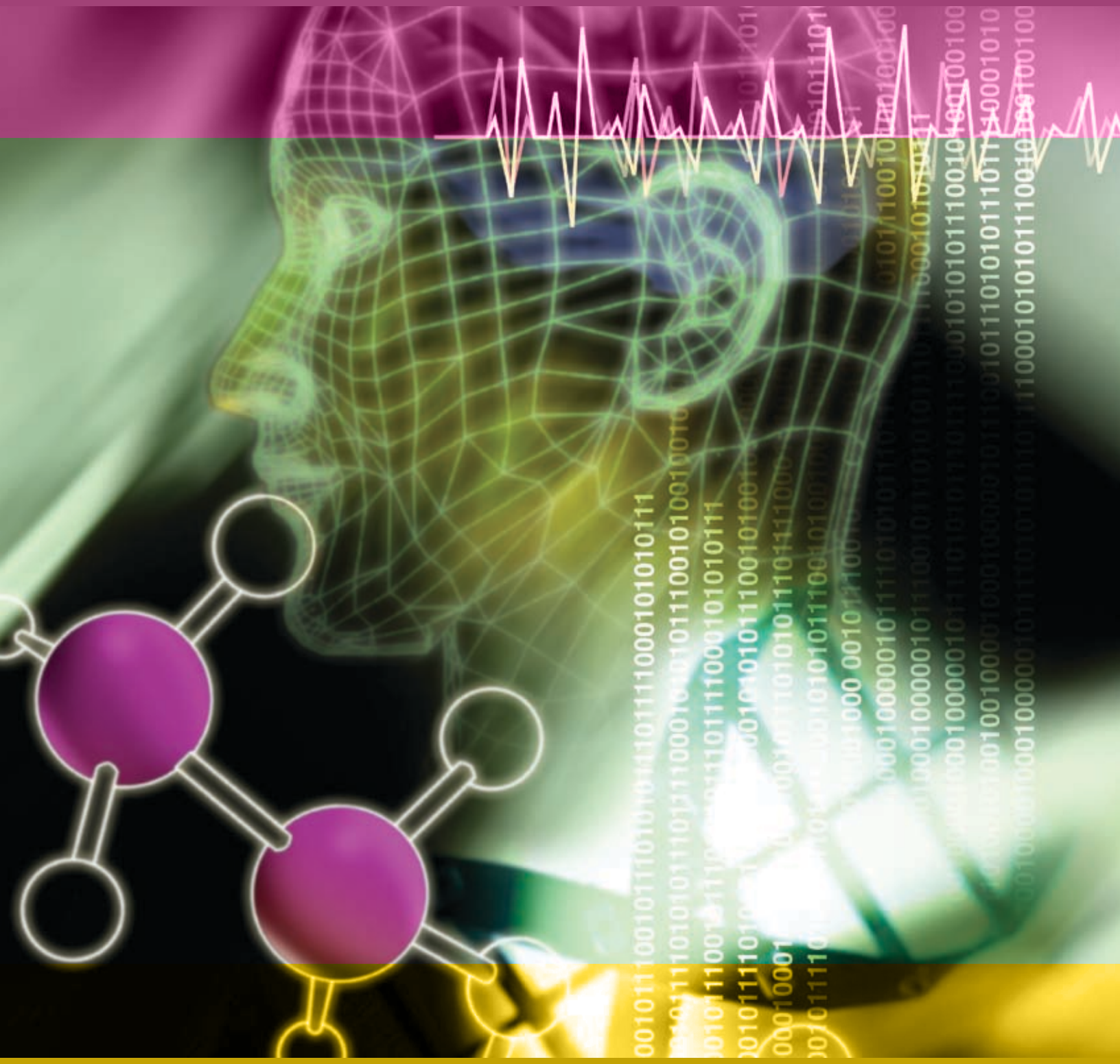
Pharmaceutical, Chemical and Biotech Year in Review 2008



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Introduction

While 2007 was a year of blockbuster decisions, 2008, in contrast, will not be known for any landmark decision, by either the U.S. Supreme Court or by the Federal Circuit. In 2007, cases such as *KSR*[1] and *MedImmune*[2] fundamentally changed the legal landscape in the areas of obviousness and declaratory judgment jurisdiction, respectively. For 2008, however, one would find it difficult to name a single Supreme Court or Federal Circuit decision of sweeping impact, at least in the areas affecting biotechnology, pharmaceuticals, or chemistry. The importance of 2008, rather, lies in its being the first full year in which the Federal Circuit could explore the ramifications of *KSR* and *MedImmune*, and the court did not disappoint. As a result, we now have a much better idea how courts will apply the doctrines enunciated in those two cases.

Ironically, three of the most significant decisions were neither Supreme Court nor Federal Circuit decisions. In *Tafas v. Dudas*,[3] the district court for the Eastern District of Virginia overturned the PTO's new continuation rules; in *Wyeth v. Dudas*,[4] the district court for the District of Columbia overturned the PTO's

[1] *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385 (2007).
[2] *MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764, 81 U.S.P.Q.2d 1225 (2007).
[3] 541 F. Supp. 2d 805, 86 U.S.P.Q.2d 1623 (E.D. Va. 2008).
[4] 580 F. Supp. 2d 138, 88 U.S.P.Q.2d 1538 (D.D.C. 2008).

interpretation of the patent term adjustment provisions of the American Inventors Protection Act; and in *Ex parte Kubin*,[5] the Board of Patent Appeals and Interferences enunciated a new "post-*KSR*" standard for the obviousness of polynucleotides and further held that it was not bound by the PTO's Written Description Guidelines. All three of these cases have been appealed to the Federal Circuit.

In its evaluation of obviousness post-*KSR*, the Federal Circuit has made clear that while it no longer applies its "teaching-suggestion-motivation" test ("TSM") as a rigid test, TSM more flexibly applied still remains relevant. Many had feared after *Pfizer*[6] and *KSR* that an invention would be considered obvious if it were merely "obvious to try," such as where the prior art sets forth a finite number of alternatives and the inventor finds the alternative that works. Indeed, every putative infringer now cites the quote from *KSR* that "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp."[7] By contrast, every patent holder points out that the Supreme Court qualified its discussion in *KSR* by explaining that the "problem" should have "a finite number of identified, predictable solutions," to render an invention unpatentable as "obvious to try."[8] While we were harshly critical of the Federal Circuit in 2007, the court in 2008 seems to have taken a much more balanced approach in evaluating these competing considerations.

In the area of anticipation, the court likewise has taken a more reasoned approach. In previous reviews, we bemoaned the court's adoption of "obviousness" inherency whereby the court would find anticipation in situations where the prior art required one of ordinary skill in the art to make selections (e.g., *Perricone*[9]). The court in 2008, however, seems to have returned to its more traditional viewpoint of anticipation as requiring all the elements arranged as in the claim.

Not all of the news in 2008, however, was good. After a nearly five-year respite, the court has again begun invalidating molecular biology patents for lack of written description. As discussed in greater detail below, we believe that the court's continued insistence on seeing "pictures" of things is a throwback to the small molecule inventions of the last century and represents an instance in which the law simply is not adapting to new technology.

Finally, the court issued several decisions in the area of declaratory judgment jurisdiction and has begun to define the upper and lower bounds thereof post-*MedImmune*.

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[5] 83 U.S.P.Q.2d 1410 (Bd. Pat. App. & Int. 2007).

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

[7] *KSR*, 127 S.Ct. at 1742.

[8] *Id*.

[9] *Perricone v. Medicis Pharm. Corp*., 432 F.3d 1368, 77 U.S.P.Q.2d 1321 (Fed. Cir. 2005).

Anticipation/Obviousness

Citing KSR, the Board of Patent Appeals and Interferences concludes that cDNA is obvious in view of the protein sequence the cDNA encodes combined with ordinary skill in the art.

In *Ex parte Kubin*, 83 U.S.P.Q.2d 1410 (Bd. Pat. App. & Int. 2007), the Board of Patent Appeals and Interferences, in a rare "precedential" opinion, set forth its "post-*KSR*" approach. Kubin's patent claims relate to polynucleotides encoding NK (natural killer) Cell Activation Inducing Ligand ("NAIL") polypeptides. NAIL is a cell surface marker, or receptor, on the surface of NK cells that modulates the activity of NK cells, thereby stimulating or inhibiting the immune response. The claim was directed to:

> An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO: 2, wherein the polypeptide binds CD48. *Id*. at 1412.

The examiner rejected Kubin's claims as obvious, contending that a skilled artisan would have been motivated to isolate the nucleic acid sequence corresponding to NAIL based on the prior art disclosure of the NAIL protein (called p38) combined with conventional techniques for isolating a cDNA encoding a protein. Citing *In re Deuel,*[10] Kubin argued that it was improper "for the Office to use the p38 protein identified in the [prior art] together with the [prior art isolating methods] to reject claims drawn to specific sequences." *Id*.

The Board framed the issue this way:

> Would Appellants' claimed nucleotide sequence have been obvious to one of ordinary skill in the art, based on [the prior art's] disclosure of p38 and his express teachings how to isolate its cDNA by conventional techniques? *Id*.

