inventor had testified that he reviewed the article with some care to make sure that it was a proper article for the company to be publishing; and (3) he was dissatisfied with the clinical brochure for Taxotere because it did not list the reference and affirmatively took steps to ensure that the reference was identified, yet six months later when signing his patent declaration, he failed to disclose the reference to the PTO. Relying on this evidence, the district court found that the inventor was aware of the reference's materiality and purposefully decided not to disclose it despite this knowledge. *Id*.

This case has several interesting takeaways. First, it is certainly of no surprise that if a withheld reference invalidates a claim, it is *per se* material. Second, it is interesting to note that although the patent challenger must prove inequitable conduct by clear and convincing evidence, the materiality prong of the defense need only be proven under the preponderance of the evidence standard. The intent element requires proof by clear and convincing evidence. Third, the court here affirms that for purposes of determining materiality, it will construe the claims using the standard employed by the PTO in prosecution, i.e., the broadest reasonable construction consistent with the specification. One can thus envision cases with multiple claim constructions, one for assessing the validity of the claims and the other for assessing inequitable conduct. To the extent that anyone concluded after *Therasense* that it would be well-nigh impossible to prove

inequitable conduct in situations where an applicant omitted a reference (as opposed to making an affirmative misrepresentation, which does not require application of the "but-for" test), this case puts that notion to rest. Finally, if the applicant's alternative explanation for not submitting a reference contradicts other evidence in the record, that explanation may not carry the day.

## Reissue

***While reissue cannot be used to undo the consequences of an attorney's conscious decision with knowledge of its consequences, patentee's failure to file an IDS citing certain references and to present a specific claim to the preferred species was not a deliberate choice to omit or abandon the preferred species.***

In *In re Rosuvastatin Calcium Patent Litigation*, 703 F.3d 511, 105 U.S.P.Q.2d 1437 (Fed. Cir. 2012), the defendants argued that the reissue filed by the patentee Shionogi that canceled the generic claim and limited the patent to the specific commercial pharmaceutical compound, rosuvastatin, was improper because (1) there was no error; and (2) there was deceptive intent. The defendants argued no error correctable by reissue because in its original prosecution, Shionogi deliberately (1) presented a claim that overlapped with the products in the prior art reference in an attempt to get greater protection; and (2) obtained only generic claims in order to conceal the preferred commercial rosuvastatin species, which was specifically described in the specification as the most effective of the four tested compounds. The defendants argued that deliberate prosecution decisions can never be corrected through reissue, citing *In re Serenkin*.[46]

On appeal, the court noted that in *Serenkin*, the attorney made a conscious decision, with knowledge of its consequences, between keeping an earlier international filing date without drawings or accepting a later date with the drawings. The Federal Circuit held that Serenkin could not seek through reissue to recover the original filing date, holding that Serenkin was impermissibly "attempting to use the reissue process to undo the consequences of his attorney's conscious decision to give up an earlier filing date so that certain material, which was considered important at the time, would be considered with his PCT application."[47] The court in Serenkin stressed that the actions there had been taken "with knowledge of their consequences." 703 F.3d at 523. By contrast, there was no evidence that Shionogi's failure to file an IDS citing certain references and to present a specific claim to the preferred species was the result of "a deliberate choice to omit or abandon the rosuvastatin species, which was described in the specification as the most effective product." *Id*. at 523-24. The court also rejected the defendants' argument that Shionogi cannot narrow the claims by reissue on the grounds that omission of a dependent claim does not render the patent inoperative. Finally, the court noted that cases cited by the dissent did not establish the impermissibility of using a reissue to submit an IDS. *Id*. at 524.

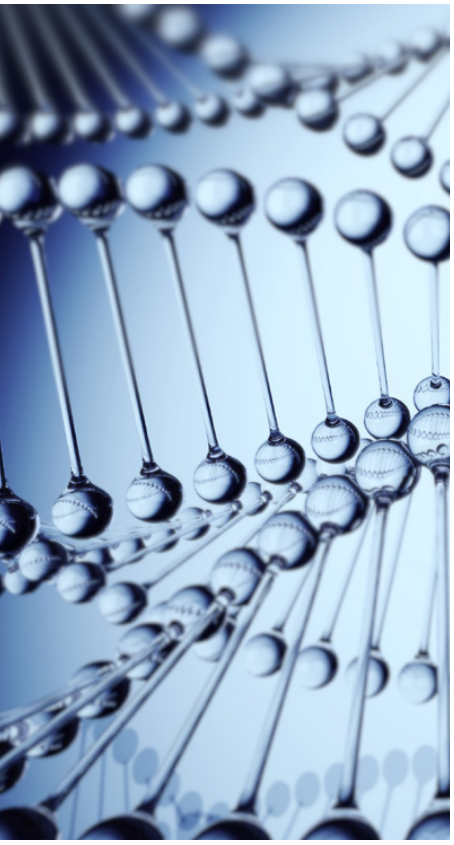
The court also rejected defendants' argument that Shionogi had acted with deceptive intent and in particular defendants' argument that deceptive intent in the reissue statute requires less rigorous proof than in connection with charges of inequitable conduct: "We discern no sound basis for this distinction, for the complexities of patent solicitation in all its stages have been shown susceptible to the 'plague' of opportunistic accusations." *Id*. at 525. Specifically the court found no deceptive intent in Shionogi's failure to file the IDS because it was found to have been an error rather than intentional and because Shionogi was diligent in filing the reissue once it discovered the error.

***Where the specification makes clear that a particular compound is the preferred compound, there was no deceptive intent in the patentee's failure to claim that preferred compound in the original application and patentee may claim such compound by reissue.***

The court also found no deceptive intent in its failure to claim the specific commercial compound, rejecting defendants' argument that Shionogi omitted a claim specific to rosuvastatin from its application in order to conceal the compound from competitors. The court found that "rosuvastatin was explicitly described in the Shionogi specification as the preferred compound. It was specifically identified, including its synthesis and test results. This is not compatible with concealment." *Id*. at 526. Thus, "[t]he patentee's decision to limit the reissue to the compound that was described in the specification as the most potent of the compounds specifically described is not evidence that the most potent compound was deceptively concealed." *Id*.


[46] 479 F.3d 1359, 1362, 81 U.S.P.Q.2d 2011, 2014 (Fed. Cir. 2007).

[47] 479 F.3d at 1365.



## Inventorship and Priority

***Where a method of making a novel compound requires more than routine skill, the person who developed such method is properly named as an inventor even for claims directed to the compound itself.***

In *Falana v. Kent State University*, 669 F.3d 1349, 101 U.S.P.Q.2d 1414 (Fed. Cir. 2012), the court reviewed the district court's holding that defendants Kent State improperly failed to include Falana as one of the inventors of a patent directed to an "optically active compound" employed as a chiral additive that can be used to improve the performance characteristics of LCDs.

The court noted that the burden of showing misjoinder or nonjoinder of inventors is a heavy one and must be proved by clear and convincing evidence. Citing *American BioScience,*[48] defendants contended that even if Falana contributed the method of synthesizing the compounds, such contribution was insufficient to make him a coinventor of the claims that are all directed to chemical compositions and not methods. The Federal Circuit disagreed, concluding that "*American BioScience* did not hold that a putative inventor's contribution of the method for making a novel genus of claimed compounds is irrelevant on the question of inventorship of the patent." 669 F.3d at 1358. To the contrary, "the conception of a chemical compound necessarily requires knowledge of a method for making that compound." *Id*.

The court distinguished between methods of making a compound requiring nothing more than the use of ordinary skill (which would not normally be sufficient to amount to joint inventorship) versus those requiring more than ordinary skill (where the discovery of the method is as much a contribution to the compound as the discovery of the compound itself). *Id*. Here, because Falana's contribution was greater than the exercise of ordinary skill, he was properly added as an inventor. The court also regarded as irrelevant defendants' argument that Falana did not contribute to the conception of one particular compound (Compound 9) because the claims of the patent are not limited to Compound 9 but instead claim an entire genus to which Falana contributed. *Id* at 1359.

[48] *Bd. of Educ. ex rel. Bd. of Trustees of Fla. State Univ. v. Am. BioScience, Inc.,* 333 F3d 1330, 67 USPQ2d 1252 (Fed. Cir. 2003).

***Multiple pre-critical date claims that are "sufficiently congruent" to post-critical date claims demonstrate an intent to claim the subject matter and compliance with the copying requirement of 35 U.S.C. §135(b).***

In *Pioneer Hi-Bred International, Inc. v. Monsanto Technology LLC*, 671 F.3d 1324, 101 U.S.P.Q.2d 1849 (Fed. Cir. 2012), the court reviewed whether the Board correctly found in Monsanto's favor that (1) Monsanto's claims were not time-barred under the one-year claim copying requirement of 35 U.S.C. §135(b); and (2) Pioneer was not entitled to the benefit of its parent application, resulting in an award of priority to Monsanto. Monsanto filed its patent application more than a year after the Pioneer patent issued but relied on multiple pre-critical date claims to provide a basis for showing that the later claim was actually made before the one-year bar in §135(b)(1). The Board concluded that the pre-critical date aggregated claims were "sufficiently congruent" with the later claims to demonstrate an intent by Monsanto to claim the subject matter in question before the critical date.