[10] 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995).

Despite factual similarities to *In re Deuel*, the Board distinguished that case and upheld the examiner's rejection of the invention as obvious. The Board noted that the Supreme Court in *KSR* cast doubt on the continued viability of *Deuel* to the extent that case rejected an "obvious to try" test. It explained that, under *KSR*, it is now apparent that an "obvious to try" rationale may be appropriate in more situations than previously contemplated. In the case before it, the "problem" facing those in the art was to isolate NAIL cDNA, and there were a limited number of methodologies available to do so. Thus, according to the Board, a skilled artisan would have had a reason to try these methodologies with the reasonable expectation that at least one would succeed. As such, isolating NAIL cDNA was "the product not of innovation but of ordinary skill and common sense." *Id*. at 1415 (citing *KSR Int'l Co. v. Teleflex, Inc*., 127 S.Ct. 1727, 1742 (2007)). This case, now pending before the Federal Circuit, has drawn a lot of attention.

One point that might have been lost on the Board is that even if the so-called "limited number of methodologies" would have made it obvious to try one of the methodologies with an expectation that one or more of them would work, the fact remains that the predictability of the methodology does not predict, or render obvious, the structure of cDNA. By contrast, when one selected among the limited number of salts in the *Pfizer* case, one obtained the claimed salt itself, not the method for obtaining an unpredictable structure. For this reason, among others, the PTO may be getting somewhat ahead of the Federal Circuit in terms of relaxing the standard for obviousness. Furthermore, before *Kubin* and *KSR* there seemed to have been an unofficial *quid pro quo* in patent prosecution for more than ten years, whereby the PTO found novel cDNA sequences nonobvious even if the protein and methodology employed to obtain the cDNA was known. In exchange, the PTO limited the applicant to the specific sequence(s) obtained, typically through strict application of the written description requirement. If the Federal Circuit affirms *Kubin*, we may have the worst of both worlds. On the one hand, an applicant will still be constrained by the written description requirement such that a description of the protein will not describe the DNA encoding it; on the other hand, the same disclosure in the prior art will render all obvious, even the specific cDNA encoding the protein.[11]

Even though there is no longer a rigid rule requiring a "teaching, suggestion or motivation" post-KSR, prior art knowledge of a problem and motivation to solve it are not sufficient by themselves to combine references; a reason or explanation is still necessary to prevent hindsight reconstruction.

In *Innogenetics N.V. v. Abbott Labs*., 512 F.3d 1363, 85 U.S.P.Q 1641 (Fed. Cir. 2008), Abbott alleged that Innogenetics' claims directed to diagnostic tools for detecting and classifying hepatitis C virus (HCV) genotypes in a biological sample were obvious. Although Abbott's expert suggested that one with skill in the art would be motivated to find such method because the prior art disclosed that different genotypes of HCV respond differently to interferon therapy, the district court found that knowledge of a problem and motivation to solve it are entirely different from motivation to combine particular references to reach the particular claimed method. On appeal, the Federal Circuit agreed. The court acknowledged that it was "mindful that in *KSR*, the Supreme Court made clear that a finding of teaching, suggestion, or motivation to combine is not a 'rigid rule that limits the obviousness inquiry.' " *Id*. at 1374 n.3 (citing *KSR* at 1741). Here, however, "[t]here was a complete absence of any proof that one skilled in the art would find the particular claimed method obvious based upon [the expert's] list of prior art references or the knowledge generally available to those of ordinary skill in the art for any reason." *Id*. (emphasis in original). The court noted that "[w]e must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention." *Id*.

Weighing the* Wands *factors, the court concluded that prior art is nonenabling and therefore not anticipatory because one of skill in the art could not have identified riluzole as a treatment for ALS in view of the large number of compounds and speculative linkage between the compounds and ALS treatment.

In *Impax v. Aventis*, 545 F.3d 1312, 88 U.S.P.Q. 1381 (Fed. Cir. 2008), the court for the second time addressed whether Aventis' patent directed to the use of riluzole to treat amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease) was invalid in view of Aventis' own earlier patent. In its initial decision, the Federal Circuit held that "[t]he enablement requirement for prior art to anticipate under section 102 does not require utility, unlike the enablement requirement for patents under section 112." 468 F.3d 1366, 1381, (Fed. Cir. 2006). The court also held that "anticipation does not require actual performance of suggestions in a disclosure," but rather "that those suggestions be enabled to one of skill in the art."

[11] As discussed in the written description section, *infra*, this is exactly what the Board did in *Kubin*, thereby establishing a harsh paradigm for applicants.

Id. at 1382 (citations omitted in original). Because the district court had failed to make the proper factual determinations of whether Aventis' earlier patent was enabled, the Federal Circuit remanded the case back to the district court. On remand, the district court, weighing the "*Wands* factors,"[12] concluded that the earlier patent did not enable one of skill in the art to identify riluzole as a treatment for ALS. On appeal again, the Federal Circuit found no "error, let alone clear error, in the district court's factual findings." 545 F.3d at 1315. The court therefore held there was no anticipation.

The court's reliance on the *Wands* factors in assessing prior art enablement seemed to be a departure from the court's post-*Rasmusson* case law. In *Rasmusson*,[13] the court enunciated a reduced standard of enablement for prior art, as opposed to the higher standard of enablement applied to patent applications. As we commented in the 2005 Year in Review, we thought *Rasmusson* wrongly expanded the application of nonenabled prior art beyond the very limited situation in which a prior art teaching of a compound without a utility anticipates a later claim to that compound even though the prior art is arguably nonenabled. Does this case signal a return to the higher, pre-*Rasmusson* standard of enablement for prior art? It's hard to say. In this case, the prior art clearly failed to meet the higher enablement standard of *Wands*, but it likely also failed to meet even under the reduced enablement standard of *Rasmusson*. Further clarification from the court is clearly needed.

Claimed compound found unobvious where the prior art intermediate had no utility in its own right and there was no reason to select from among other compounds and no reason to assess its properties.

In *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 86 U.S.P.Q.2d 1196 (Fed. Cir. 2008), the court addressed whether Ortho's claimed topiramate was obvious in view of the prior art showing a structurally related compound (the only difference being that in the prior art the sulfamate is connected in every instance to the single carbon of the pyranose ring, which is not itself attached to the methylenedioxy moieties, whereas in Ortho's invention, the sulfamate moiety is attached to the carbon of the pyranose ring, which also has attached to it the R2 moiety).

Citing *KSR* for the proposition that "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options," Mylan argued that a skilled artisan seeking an FBPase inhibitor would have had good reason to choose topiramate. *Id*. at 1364. The court rejected this argument, distinguishing *KSR* as limited to situations "with a finite … small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness." *Id*. According to the court, in this case, a person of ordinary skill: (1) "would not even be likely to start with [the claimed compound];" (2) "would have to have some reason to select (among several unpredictable alternatives) the exact route that produced topiramate as an intermediate;" and (3) "would have had to (at the time of invention without any clue of potential utility of topiramate) stop at that intermediate and test it for properties far afield from the purpose for the development in the first place (epilepsy rather than diabetes)." *Id*.

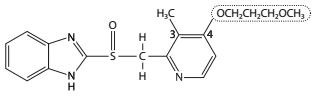
Normally, a claimed compound that is merely an isomer of a prior art compound would be considered *prima facie* obvious. Here, however, the prior art compound had no utility in its own right but was merely an intermediate. This probably carried the day for Ortho. As such, this case can be distinguished from previous cases in which the prior art compound had a utility in its own right and there was some reason to make that compound.

[12] (1) The quantity of experimentation; (2) the amount of direction or guidance present; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988).

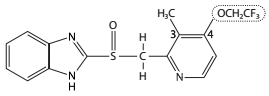
[13] *Rasmusson v. SmithKline Beecham Corp*., 413 F.3d 1318, 75 U.S.P.Q.2d 1297 (Fed. Cir. 2005).

A prior art compound with a different utility than the claimed compound can still be selected as a "lead compound" and render the invention obvious if there exists a reason to modify the prior art compound so as to arrive at the claimed compound.

In *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd*., 533 F.3d 1353, 87 U.S.P.Q.2d 1452 (Fed. Cir. 2008), the court addressed the alleged obviousness of a claim directed to the gastric acid inhibitor rabeprazole over the prior art anti-ulcer compound lansoprazole. The two compounds differ in that rabeprazole has a methoxypropoxy group whereas lansoprazole has a trifluoroethoxy group:



Rabeprazole



Lansoprazole

The court assessed whether it would have been obvious to modify lansoprazole to obtain rabeprazole. Although the two compounds have two different utilities, the court pointed out that, under *KSR*, any need or problem known in the art can provide a reason for combining the elements in the manner claimed. *Id*. at 1358. "Thus lansoprazole's candidacy as a starting point to develop new anti-ulcer compounds versus new gastric acid inhibitors does not resolve the lead compound analysis, at least not in the absence of any contrary indications." *Id*. However, while the court accepted that the fluorinated substituent of lansoprazole provides "a *special path* to achieving lipophilicity, it found "no discernible reason for a skilled artisan to begin with lansoprazole only to drop the very feature, the fluorinated substituent, that gave this advantageous property." *Id*. (emphasis in original) (citation omitted).