On appeal, Pioneer argued that the Board erred in relying on multiple pre-critical date claims to support Monsanto's later claim. Citing to decades-old precedent, *Thompson v. Hamilton*,[49] the Federal Circuit agreed with the Board and Monsanto that multiple pre-critical date claims, considered together, can provide the foundation necessary for post-critical date claims to be held timely. 671 F.3d at 1329-30. On the merits, the court agreed with the Board that the pre-critical date claims are directed to the same invention as the post-critical date claims concerning the beneficial traits coded for by the incorporated heterologous DNA and expression by the claimed plant of a selectable marker gene.

***Proper comparison for purposes of compliance with 35 U.S.C. §135(b) is whether there are material differences between pre-critical date claims and post-critical date claims, not between the post-critical date claims and the claims from the copied patent.***

In *Adair v. Carter*, 668 F.3d 1334, 101 U.S.P.Q.2d 1625 (Fed. Cir. 2012), the court reviewed the Board's finding that Adair's copied claims directed to antibodies failed to comply with the one-year copying requirement of 35 U.S.C. §135(b) because

[49] 152 F.2d 994 (C.C.P.A. 1946).

Adair had amended its pre-one-year claims after the one-year date in response to rejections made by the Patent Office, leading the Board to conclude that "material differences presumptively existed between the post- and pre-critical date claims that Adair failed to rebut." The Board stated that an applicant cannot expect to avoid the bar of §135(b) by timely copying a claim from an issued patent when that claim is not patentable to that applicant.

On appeal, Adair argued that the Board erred by failing to assess material differences in view of the patent claim being copied, i.e., that the proper comparison is not between Adair's pre- and post-one-year claims but rather between the post-critical date claim and Carter's claim that Adair copied. The court agreed with Carter, however, that the correct inquiry looks to whether there is a sufficient degree of identity between Adair's pre- and post-critical date claims for compliance with §135(b), an inquiry independent from any comparison with the patent claims copied, citing *Regents.*[50] 668 F.3d at 1337. The court also reaffirmed the principle that the question of material differences between post- and pre-critical date claims for purposes of overcoming a §135(b) bar is a distinctly different question from whether claims are directed to the same or substantially the same subject matter for purposes of provoking an interference. *Id*. at 1338.

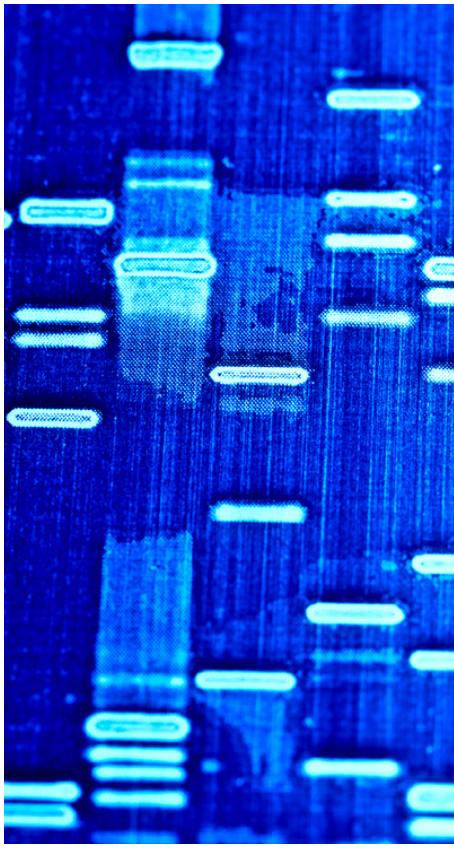
***Post-critical date amendments made to overcome a rejection are presumptively material and subject to the surrender presumption of* Festo*; however, there is no absolute requirement that pre-critical date claims be patentable.***

The court also agreed with Carter that "[w]hen an applicant adds limitations in response to an examiner's rejection, and those limitations result in allowance, there exists a well established presumption that those limitations are necessary to patentability and thus material," holding that the surrender presumption of *Festo*[51] "applies with equal force in the interference context." *Id*. at 1339. Finally, the court disagreed with Adair that the Board's decision established an "absolute requirement that the pre-critical date claims be patentable to the applicant for the applicant to rely on those claims to avoid the §135(b) bar" and noted that "[t]he court in *Regents* did not articulate a per se patentability requirement for an applicant to rely on pre-critical date claims, but rather observed that where material limitations are added to overcome an examiner's rejection after the critical date, there is 'no inequity' in finding the later-added claims barred under §135(b)(1)." *Id*. at 1339-40. Thus, canceled claims may be relied upon to avoid the §135(b) bar.