In assessing the obviousness of a chemical compound,* KSR *assumes selection of a "lead compound" as the starting point in the analysis as well as "reasons" to make the particular selections required to arrive at the claimed compound.

The court next addressed the role of choosing a "lead compound" in conducting an obviousness analysis, finding that: (1) "*KSR* assumes a starting reference point or points in the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions;" (2) "*KSR* presupposes that the record … would give some reasons … to make particular modifications to achieve the claimed compound;" and (3) "*KSR* presumes that the record … would supply some reasons for narrowing the prior art universe to a 'finite number of identified, predictable solutions.' " *Id*. at 1359. Accordingly, "post-*KSR*, a *prima facie* case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound." *Id*. In this case, the court found that Teva had failed to create "a genuine issue of material fact on obviousness through the unsupported assertion that compounds other than lansoprazole might have served as lead compounds." *Id*. The court concluded that "the record contains no reasons a skilled artisan would have considered modification of lansoprazole by removing the lipophilicity-conferring fluorinated substituent as an identifiable, predictable solution." *Id*.

It is hard to argue with the court's rationale or the conclusions it reached in this case. It may also signal that some of the more troubling decisions of 2007, such as *Pfizer*,[14] *PharmaStem*,[15] and *In re Omeprazole*,[16] are being reassessed. At the very least, the court has, thankfully, refused to extend *Pfizer* to every instance in which one could make a finite number of selections and assess their efficacy. The question left open after *Eisai* was whether the court would extend the rationale in that case to an invention that is not a novel active, but rather a novel formulation of an old active. As discussed below, the court in *Sandoz*[17] answered this question.

Claimed enantiomer salt not anticipated by prior art racemic mixture containing that enantiomer where prior art disclosed many other racemates and salts and where prior art did not actually carry out separation.

In *Sanofi-Synthelabo v. Apotex, Inc*., 550 F.3d 1075, 89 U.S.P.Q.2d 1370 (Fed. Cir. 2008), the court addressed the validity of claims directed to clopidogrel bisulfate, known commercially as Plavix®, for inhibiting the aggregation of blood platelets to treat or prevent blood-thrombotic events. The claim read as follows:

> 3. Hydrogen sulfate of the dextro-rotatory isomer of methyl alpha-5(4,5,6,7-tetrahydro(3,2-c)thienopyridyl) (2-chlorophenyl)-acetate ["(MATTPCA)"] substantially separated from the levo-rotatory isomer. *Id*. at 1077.

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

[15] *PharmaStem Therapeutics, Inc. v. ViaCell, Inc*., 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007).

[16] *In re Omeprazole Patent Litig*., 483 F.3d 1364, 82 U.S.P.Q.2d 1643 (Fed. Cir. 2007).

[17] *Abbott Labs. v. Sandoz, Inc*., 544 F.3d 1341, 89 U.S.P.Q.2d 1161 (Fed. Cir. 2007).

The prior art was Sanofi's own patent disclosing the racemate of clopidogrel, PCR 4099, and generically disclosing such a compound as a salt. Apotex argued that it suffices for anticipation that the reference: (1) shows the specific racemate; (2) states that the compounds in the reference have enantiomers; and (3) includes enantiomers in the invention. Apotex argued that "the separation of enantiomers is routine, even if time-consuming or requiring some experimentation, and thus … the separation need not have been performed or described in the reference." *Id*. at 1083. Apotex further argued that the properties of the enantiomers of the mixture are inherently and necessarily present in its known racemate, so that when the enantiomers are separated, the previously observed properties are "immediately recognized" in one or the other enantiomer. As for the sulfate salt, Apotex stressed that the reference's claims refer to "addition salts with pharmaceutically acceptable mineral or organic acids." *Id*.

The court rejected Apotex's arguments. It held that, to anticipate, the reference must not only disclose all elements of the claim, but must also disclose those elements as arranged in the claim. The court agreed with the district court's finding that the claimed bisulfate salt enantiomer was a species falling within the prior art genus of numerous other racemates as well as numerous other salts. The court distinguished previous cases, like *In re Petering*[18] and *In re Schaumann*,[19] in which the prior art generic disclosure identified "specific preferences" met by the later-claimed species: "the references herein contained no such specific preferences" because the prior art racemate "is shown in the references as one of several compounds with desirable biological properties," and the prior art "would not have led one of ordinary skill to recognize either an explicit or an inherent disclosure of its dextrorotatory enantiomer, as well as the bisulfate salt." *Id*. at 1084. The court also rejected Apotex's argument that knowledge of the existence of enantiomers is a description of a specific enantiomer substantially separated from the other, holding that "[t]he knowledge that enantiomers may be separated is not 'anticipation' of a specific enantiomer that has not been separated." *Id*.

Citing the* Wands *factors, the court holds that undue experimentation would have been required to separate the racemate into enantiomers, especially in view of prior art's failed attempts.

Apotex also appealed the district court's holding that the references were nonenabling because they contain no guidance on how to separate the enantiomers of the prior art racemate. Apotex argued that "because the asserted references are patents, which are presumed to be enabling because they are presumed valid," the references were "entitled to a presumption of enablement." *Id*. Relying on the general statements of the separate enantiomers of PCR 4099, Apotex argued "that it is irrelevant whether the separation of this specific enantiomer is shown in the references, because a person of ordinary skill in this field would know all of the existing techniques for separating stereoisomers, and would presumptively succeed in this particular separation." *Id*. at 1085. Referring to the *Wands* factors, "[t]he district court found that these references contain no description of how to separate the enantiomers of PCR 4099, and that '[d]iscovering which method and what combination of variables is required is sufficiently arduous and uncertain as to require undue experimentation, even by one skilled in the relevant art.' " *Id*. (citation omitted). One point in particular noted by the court was that "success came only after several failures using other known strategies for enantiomer separation."[20] *Id*. at 1088. The Federal Circuit found no clear error.

Even if routine testing would have revealed the superior properties of the claimed enantiomer, its properties were unexpected because the art did not predict its combination of antiplatelet activity without the adverse neurotoxicity.

Apotex argued "that the recognition in the prior art that PCR 4099 is composed of enantiomers outweighs the effect of any unexpected or unpredictable properties of the separated dextrorotatory enantiomer." *Id*. at 1086. According to Apotex, "it was well known that enantiomers can have different levels of biological activity even if the exact allocation of properties is unpredictable, thereby rendering it obvious to separate the enantiomers and determine their properties." *Id*. Apotex also argued "that there was motivation to separate the enantiomers of PCR 4099 … using known procedures, even if some experimentation was required, and then, upon separation of the enantiomers, routine testing would have revealed the favorable allocation of properties in the dextrorotatory isomer," citing *Pfizer*[21] for the proposition that "it is not material that this allocation was unknown in advance and unpredictable" because "what matters is whether a person of ordinary skill would have had a reasonable probability of success in the separation

[18] *In re Petering*, 301 F.2d 676, 133 U.S.P.Q. 275 (Ct. Cust. & Pat. App. 1962).

[19] *In re Schaumann*, 572 F.2d 312, 197 U.S.P.Q. 5 (Ct. Cust. & App. 1978).

[20] *See also Forest Labs., Inc. v. Ivax Pharm., Inc*., 501 F.3d 1263, 1268-69, 84 U.S.P.Q.2d 1099 (Fed Cir. 2007), where the court found Forest's enantiomer unobvious for the same reason.

[21] 480 F.3d at 1364.

and evaluation of the enantiomer." *Id*. at 1087. The court found no error in the district court's holding "that a person of ordinary skill in this field would not reasonably have predicted that the dextrorotatory enantiomer would provide all of the antiplatelet activity and none of the adverse neurotoxicity." *Id*.

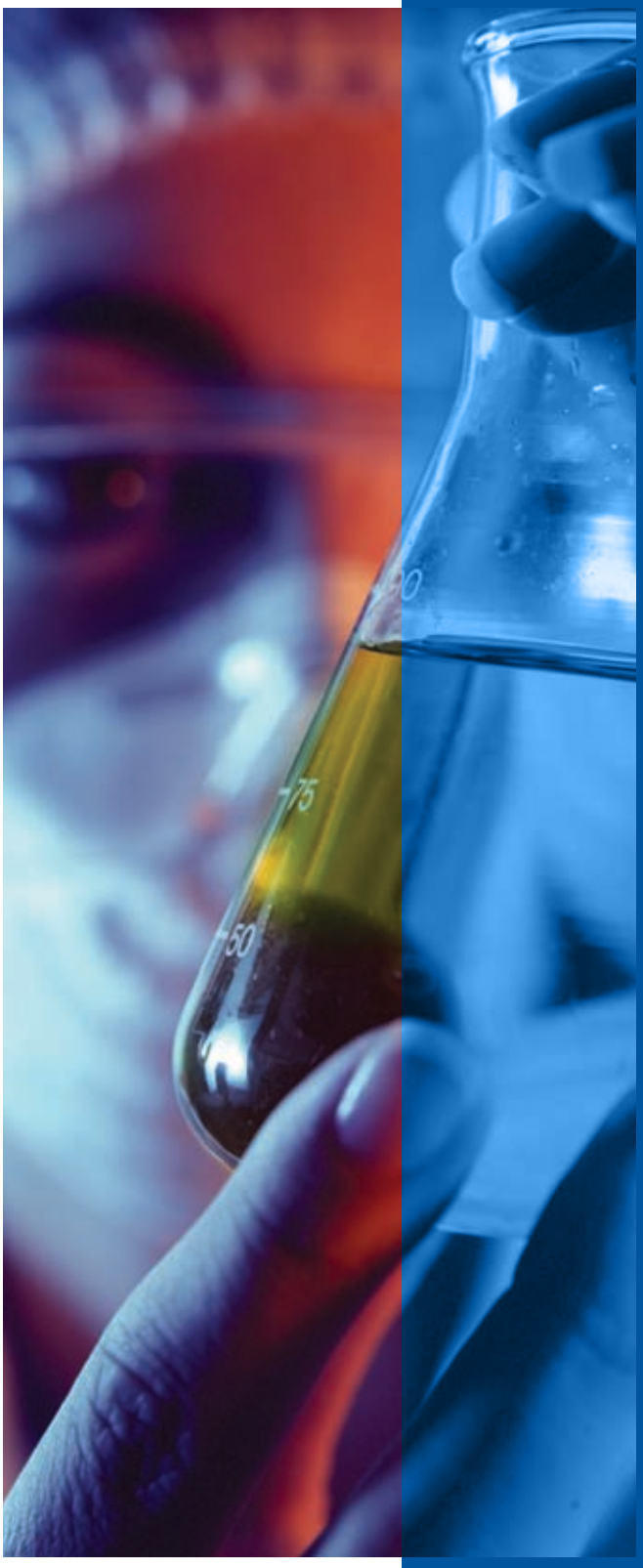
Prior art's disclosure of 80 salt-forming acids did not suggest the claimed sulfate salt where there was evidence that the prior art taught away from the claimed salt of a strong acid.

The district court also rejected Apotex's argument that the prior art taught the bisulfate salt of the enantiomer, noting that the racemate shown in the prior art is the hydrochloride, not the bisulfate. The district court observed that the scientific literature listed 80 acids as candidates for forming salts with basic drug compounds, 53 of which acids had been used in FDA-approved drugs. Because it was unpredictable whether a pharmaceutically suitable crystalline salt would form from a particular acid-base combination, the court distinguished the case from *Pfizer*, where there was evidence that a skilled artisan would have narrowed the possible salts to only a few including the claimed besylate. By contrast, Sanofi presented evidence that the prior art taught away from the use of sulfuric acid with an enantiomer, because strong acids could encourage re-racemization. *Id*. at 1088-89.

There are several interesting "takeaways" from the *Apotex* case. First is that disclosing a "plan" is insufficient to establish anticipation. Thus, it did not matter that the prior art taught that the racemate could be separated into its enantiomers and then salts of those enantiomers formed with a strong organic acid.

Second, the court for the second time referenced the *Wands* factors in assessing enablement of a prior art reference, raising the issue of whether the court is prepared to finally abandon *Rasmusson*, which held that the standard of enablement for section 102 is lower than for section 112 purposes. One begins to sense that the court is returning to its earlier precedent, where the standards for prior art and patent application enablement are the same, with the narrow exception of when the prior art discloses a compound without a utility that can still anticipate a claim to that compound. This would be a welcome development for those of us who think the standard for enablement ought not to vary according to context.

Third, this case suggests that those who feared that last year's *Pfizer* was a harbinger of a new age of invalidation — us included — may have reason to breathe a sigh of relief. After all, it was in *Pfizer* that the court found that the besylate



salt of amlodipine was obvious despite the properties of the besylate salt having been unknown and unpredictable. The court in *Pfizer* found that it was "of no consequence" that "*Pfizer* had to verify through testing the expected traits of each acid addition salt." 480 F.3d at 1367. It is thus not surprising that Apotex, using *Pfizer* as its blueprint, similarly argued that one could have simply obtained the enantiomer and then, through "routine testing," evaluated the properties. The court in Apotex correctly rejected this argument. Unlike *Pfizer*, which focused on the "reasonable expectation of success" in finding the claimed compound, the *Apotex* court assumed *prima facie* obviousness and focused its analysis on unexpected results, namely the unpredictable properties of the claimed compound. The other aspect of *Pfizer* cited prominently by Apotex was the notion that a showing of *prima facie* obviousness could be so strong that it cannot be rebutted with evidence of secondary considerations. In particular, Apotex argued "that the recognition in the prior art that PCR 4099 is composed of enantiomers outweighs the effect of any unexpected or unpredictable properties of the separated dextrorotatory enantiomer." 550 F.3d at 1086. The court correctly rejected Apotex's argument, effectively diluting the potency of that controversial aspect of the *Pfizer* decision.

The final takeaway from *Apotex* is that an enantiomer of a known racemic mixture continues to be *prima facie* obvious, and a strong showing of unexpected results is required to overcome such *prima facie* obviousness.

Precritical date formulation was not reduced to practice where sufficient* in vivo *and long-term stability data was lacking.

In *In re Omeprazole Patent Litig*., 536 F.3d 1361, 87 U.S.P.Q.2d 1865 (Fed. Cir. 2008), the Federal Circuit affirmed yet another victory for AstraZeneca in that company's long-running battle against generic drug companies who filed ANDAs for its drug Prilosec®. The district court ruled that Astra's patents were valid and that defendants Apotex and Impax infringed. On appeal, Impax argued that precritical date clinical studies commissioned by Astra to obtain FDA approval constituted a public use of the claimed formulation under section 102(b). Affirming the district court, the Federal Circuit agreed that Astra's precritical date formulation was neither reduced to practice nor ready-for-patenting. It held that the formulation still required extensive clinical testing and real-time stability testing to determine whether it could treat gastric acid diseases safely and effectively.

Experimental use exception inapplicable once the invention has been reduced to practice.

The Federal Circuit did, however, take exception to the district court's statement that, even had the formulation been ready for patenting, the clinical studies were experimental and thus exempt from section 102(b). The court explained that "it is clear from this court's case law that experimental use cannot negate a public use when it is shown that the invention was reduced to practice before the experimental use." *Id*. at 1372. In other words, once an invention has been reduced to practice, the experimental use exception cannot shield that invention from section 102(b).

It was not obvious to include a subcoating between a drug core and an enteric coating when the prior art failed to disclose preparations containing such subcoatings or any reason to include such a subcoating.

The court also addressed the obviousness of Astra's claim directed to:

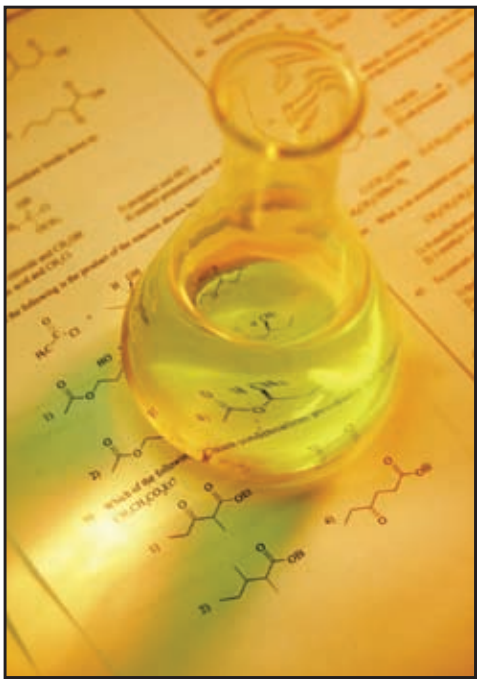
> A pharmaceutical preparation comprising:
>
> (a) an alkaline reacting core comprising an acid labile pharmaceutically active substance and an alkaline reacting compound [("ARC")] different from said active substance, an alkaline salt of an acid labile pharmaceutically active substance, or an alkaline salt of an acid labile pharmaceutically active substance and an alkaline reacting compound different from said active substance;
>
> (b) an inert subcoating … and
>
> (c) an enteric coating layer surrounding said subcoating layer. *Id*. at 1366.

The district court had found that the inclusion of a subcoating was not obvious because the prior art does not disclose or suggest a negative interaction between the drug core and the enteric coating, which might have provided a reason to include a subcoating. The Federal Circuit agreed, holding that Apotex had not shown "that a person of skill in the art would have appreciated the need to include a subcoating" in the prior art example. *Id*. at 1380. The court further found no error in the district court's holding that, even if a person of skill in the art would have recognized that there would be a negative interaction between the enteric coating and the drug core, it would not have been obvious to use a subcoating to solve the problem. It noted that there were "multiple paths" one of ordinary skill in the

art could have followed, and it was not obvious to choose the water-soluble subcoating of the claimed invention. *Id*.

***A finding that one of ordinary skill in the art would not have seen a "reason" to insert a subcoating onto the prior art formulation did not amount to an insistence by the district court on absolute predictability of success in violation of* KSR**.