## Reexamination

**En banc *court holds that claims unamended during reexamination cannot be subject to intervening rights.***

In *Marine Polymer Technologies, Inc. v. HemCon, Inc.*, 672 F.3d 1350, 102 U.S.P.Q.2d (Fed. Cir. 2012) (*en banc*), the Federal Circuit decided *en banc* the important question of whether intervening rights can apply to claims that survive reexamination without amendment. As we reported last year,[52] the Federal Circuit panel in *Marine Polymer* found intervening rights based on a narrowing of the literal scope of the claimed preamble term "biocompatible" during reexamination. Although the district court's interpretation was the same before and after reexamination, the Federal Circuit panel found that the narrower interpretation was only appropriate after the patent owner had canceled dependent claims that were arguably inconsistent with the narrower construction. Essential to the panel's holding was that intervening rights could apply to a claim that survives reexamination without amendment.



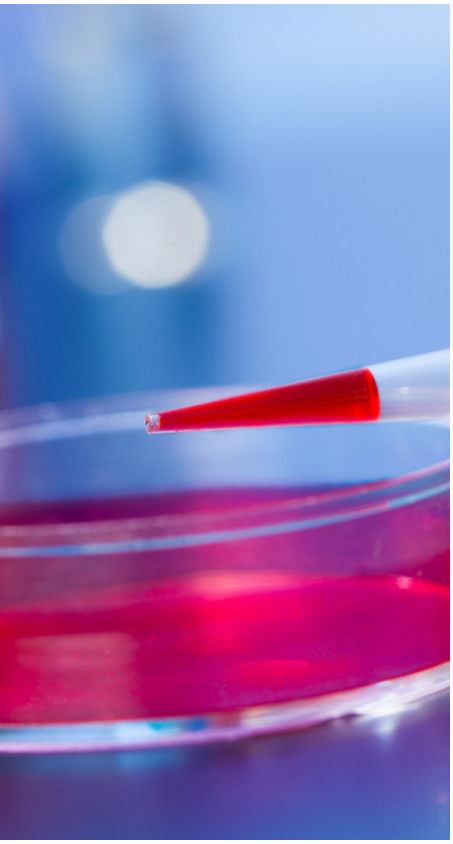
While everyone agrees that claims substantively amended during reexamination give rise to absolute intervening rights that completely absolve an infringer for liability due to actions predating the reexamination certificate, the panel decision sparked controversy when it found that arguments regarding the scope of an unamended claim could also give rise to intervening rights. To the relief of patent owners everywhere, the Federal Circuit's *en banc* ruling restored the status quo and held that if a claim is not amended, intervening rights do not apply to that claim.

The *en banc* court framed the intervening rights issue by acknowledging that the panel's decision was premised upon its finding that the original district court construction prior to reexamination was unduly narrow and should have been broader, but that events during reexamination affected the claim

[50] *Regents of the Univ. of Cal. v. Univ. of Iowa Research Found.*, 455 F.3d 1371, 1374, 79 U.S.P.Q.2d 1687, 1689 (Fed. Cir. 2006).

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

[52] Robert M. Schulman, Jeff B. Vockrodt & David A. Kelly, "Pharmaceutical, Chemical & Biotech Year in Review 2011" 31-32 (2012).



construction analysis such that the narrow construction was proper after reexamination. 672 F.3d at 1362. The *en banc* court, however, rejected the panel's premise, noting that HemCon's arguments "essentially amount to a conflict between teachings in the specification and the doctrine of claim differentiation" but that "claim differentiation is 'not a hard and fast rule and will be overcome by a contrary construction dictated by the written description or prosecution history.'" *Id*. at 1359 (citation omitted). Because the court found that the district court's initial construction for "biocompatible" was correct, the claim scope was unaffected by reexamination and therefore intervening rights did not apply.