Finally, the court rejected Apotex's argument that the district court's analysis conflicts with the analysis required by the Supreme Court's decision in *KSR*, "because the district court insisted on absolute predictability instead of a reasonable expectation of success and because the district court failed to recognize that adding a subcoating would be 'obvious to try,' a standard referred to in *KSR." Id*. at 1381. In particular, the Federal Circuit found that "Apotex … mischaracterizes the district court's decision. The court found that a person of skill in the art would not have seen a reason to insert a subcoating in the prior art formulation" "based on Apotex's failure to demonstrate that a person of skill in the art would conclude that a negative interaction would take place between the enteric coating and the drug core." *Id*.



Controlled-release formulation of antibiotic and polymer with a specific release profile not anticipated by prior art disclosing antibiotic combined with large number of release agents because undue experimentation would be required to obtain the recited release profile with a given polymer.

In *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 89 U.S.P.Q.2d 1161 (Fed. Cir. 2008), the Federal Circuit reviewed the district court's grant of a preliminary injunction based on Abbott's likelihood of establishing that its claims to extended release erythromycin derivatives (e.g., clarithromycin) having a certain *in vivo* pharmacokinetic profile were both valid and infringed. The composition and method claims read as follows:

> A pharmaceutical composition for extended release of an erythromycin derivative in the gastrointestinal environment, comprising an erythromycin derivative and … a pharmaceutically acceptable polymer, so that upon oral ingestion, maximum peak concentrations of the erythromycin derivative are lower than those produced by an immediate release pharmaceutical composition, and area under the concentration-time curve and the minimum plasma concentrations are substantially equivalent to that of the immediate release pharmaceutical composition.
>
> A method of reducing gastrointestinal adverse side effects comprising administering an effective amount of extended release pharmaceutical composition comprising an erythromycin derivative and a pharmaceutically acceptable polymer. *Id.* at 1344.

Dependent claims further defined the erythromycin derivative as clarithromycin.

The court first addressed the issue of anticipation. Sandoz argued that the claims were anticipated by "the '571 publication," which discloses a sustained-release antimicrobial, such as erythromycin, but no *in vivo* pharmacokinetic data. Sandoz argued that the claimed pharmacokinetic limitations are inherent in the extended release compositions of the publication. Abbott responded that the '571 publication neither discloses the claimed pharmacokinetic profile nor enables compositions having such a profile since significant experimentation would be required to ascertain the pharmacokinetic profiles of the large number of compositions disclosed in the publication. The district court agreed with Abbott that the '571 publication was nonenabling because it "does not offer any *in vivo* dissolution data" nor state "the pharmacokinetic profile of its own formulations." The Federal Circuit agreed, noting that the '571 publication "neither describes the product of the [claims] nor enables the pharmacokinetic properties that are set forth in the [claims]." *Id.* at 1346.

Because the "known options" in the prior art were not "finite, identified, and predictable," the claimed extended release antibiotics were not obvious.

Next, the court addressed whether the claimed invention was *prima facie* obvious in view of the '571 publication

in combination with a PCT disclosing release profiles of azithromycin and the '190 patent, allegedly teaching equivalence of azithromycin and clarithromycin. Sandoz argued that no more than routine experimentation was needed to find an extended release formulation that would meet the pharmacokinetic requirements stated in the claims. Citing *KSR*'s statement that "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp," Sandoz argued that Abbott merely pursued known options. *Id.* at 1347. Abbott pointed out that the Supreme Court qualified the statement by explaining that, to be obvious, the "problem" should have "a finite number of identified, predictable solutions." Abbott acknowledged that the basic principles of pharmacokinetics were known, but argued that the claimed pharmacokinetic properties were not achieved in any reference or combination of references. *Id.* at 1348. The profiles disclosed in the PCT were simply *in vitro* data for azithromycin, which Abbott presented evidence was nonequivalent to clarithromycin, and the C_{max} values in the '190 patent were not significantly different for immediate and extended release.

The Federal Circuit began by acknowledging that when the problem is known, the possible approaches to solving the problem are known and finite, and the solution is predictable through use of a known option, then the pursuit of the known option may be obvious even absent a "teaching suggestion, or motivation" concerning that option. When "this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *Id.* at 1351 (citing *KSR* at 1742). Here, however, the court agreed with Abbott that the "known options" in the prior art were not "finite, identified, and predictable" given the large number of options and "the difficulties in predicting the behavior of any composition in any specific biological system." Citing to decades-old precedent[22] for the proposition that "there is usually an element of 'obviousness to try' in any research endeavor," the court explained:

> The court in *KSR* did not create a presumption that all experimentation in fields where there is already a background of useful knowledge is 'obvious to try,' without considering the nature of the science or technology. The methodology of science and the advance of technology are founded on the investigator's educated application of what is known, to intelligent exploration of what is not known. Each case must be decided in its particular context, including the characteristics of the science or technology, its state of advance, the nature of the known choices, the specificity or generality of the prior art, and the predictability of results in that area of interest. *Id*. at 1352.

The *Abbott* case is yet another illustration of a new paradigm developing in obviousness. Where the claimed elements all fall within the prior art, the question of obviousness seems to resolve on whether the "known options" in the prior art were "finite, identified, and predictable," or not.

Evidence of commercial success need not include every conceivable embodiment of the claims, but the applicant must at least show that the success owes to the features of the claimed invention and not the marketing efforts or general popularity of the product.

In *In re DBC*, 545 F.3d 1373, 89 U.S.P.Q.2d 1123 (Fed. Cir. 2008), the patent applicant DBC appealed the PTO Board's rejection of its reexamined patent directed to a nutraceutical composition comprising a mixture of the pulp and pericarp of the mangosteen fruit.

The Board rejected DBC's showing of commercial success, holding that the company had failed to establish: (1) what product was marketed and when; (2) that the product was commensurate with the scope of the claims; and (3) that the sales were a result of anything other than network marketing, the increasing popularity of mangosteen, and improved availability of the mangosteen fruit in general. *Id*. at 1383.

The Federal Circuit found error in the Board's holding that "the commercial embodiment of the claim must contain both a fruit juice and a vegetable juice since the claim recites 'at least one second juice selected from the group consisting of fruit juice and vegetable juice.' " The court held that "DBC need not sell every conceivable embodiment of the claims in order to rely upon evidence of commercial success, so long as what was sold was within the scope of the claims." *Id*. at 1384. Nonetheless, the court did affirm the Board's holding of "no nexus between the claimed invention and the submitted evidence of commercial success," finding that "DBC has done little more than submit evidence of sales," which "does not reveal in any way that the driving force behind those sales was the claimed combination" or "that sales … were not merely attributable to the increasing popularity of mangosteen fruit or the effectiveness of the marketing efforts employed." *Id*.

[22] *In re Tomlinson*, 363 F.2d 928, 931, 150 U.S.P.Q. 623 (Ct. Cust. & Pat. App. 1966).

Double Patenting

An applicant subject to a restriction requirement who files a CIP application to its nonelected claims loses section 121 protection against double patenting.

In *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353 86 U.S.P.Q.2d 1001 (Fed. Cir. 2008), the court addressed the question of whether the protection against double patenting rejections afforded by 35 U.S.C. § 121 for claims subject to a restriction requirement applied when the applicant filed its nonelected claims in a continuation-in-part ("CIP") rather than in a divisional.[23] Pfizer argued that the terms "divisional" and "continuation-in-part" are merely labels used for administrative convenience, and thus an application termed a CIP is in effect a divisional for purposes of section 121. The Federal Circuit disagreed: "[T]he statute provides a safe harbor (for patents or applications derived as the result of a restriction requirement) from attack based on the original application (or a patent issuing therefrom), or based on applications or patents similarly derived from the same restriction requirement. That safe harbor, by its literal terms, protects only 'divisional application[s]' (or the original application) and patents issued on such applications." *Id.* at 1360. The court concluded "that the protection afforded by section 121 to applications (or patents issued therefrom) filed as a result of a restriction requirement is limited to divisional applications."[24] *Id.* at 1362.

[23] Section 121 states that "[a] patent issuing on an application with respect to which a requirement for restriction … has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the [PTO] or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application."

[24] The PTO does not appear to share the court's novel viewpoint, as the PTO's own listing of "situations where the prohibition against double patenting" does not apply does not list a CIP situation among them. Given the frequency with which applicants file CIPs, this omission would be a rather striking one if the PTO viewed the situation as the Federal Circuit does. MPEP § 804.01

The court's analysis, however, is difficult to square with either the statute or public policy. It seemed to ignore that CIPs and divisionals are not necessarily mutually exclusive. Indeed, the statute itself makes this clear in the penultimate sentence of section 121, which states, ***"If a divisional application is directed solely to subject matter described and claimed in the original application*** as filed, the Director may dispense with signing and execution by the inventor." (emphasis added). The Federal Circuit's construction of the statute renders the highlighted phrase redundant if, by definition, a divisional cannot include new matter.

It is also difficult to fathom what public policy this decision advances. The public benefits when an applicant provides the most comprehensive disclosure of the invention and the law should encourage further disclosure as an inventor continues to generate additional experiments. Yet now, a patentee who generates additional data and examples that could benefit the public's understanding of the invention will be dissuaded from providing those added examples after a restriction requirement, lest that inventor lose the protection of section 121. This benefits neither the public nor the inventor.

In rejecting a method claim for double patenting in view of an earlier composition claim, the court may properly refer to the uses disclosed in the specification in construing the claims of the composition patent.

Having found that Pfizer's restricted claims were not entitled to the protection of section 121 against double patenting, the court next assessed whether the relevant claims of the two patents were patentably distinct. The claims at issue recited methods of administering a "therapeutically-effective amount" of a composition whereas the claims of the earlier patent recited the composition itself present in "a therapeutically effective amount." The court found that the patent-in-suit "merely claims a particular use described in the [earlier] patent of the claimed compositions of the [earlier] patent" and "are therefore not patentably distinct over the claims of the [earlier] patent." *Id*. at 1363. In response to Pfizer's argument that the court could not rely on the teachings of the specification or claims of the earlier patent to reject the subsequent method claims, the court held that "[t]here is nothing that prevents us from looking to the specification to determine the proper scope of the claims." *Id*. n.8.

The phrase "therapeutically effective amount" in the earlier compositions claims apparently provided the court with a hook to import all the uses disclosed in the specification into the claims. That done, the court had little difficulty rejecting as obvious the subsequent method claims directed to administering a "therapeutically effective amount" of the compositions.

Relying on the species disclosed in the prior patent's specification, the court invalidates a later patent claiming a different species based on obviousness-type double patenting.

In *In re Basell Poliolefine Italia*, S.P.A., 547 F.3d 1371, 89 U.S.P.Q.2d 1030 (Fed. Cir. 2008), the court reviewed an adverse decision by the PTO on reexamination initiated by the Director, finding all the claims of the patent as unpatentable under the doctrine of obviousness-type double patenting. The patent-in-suit recites polymerizing alpha olefins having ***four or more carbon atoms*** specifically with ***ethylene*** whereas the prior patent recites polymerizing alpha olefins having ***three to six carbon atoms*** with another ***generic olefinic monomer***. Furthermore, whereas the patent-in-suit specifically recites a catalyst obtained from an ***aluminum*** alkyl compound and a ***titanium*** halide compound, the prior patent recites a more generic catalyst obtained from an alkyl compound of a ***Group II or III element*** with a halide of ***a transition metal***.

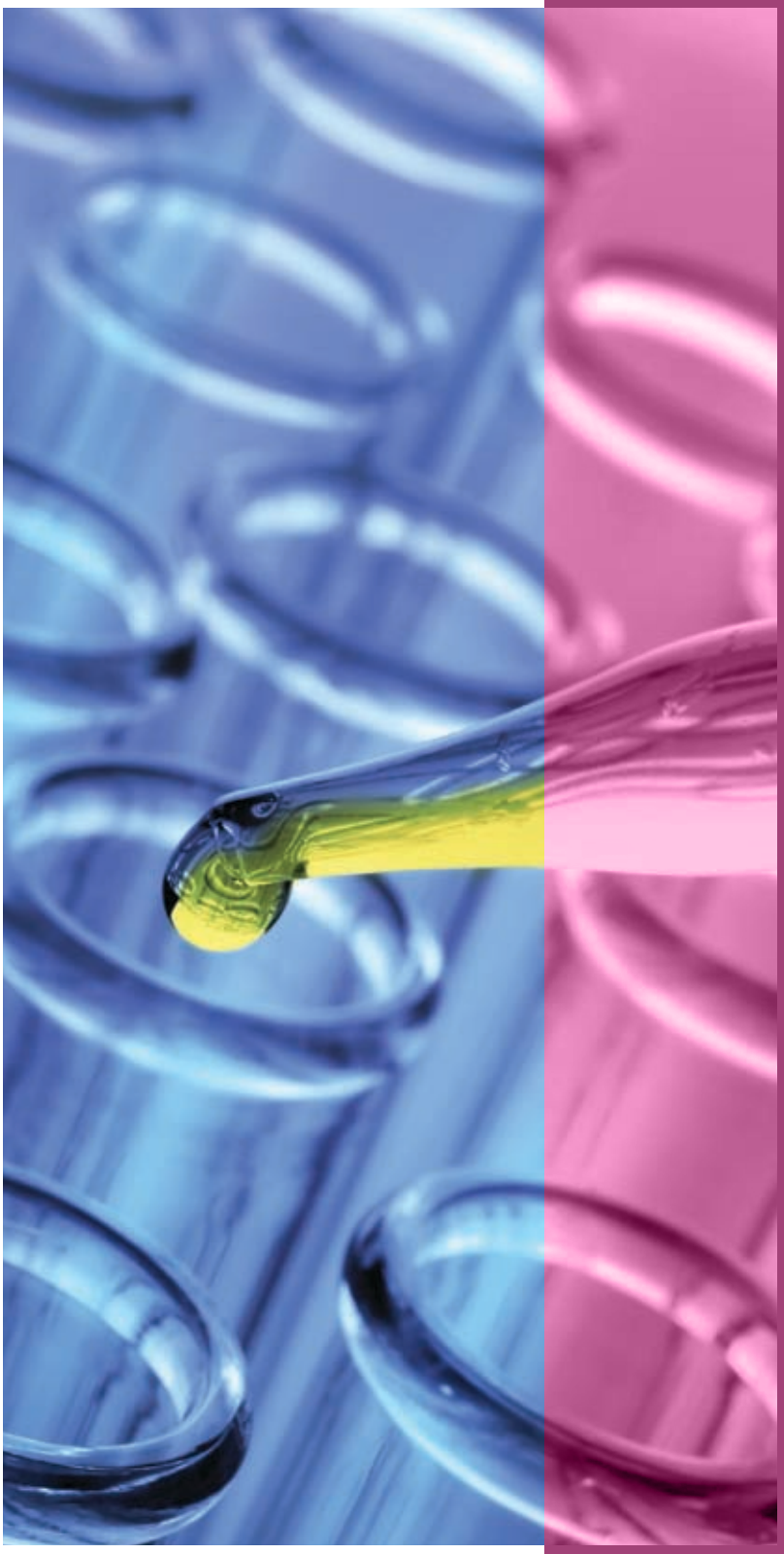
The prior patent claims were found to "render obvious the claims of [the patent-in-suit] directed to polymers of the homologous, well-known ethylene and C4 olefins." *Id*. at 1378. The court noted that "homologs are presumptively obvious over known compounds." *Id*. The court found it "worthy of note that, while claim 1 of the [patent-in-suit] recites ethylene, its specification is almost entirely directed to propylene, which is encompassed by [prior patent's] claim 1" and that "the discussion of ethylene is limited and it is mentioned briefly in a statement that a small amount of ethylene does not interfere with the polymerization of propylene." *Id*. The court also noted that "propylene is squarely within the scope of the [prior] patent's C_3 to C_6 scope" and that "the specification of the [prior] patent itself refers to ethylene, propylene, butene, and other olefins which indicates that those olefins were intended to fall within the meaning of the claims. Thus, the PTO had good basis for its conclusion that the claims of the [prior] patent rendered obvious the claims of the [patent-in-suit] and that the latter claims are invalid for obviousness-type double patenting." *Id*.

As in *Pfizer*, the court in *Basell* used a hook to refer to the specification to broaden the ordinary meaning of the claim language. In this case, the hook was the '687 patent claims' recitation of a genus (i.e., any alpha-olefin C_4 or higher), which the court used as an excuse to refer to the '987 patent's specification. Collectively, the *Basell* and *Pfizer*

cases suggest that the Federal Circuit may be more willing to look to the specification in support of double patenting rejections than in the past, where its double patenting analysis tended to be limited to just the claims.

Application of "two-way" double patenting test is a "narrow exception" to the general rule and not applicable in a case in which the patentee did not present claims resembling those at issue in its application for many years and also spent years provoking interferences.

The court also rejected Basell's argument that the Board should have applied a "two-way" obviousness-type double patenting analysis because the delays in the prosecution of the patent were attributable to the PTO. The court noted that "[t]he two-way test is 'a narrow exception to the general rule of 'the one-way test' " limited to "when the applicants filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in reverse order of filing, rejecting the basic application although it would have been allowed if the applications had been decided in the order of their filing." *Id*. at 1375-1376 (citing *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998)). But the court held that "those circumstances … are not present here." *Id*. at 1376. Specifically, the court found that Basell had failed to present any claims resembling those at issue until nearly a decade after the first application in the chain had been filed and well after the application resulting in the '987 patent had been filed. The court further found that Basell had a history of filing claims for interference purposes only, and that appeared to be the case here as well. Moreover, during the critical period of time that the applications for the '687 patent and the '987 patent were co-pending, the inventor could have filed the claims at issue, and chose not to. Because the applicant was thus directly responsible for any delay in prosecution, the two-way test for double patenting did not apply. *Id*.