As an alternative basis, the *en banc* court found even if the district court's initial construction was incorrect, intervening rights could not apply to claims that were not amended during reexamination. The court cited §307(b), which is the part of the reexamination statutory framework that incorporates and applies the intervening rights provisions §252 for reissue to "amended or new" claims in reexamination. *Id*. at 1362-63. The *en banc* court noted that "HemCon ignores this threshold statutory requirement and asks that we proceed directly to the subsidiary 'substantive change' analysis, which derives from §252." *Id*. at 1363. The court made clear that "patent applicants' actions and arguments during prosecution, including prosecution in a reexamination proceeding, can affect the proper interpretation and effective scope of their claims." *Id*. at 1365. However, with respect to intervening rights, "we are not here interpreting claims[;] [r]ather, we are interpreting a statute that provides for intervening rights following reexamination only as to 'amended or new' claims." *Id*.

The *en banc* court's ruling that intervening rights only apply to amended or new claims establishes a safe harbor for patents subject to reexamination where significant past damage claims are at issue. Coupled with the Federal Circuit's trend of reining in the Patent Office's broadest reasonable interpretation standard, patent owners may be emboldened to resist claim amendments during post-grant Patent Office proceedings in the hope that their claims for past damages will survive unscathed.

***Giving claims their "broadest reasonable interpretation" does not require that the specification expressly disavow coverage of a particular embodiment to exclude an embodiment.***

In *In re Abbott Diabetes Care Inc.*, 696 F.3d 1142, 104 U.S.P.Q.2d (Fed. Cir. 2012), the Federal Circuit once again weighed in on how the Patent Office should apply its "broadest reasonable construction" standard in an appeal by the patent owner of rejections made in an *ex parte* reexamination. In recent years, the trend has been to rein in Patent Office claim constructions that were not reasonable in light of the specification.[53] The Federal Circuit continued that trend by reversing the Board's construction of the terms "electrochemical sensor" and "substantially fixed" in Abbott's claims to a sensor useful in monitoring glucose in diabetic patients.

Abbott's patent described electrochemical sensors that avoided the need for external cables and wires used in the prior art by combining the sensor elements with a sensor control unit including radio frequency transmitter. The Board framed the issue on appeal as whether the correct construction of "electrochemical sensor," includes "wires and cables." The Board recognized that Abbott's specification criticized the cables and wires of the prior art sensors, but found that the specification lacked any disclaimer of such subject matter and that "when giving the term 'electrochemical sensor' the broadest reasonable interpretation in light of the [s]pecification, the electrochemical sensor includes wires and cables." 696 F.3d at 1146 (alteration in original) (internal quotation marks omitted). The Board also held that connecting the transcutaneous sensor to the control on a wristwatch-type device in the prior art met the limitation that the control and sensor be "substantially fixed" because that term would "be understood by the skilled worker to allow some movement of the sensor relative to the position of the sensor control unit." *Id*. (internal quotation marks omitted).

The Federal Circuit, in reversing, addressed the Patent Office's argument that the specification did not disclaim or disavow a device including wires and/or cables. Initially, the Federal Circuit pointed to "claim terms like 'coupl[ed]' and 'receiv[ed]' [that] are entirely consistent with and even support the specification's exclusive depiction of an electrochemical sensor without external cables or wires." *Id*. at 1149-50. The court distinguished cases where statements

[53] *See, e.g., In re Suitco Surface Inc.,* 603 F.3d, 94 U.S.P.Q.2d1644 (Fed. Cir. 2011) ("[T]his court has instructed that [the broadest reasonable] construction be 'consistent with the specification, … and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.' ") (alteration in original) (citation omitted).