Written Description

Noting that* Eli Lilly *is not limited to novel DNA sequences, the court invalidates claimed plasmids encoding DNA polymerase I from any bacterial source because three species disclosed were not representative of the broader genus claimed.

In *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 88 U.S.P.Q.2d 1233 (Fed. Cir. 2008), the court invalidated claims to recombinant plasmids encoding DNA polymerase I from any bacterial source for lacking adequate written description. The court began its analysis by citing *Regents of the Univ. of Cal. v. Eli Lilly & Co.*,[25] which held that a claim to a cDNA encoding human insulin was not adequately described merely by identifying the cDNA by function, i.e., by what it encodes. "An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the claimed invention, requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." *Id.* at 1122 (citing *Lilly* at 1566). Moreover, "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* (citing *Lilly* at 1569).

Carnegie Mellon sought to distinguish *Eli Lilly* because the invention in that case was tied to a specific cDNA sequence, whereas Carnegie Mellon's invention involved "a combination of well known elements that create a generic biotechnological tool." *Id.* Specifically, "at the time of the invention, both DNA polymerase I and the *polA* gene were well known in the art." *Id.* at 1123. Roche, on the

[25] 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997).

other hand, argued that the holding in *Eli Lilly* was not limited to inventions involving novel DNA sequences.

Siding with Roche, the court expressly rejected "appellants' assertion that this case is distinguishable from *Eli Lilly*," finding that "nothing in *Eli Lilly* indicates that that holding was limited to inventions involving novel DNA sequences." *Id*. at 1124. Rather, "the basic principle" of *Eli Lilly* was "that a person of skill in the art must be able to 'visualize or recognize the identity of the members of the genus.' " *Id*. The court concluded that Carnegie Mellon's claims "encompass a genus of recombinant plasmids that contain coding sequences for DNA polymerase or nick-translation activity from any bacterial source," whereas the specifications "only disclose the polA gene coding sequence from one bacterial source, *viz., E. coli." Id*. at 1125. Furthermore, the court noted that (1) "the disclosure of the *E. coli polA* gene was not representative of and failed to adequately support the entire claimed genus" because "at the time of the invention, only three bacterial *polA* genes*, viz., E. coli, K. aerogenes* and *K. pneumoniae*, out of thousands of bacterial species had been cloned, and only *E. coli* was described in the patents," and (2) "the written descriptions of the … patents clearly indicate that the *polA* gene is critical to the claimed invention." *Id*.

In so holding, the court distinguished *Capon v. Eshhar*,[26] which had overturned a Board decision holding that the written description requirement was not met because the disclosures failed to recite the structure, formula or chemical name for the claimed chimeric genes. "Unlike the situation in *Capon*, however, where the prior art contained 'extensive knowledge of the nucleotide structure of the various immune-related segments of DNA,' including 'over 785 mouse antibody DNA light chains and 1,327 mouse antibody DNA heavy chains,' … the record here shows that only three bacterial *polA* genes out of thousands of genes had been cloned." *Id*. at 1126.

This case represents an unwelcome end to a nearly five-year repose from written description invalidations. The court's attempt to distinguish *Capon* seems contrived in that the claim in *Capon*[27] was generic to all species of animals having an immune system, yet the examples were limited to mice. The problem may be that Carnegie Mellon was asserting validity of claims dependent on functional limitations in an infringement case where the infringement issue emphasized the functional differences between the *E. coli* polymerase exemplified in the specification and the *Taq* polymerase asserted to infringe.

The court invalidates method for treating cancer using a family of antibodies, for lack of written description when the specification failed to disclose the characteristics of the antibody family, such as structure, epitope characterization, binding affinity, specificity or pharmacological properties.

In *In re Alonso*, 545 F.3d 1015, 88 U.S.P.Q.2d 1849 (Fed. Cir. 2008), the claimed invention recited a method for treating neurofibrosarcoma cancer that uses human monoclonal antibodies ("mAbs") targeted at a patient's tumor.

Alonso's application only described the preparation of a single mAb produced by the hybridoma cell line designated "HB983." The Board held that this was insufficient written description to support the claims: "There is ample evidence of record that the specificities of antibodies falling within the scope of the genus (and the structures of the antigens they bind) would be expected to vary substantially …. This acknowledged heterogeneity is reflected in the goal of the claimed method — to raise customized antibodies to possibly unique antigens on a particular patient's tumor." *Id*. at 1019, 1020. The Board noted that "for purposes of satisfying the written description requirement, it is not enough merely to disclose a method of making and identifying compounds capable of being used to practice the claimed invention" and therefore found that "the single antibody described in the Specification is insufficiently representative to provide adequate written descriptive support for the genus of antibodies required to practice the claimed invention." *Id*. at 1020.

The Federal Circuit affirmed, reiterating that "a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated," and agreeing with the Board that "the antibodies required to perform Alonso's claimed method vary substantially in their composition." *Id*. (citing *Noelle v. Lederman*, 355 F.3d 1343, 1350 (Fed. Cir. 2004)). According to the court, Alonso's "specification teaches nothing about the structure, epitope characterization, binding affinity, specificity, or pharmacological properties common to the large family of antibodies implicated by the method." *Id*. at 1021-22. This was "clearly insufficient" to satisfy the written description requirement. *Id*. at 1021.

[26] 418 F.3d 1349, 1358, 76 U.S.P.Q.2d 1078 (Fed. Cir. 2005).
[27] *See* id. at 1353-54.

As the court itself acknowledged, antibodies employed in cancer treatments based on the patient's own physiology necessarily are going to vary from patient to patient. Accordingly, this decision has the potential to foreclose meaningful patent protection in the area of personalized medicine. Unfortunately, through its continued insistence on seeing "pictures" of things for purposes of written description, the court is still locked in the small molecule mindset of the twentieth century. Molecular biology simply does not lend itself to such treatment, as this case illustrates. Moreover, there is simply no need for this; the enablement requirement is more than adequate to police cases of overreaching, as it did for decades before the *Eli Lilly* case issued in 1997.

Claims to a nucleic acid encoding a polypeptide "at least 80% identical to" a SEQ ID protein lack adequate written description where specification fails to provide representative number of nucleic acids falling within the claimed genus.

In *Ex parte Kubin*, 83 U.S.P.Q.2d 1410 (Bd. Pat. App. & Int. 2007), the Board affirmed the examiner's written description rejection of applicant's claim to:

> An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO:2, wherein the polypeptide binds CD48. Id. at 1412.

Citing *Eli Lilly*, the Board noted that to adequately describe a genus, such as the claimed nucleic acid molecule, the specification must contain "a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *Id*. at 1417 (citing *Eli Lilly*, 119 F.3d at 1568). The Board held that "[p]ossession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features." *Id*. In Kubin's case, the Board found that, of the two nucleic acids and three fusion proteins disclosed in the specification, none varies amino acids 22-221 of the polypeptide, and thus none supported a genus claim. "Thus, under *Lilly* and its progeny, [Kubin's] Specification would not have shown possession of a sufficient number of sequences falling within their potentially large genus to establish possession of their claimed genus." *Id*. The Board held that "[w]ithout a correlation between structure and function, the claim does little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement." *Id*.

The most interesting aspect of this case is that Kubin's claim was modeled after a hypothetical example in the PTO's *Written Description Guidelines* of a claim satisfying the description requirement. Kubin argued that, by following the PTO's own Guidelines, it must have satisfied the description requirement. But the Board disagreed: "While the Written Description Guidelines and the hypothetical examples in the Office's Synopsis can be helpful in understanding how to apply the relevant law (as it existed in 2001 when the Guidelines were adopted), they do not create a rigid test." *Id*.

Enablement

Claims to a nucleic acid encoding a polypeptide "at least 80% identical to" a specific SEQ ID protein is enabled under* Wands *factors where, given the state of the art, and the level of skill in the art, the experimentation required, even if extensive, would have been routine.

The Board in *Kubin*, addressing whether the claims citing the "80% identity" language were enabled, concluded that they were. The examiner rejected the claims as nonenabled due to the absence of any working examples, other than SEQ ID NOS: 1 and 2, and that small changes in sequence, even one amino acid, can yield a different function. Kubin responded that "many references … positively demonstrate that proteins can be mutated and maintain a biological function" and that "the specification provides extensive guidance for creating and screening mutants[,]" such as describing "how to: 1) make variants of SEQ ID Nos: 1 and 2; 2) calculate the percent identity between SEQ ID Nos: 1 and 2 and the variant sequence; and 3) test the variant sequence to determine if it binds to CD48." *Id*. at 1415.

The Board began by reiterating that, although there is often significant overlap between the enablement and written description requirements, they are nonetheless independent of each other. Then, citing the *Wands* factors, the Board reversed the examiner. Noting that "molecular biology is generally an unpredictable art," the Board nevertheless found that "the other *Wands* factors weigh in [Kubin's] favor, particularly 'the state of the art' and 'the relative skill of those in the art.' " *Id*. at 1416. It concluded that "[t]he amount of experimentation to practice the full scope of the claimed invention might have been extensive, but it would have been routine. The techniques necessary to do so were well known to those skilled in the art." *Id*.