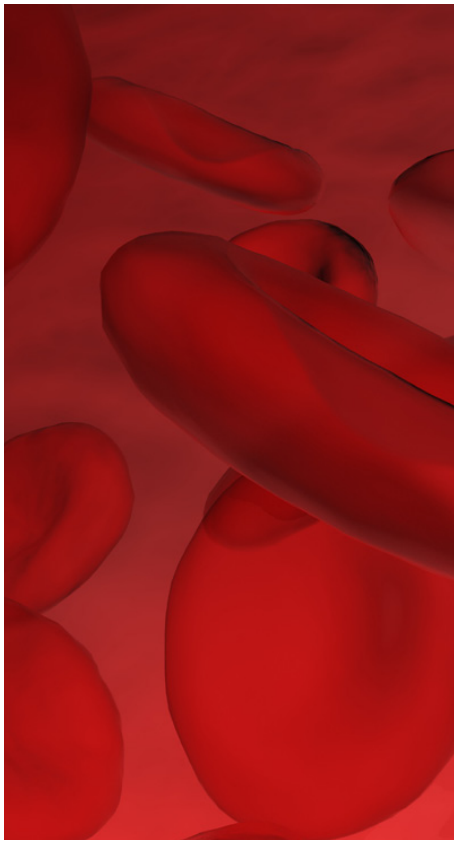
allegedly disparaging the prior art in the background were insufficient to disclaim or limit the invention. *Id*. at 1150. In *American Academy of Science*,[54] the patentee argued that it disparaged and therefore disclaimed multiuse computers such as mainframes but the Federal Circuit found that the same background and specification as a whole actually supported a construction including multiuser computers. In *Retractable Technologies*,[55] the Federal Circuit noted that the background's supposed disclaimer of "cutting" was undermined by an embodiment in the specification that indicated that some forms of cutting fell within the specification. In contrast, the court in *Abbott* found that where the background disclosed devices having wires or cables, and nothing else suggested that wires or cables could be used, the broadest reasonable interpretation did not encompass devices with wires or cables. *Id*.

Regarding the limitation that the control and sensor be "substantially fixed," the court noted that no dispute exists that the patent under review allows for "some movement of the sensor relative to the position of the sensor control unit." *Id*. at 1150-51 (internal quotation marks omitted). However, the prior art sensor was only "somewhat restrained" because it was tethered to a watch-shaped assembly and therefore only restrained by human arm or wrist movement. The Board found that the prior art's teaching of wires that are flexible "are still somewhat restrained in movement, and are therefore 'substantially fixed,' by virtue of being tethered to the watch assembly unit." *Id*. at 1147 (internal quotation marks omitted). The Federal Circuit found that this degree of restraint was much less than that described in the specification, which taught a support structure that holds and guides the sensor into the correct position. The court found the Board's construction was not reasonable in light of these teachings of the specification. *Id*. at 1151.

The Abbott decision clarifies that the "broadest reasonable interpretation" cannot be taken to the extreme just because the specification does not expressly disavow coverage. The claims must be construed in light of the specification in the first instance. Moreover, where terms of degree such as "substantially fixed" are under consideration, the specification's teachings are highly instructive as to the correct construction.

## Conclusion

As of this writing, we are still awaiting the Supreme Court's decision in *Myriad*. The consensus in the bar seems to be that the Court will hold that isolated DNA is not statutory, effectively wiping out 30 years of judicial precedent and invalidating whole patent estates. The bar's consensus seems reasonable in light of the statements made during oral argument and the Supreme Court's recent *Prometheus* decision. One justice queried how isolating the DNA encoding a single gene from the genome is any different from removing sap from a tree. While the metaphor may have superficial appeal, it suggests a willingness to oversimplify in a way that does not bode well for isolated DNA claims. Indeed, both aspirin and taxane, like sap, are materials which are derived from trees and inarguably benefitted the public greatly.



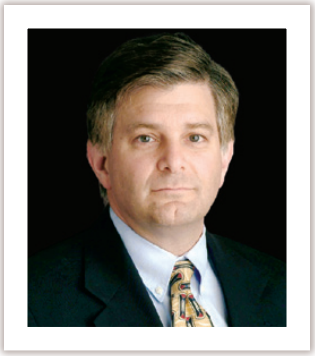
Further, if something is truly a "product of nature," then it is unpatentable as anticipated. After all, if one claimed "a tree," then it would be anticipated by…trees. However, the Supreme Court in *Prometheus* demonstrated its unwillingness to consider whether a product of nature is anticipated or obvious before moving on to the thornier question of statutory subject matter. Against this backdrop, it seems likely that the Supreme Court will hold isolated DNA to be non-statutory subject matter, making it per se ineligible for patenting.

On the anticipation and obviousness front, we can only wonder whether the Federal Circuit will regain its bearings. In a year punctuated by so many cases involving anticipation and obviousness questions for chemical and biological patents, it seems possible that some of these cases will be viewed as aberrations.

We expect that next year we will see an increase in Federal Circuit appeals from Patent Office proceedings including *inter partes* reexaminations which have been increasingly working their way toward the Federal Circuit over the years. The first wave of appeals from the new *inter partes* review proceedings will also begin to impact the Court's docket late next year, although decisions will not likely come in earnest until the following year. It will be interesting to see how the Federal Circuit deals with its increasing caseload over the next two years.

[54] *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d, 70 U.S.P.Q.2d, 1833 (Fed. Cir. 2004).

[55] *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d99 U.S.P.Q.2d1241 (Fed. Cir. 2011).



## Practices

Intellectual Property

Intellectual Property and Life Sciences

Patent Litigation

Patent Prosecution and Litigation

## Contact

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## Education

JD, American University, Washington College of Law, 1983

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

## Bar Admissions

District of Columbia

US Patent and Trademark Office

# Robert M. Schulman

Rob's practice focuses on all phases of patent law in the areas of biotechnology, pharmaceuticals and chemical inventions.

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 contested cases at the Patent Office, including interferences, reexaminations (both *ex parte* and *inter partes*), as well as *inter partes* reviews for all types of inventions. Rob also frequently provides advice on validity, non-infringement and claim construction issues in litigation. He has extensive experience in the area of clearance studies for both established and start-up companies.

Rob's practice includes development of patent portfolios, patent prosecution including application drafting, prosecution of applications and appellate review. Rob has also helped companies establish best practices for patent application writing and claim drafting. Rob has had a special focus in recombinant plant technology, general agricultural technology, vaccines, drug delivery technology, medical devices and polymers.

He regularly speaks at bar association meetings and in front of clients on case law developments in the biotech, chemical and pharmaceutical areas and has been publishing an annual Year in Review relating to such case developments since 2003.

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 database 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, 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

- Author, "Is Obviousness The New Anticipation?," *Law360*, October 2, 2012
- Co-author, Pharmaceutical, Chemical and Biotech Year in Review, 2007-2012
- Author, Pharmaceutical, Chemical and Biotech Year in Review, 2003-2006
- 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

- Speaker, "Is Obviousness Becoming the New Anticipation?" The Federal Circuit's New Paradigm in Reviewing Prior Art, New Jersey Intellectual Property Law Association, December 5, 2012
- Speaker, "Subject-Matter Eligibility In The Wake of *Mayo v. Prometheus*," April 2012
- Speaker, "Highlights of the America Invents Act," Conference in Montpellier, France, October 2012
- Presenter, "Developments in Biotechnology, Chemical and Pharmaceutical IP Law," March 8, 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, November 1, 2010
- Speaker, "Federal Circuit Cases Relating to Patent Interferences," Intellectual Property Owners Meeting, Washington, DC, November 1, 2008

### Awards & Recognition

- *Washington DC Super Lawyers* (Intellectual Property), 2013
- Selected for inclusion as a "Best Lawyer," Intellectual Property, *The Best Lawyers in America*, 2010-2013
- Listed as one of top intellectual property attorneys in 2010 in *Virginia Business* magazine
- Listed as one of 20 top intellectual property attorneys in *Washington Post* survey, 2010 and 2011
- Listed as one of 25 top intellectual property and technology attorneys in the December 2000 issue of *Virginia Business* magazine

## Practices

Intellectual Property

Patent Prosecution and Litigation

Patent Litigation

Intellectual Property and Life Sciences

Post-Grant Patent and Administrative Trials Practice

## Contact

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## 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's practice focuses on intellectual property law, with an emphasis on chemical and pharmaceutical industries.

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 represented both patent owners and challengers in disputes involving a diverse range of technologies, including semiconductors, medical devices, pharmaceuticals, biotechnology and chemical processing. Jeff serves as lead counsel in *inter partes* review proceedings before the newly created Patent Trial and Appeal Board, and has significant prior experience throughout all stages of *ex parte* and *inter partes* reexaminations as well as interference proceedings before that tribunal.

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, pretrial and trial stages of ITC litigation.

### Relevant Experience

- Serves as lead and backup counsel in *inter partes* review proceedings before the newly created Patent Trial and Appeal Board.
- Represents multinational companies in the consumer products and medical device sectors, filed requests for *ex parte* and *inter partes* reexamination, obtained decisions staying district court litigation pending the outcome of reexamination and represented those clients throughout all stages of the reexamination proceedings.
- Represented multinational companies and startups in the chemical, semiconductor, biotechnology and medical device industries in interference proceedings before the Interference Trial Section of the Board of Patent Appeals and Interferences.
- Represents a patent owner in the field of wireless networking, secured confirmation of all original and several newly added claims in two *inter partes* reexaminations of a patent involved in litigation in the Eastern District of Texas.
- Represented multinational companies in complex district court litigation involving multiple patent claims and state law causes of action.
- Prepared and prosecuted numerous patent applications in the United States Patent & Trademark Office and directed patent strategy and procurement for several patent portfolios, each including hundreds of patent applications worldwide in the fields of chemical processing and pharmaceuticals.
- 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, "Don't Let Your Right To Inter Partes Review Slip Away," *Law360*, August 29, 2012
- Co-author, Pharmaceutical, Chemical and Biotech Year in Review, 2009-2012
- Author, Hunton & Williams Reexamination Essentials, 2010

### Awards & Recognition

- Selected as a "Rising Star" (Intellectual Property), *Washington DC Super Lawyers*, 2013

## David A. Kelly

David is co-chair of the life sciences practice. His practice covers all aspects of intellectual property with an emphasis on patent litigation and client counseling.

David Kelly is a registered patent attorney whose practice focuses on protecting the intellectual property rights of his clients. In addition to counseling his clients on a diversity of intellectual property issues, David has extensive patent litigation experience, representing both patent owners and accused infringers, in a wide variety of technologies, including life sciences, 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. After a four-week bench trial, obtained a verdict of infringement against both defendants on all asserted patent claims, as well as a permanent injunction. Prior to trial, successfully briefed and argued *Markman* issues, obtaining favorable claim construction for all seven disputed claim terms. Also successfully briefed and argued summary judgment motions, including: (1) obtaining summary judgment of novelty and non-obviousness; (2) obtaining summary judgment of enforceability; and (3) successfully defeating all of defendants' motions for summary judgment of non-infringement and invalidity.
- Trial counsel for Fortune 1000 lawn care company accused of false advertising and unfair competition. Successfully moved to transfer competitor's complaint filed in the United States District Court for the Northern District of Georgia to the United States District Court for the Eastern District of Virginia, where a similar case brought by client against its competitor is currently pending.
- Trial counsel for plant lawn science company accused of infringing three of its competitors' patents. Successfully moved to stay the entire case after provoking reexamination of two of the patents at issue.
- Trial counsel for pharmaceutical company accused of infringing patents to abuse-resistant opioid products. After successfully defending against the patent owner's attempt to transfer and/or dismiss the case to an alternative forum, the case was settled on confidential terms favorable to the client.
- Trial counsel for life sciences company that owns patents involving DNA sequencing technology. Obtained favorable *Markman* ruling, which was affirmed on appeal. Case is currently 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 reexamination 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.
- Counsels clients on a wide range of intellectual property issues.
- Conducts due diligence, freedom-to-operate, validity and patentability analyses, and prepares formal legal opinions reflecting conclusions of such analyses.
- Prepares and prosecutes patent applications for biotechnology-, chemical-, and pharmaceutical-related inventions.

### Practices

Intellectual Property

Intellectual Property and Life Sciences

Patent Litigation

Patent Prosecution and Litigation

### Contact

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### 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

US Patent and Trademark Office

### Memberships

- Member, Atlanta Bar Association, 2005
- Atlanta IP Inn of Court, Barrister

### Publications

- Author, "*The Impact of the America Invents Acts And Recent Court Decisions on Patent Law Practitioners And Their Clients, Inside The Minds: The Impact of Recent Patent Law Cases and Developments*," Thompson Reuters (in press), 2012
- Co-author, Pharmaceutical, Chemical and Biotech Year in Review, 2007-2008, 2010-2012
- 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 in 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, "Claim Drafting and General Prosecution Tips For Pharma/Biotech Inventions," April 2012
- Presenter, "Subject Matter Eligibility In The Wake of *Mayo v. Prometheus*," April 2012
- Presenter, "Developments in Biotechnology, Chemical and Pharmaceutical IP Law," March 8, 2012
- Presenter, "To Sue or Not to Sue: Evaluating a Patent Suit," CLE-approved webinar, December 2011
- Presenter, "U.S. Patent Litigation Basics," November 2011
- Presenter, "Legislative and Judicial Developments Affecting Patenting of Biotech Inventions in the US," November 2011
- Presenter, "Effective Brief Writing," CLE-approved seminar sponsored by the Atlanta Bar Association, December 2010
- 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, March 2009
- Author and presenter, "A Crash Course in Better Legal Writing," CLE-approved seminar, 2008
- Co-author and presenter, "Indefiniteness: The Rise of Another Solid Tool to Defend Against Patent Infringement," CLE-approved seminar, September 2008

### Awards & Recognition

- "Rising Star" in Intellectual Property, *Georgia Super Lawyers*® magazine, 2013

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