Indefiniteness

Where a functional term (e.g., "fragile gel") is the point of novelty distinguishing an otherwise known composition from the prior art, a proposed construction that encompasses the prior art is fatal.

In *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 85 U.S.P.Q.2d 1654 (Fed. Cir. 2008), the court addressed the definiteness of the term "fragile gel" employed in a drilling fluid in a claim directed to a method of drilling. Halliburton argued that "fragile gel" includes as part of its definition: (1) a gel that easily transitions to a liquid state upon the introduction of force and returns to a gel when the force is removed; and (2) at rest, is capable of suspending drill cuttings and weighting materials. *Id*. at 1250. Although Halliburton could "articulate a definition supported by the specification," this did "not end the inquiry." *Id*. at 1251. According to the court, "[e]ven if a claim term's definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope." *Id*.

The court rejected Halliburton's reliance on an "L-shaped curve" shown in the specification as an objective definition of a gel that easily transitions from gel to liquid and back again. That the prior art fell within the same L-shaped curve was found to be "an important consideration in the definiteness inquiry because in attempting to define a claim term, a person of ordinary skill is likely to conclude that the definition does not encompass that which is expressly distinguished as prior art." *Id*. at 1252. The court took particular note that Halliburton relied on the figure both to define its fragile gel and to distinguish the gel from the prior art. "A person of ordinary skill would … have looked to [the figure] to try to determine the bounds of the claims." *Id*. Thus, "[b]y failing to identify the degree of the fragility of its invention, Halliburton's proposed definition would allow the claims to cover not only

that which it invented that was superior to the prior art, but also all future improvements to the gel's fragility." *Id*. at 1253.

When a proposed claim construction requires an artisan to make a separate infringement determination for every set of circumstances in which a claimed composition may be used, with the likely result of different outcomes, the claim is indefinite.

The court also concluded that a construction of "fragile gel" as "capable of suspending drill cuttings and weighting materials at rest" was indefinite because "nothing in the record suggests what degree of such capability is sufficient." *Id*. at 1254. The court rejected Halliburton's argument that a skilled artisan would know how to measure the quantity of drill cuttings suspended in a fluid and how to determine when the fluid no longer exhibited the L-shaped curve behavior: "The fact that an artisan would know how to perform these measurements and tests … says nothing about whether the artisan would also know which fluids were 'fragile gels.'" *Id*. Referring to its earlier decision of *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*,[28] the court noted that "under Halliburton's proposed construction in this case, an artisan would not know from one well to the next whether a certain drilling fluid was within the scope of the claims because a wide variety of factors could affect adequacy (formation geology, wellbore size, depth, angle, etc.)." *Id*. at 1254-55. The court concluded that "[w]hen a proposed construction requires that an artisan make a separate infringement determination for every set of circumstances in which the composition may be used, and when such determinations are likely to result in differing outcomes (sometimes infringing and sometimes not), that construction is likely to be indefinite." *Id*. at 1255.

The court warns that use of "functional" language in claims makes the task of determining their scope difficult and advises applicants to resolve this ambiguity during prosecution rather than during litigation.

Finally, the court addressed Halliburton's use of the functional language "fragile gel" and noted that "[a]lthough our predecessor court later recognized that 'there is nothing intrinsically wrong with' using functional language in claims, it noted that in some instances, use of functional language can fail 'to provide a clear-cut indication of the scope of subject matter embraced by the claim' and thus can be indefinite." *Id*. (citing *In re Swinehart*, 439 F.2d 210, 212-13 (Ct. Cust. & Pat. App. 1971)). The court warned that "[w]hen a claim limitation is defined in purely functional terms, the task of determining whether that limitation is sufficiently definite is a difficult one that is highly dependent on context (e.g., the disclosure in the specification and the knowledge of a person of ordinary skill in the relevant art area)." *Id*. The court added that "the patent drafter is in the best position to resolve the ambiguity in the patent claims, and it is highly desirable that patent examiners demand that applicants do so in appropriate circumstances so that the patent can be amended during prosecution rather than attempting to resolve the ambiguity in litigation." *Id*. The court suggested that a number of ways in which a patent drafter could resolve the ambiguities of a functional limitation, such as "by using a quantitative metric" or by providing "a formula for calculating a property along with examples that meet the claim limitation and examples that do not." *Id*. at 1255-56.

A claim is not indefinite merely because a potential infringer is unable to determine if a process infringes before practicing the claimed process.

In *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co*., 537 F.3d 1357, 88 U.S.P.Q.2d 1001 (Fed. Cir. 2008), the court reviewed the definiteness of a claim directed to a process of substantially preventing the formation of at least one nitrosamine in a harvested tobacco plant. The process recited curing the tobacco "in a controlled environment . . . to substantially prevent the formation of said at least one nitrosamine" by providing an airflow free of combustion gases and "sufficient to substantially prevent an **anaerobic** condition" around the plant. *Id*. at 1364 (emphasis added). The district court found the term "anaerobic" to be indefinite. The Federal Circuit noted, as had the district court, that "[f]ar from being insolubly ambiguous, a skilled artisan could determine whether an 'anaerobic condition' was present — or, rather, was prevented — simply by measuring the levels of [the disclosed nitrosamines]" in accordance with the upper limits specifically set forth in specification. *Id*. at 1372. Citing *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC* ,[29] the district court found the term to be indefinite "based on its misunderstanding that claim definiteness requires that a potential infringer be able to determine if a process infringes before practicing the claimed process." *Id*. (emphasis omitted). The Federal Circuit reversed, holding that in *Geneva*, "while we emphasized that a claim is indefinite if a skilled artisan cannot determine if an accused product infringes or not, we did not hold that the infringement determination must be able to be made at any particular time." *Id*. n.12 (emphasis omitted).

[28] 349 F.3d 1373, 1384, 68 U.S.P.Q.2d 1865 (Fed. Cir. 2003) (holding a construction of the phrase "synergistically effective amount" to be indefinite because "a given embodiment would simultaneously infringe and not infringe the claims, depending on the particular bacteria chosen for analysis.").

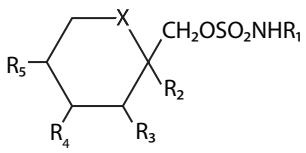
[29] 349 F.3d 1373, 1383-84, 68 U.S.P.Q.2d 1865 (Fed. Cir. 2003).

Claim Construction

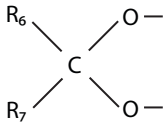
The court construes "and" to mean "or" (1) to avoid a "nonsensical" result; (2) in view of the "larger context" of the claim; (3) because other dependent claims would be rendered "meaningless"; and (4) in view of the specification.

In *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 86 U.S.P.Q.2d 1196 (Fed. Cir. 2008), the court had to construe the meaning of the word "and" in the following claim:

1. A sulfamate of the following formula (I):



Wherein
X is oxygen;
R1 is hydrogen or alkyl; and
R2, R3, R4 and R5 are independently hydrogen or lower alkyl **and** R2 and R3 and/or R4 and R5 together may be a group of the following formula(II):



wherein R6 and R7 are the same or different and are hydrogen, lower alkyl or are alkyl and are joined to form a cyclopentyl or cyclohexyl ring. *Id*. at 1361 (emphasis added).

The district court construed the underlined "and" in the claim to mean "or," and found that Mylan's topiramate product infringed, even though that product did not meet the limitation that "R2, R3, R4 and R5 are independently hydrogen or lower alkyl." The Federal Circuit agreed, holding

that "in the circumstances of this case, claim 1's use of the term *and* means *or*" because "the claim language depicts two subsets of compounds, but does not require their simultaneous existence." *Id*. Thus, "as used in this claim, *and* conjoins mutually exclusive possibilities." *Id*. at 1362. The court concluded that, "[i]n context, it is clear that one of the subunits (R2, R3, R4, or R5) does not always have to be either a hydrogen or lower alkyl." *Id*. The court also noted that this construction was consistent with both the specification, which "uses the word *and* to link alternative chemical structures," and the doctrine of claim differentiation since "[c]onstruing claim 1 to require a conjunctive meaning of *and* would render several dependent claims meaningless." *Id*.

The court acknowledged its earlier holding in *Chef America, Inc. v. Lamb-Weston, Inc.*, where it construed the phrase "heating … dough **to** a temperature in the range of about 400° F. to 850°F." to mean that the dough must reach the recited temperature, even though a person skilled in the art would immediately recognize that, as a result the dough "would be burned to a crisp."[30] The court in that case explained "that a patent must be interpreted 'as written, not as the patentees wish they had written it' " and that "even 'a nonsensical result does not require the court to redraft the claims of the … patent.' " *Id*. at 1362 (citing *Chef Am*., 358 F.3d at 1374) (alteration in original). The *Ortho* court did its best to distinguish *Chef America*: "Giving *and* its most common dictionary meaning would produce in this case the nonsensical result of not covering topiramate and rendering several other dependent claims meaningless," whereas "[i]n *Chef America*, the only possible interpretation of the claim led to a nonsensical result." *Id*. at 1363.

It is hard to argue with the result in *Ortho* because, as the court pointed out, any other interpretation would have been nonsensical. Nonetheless, even in hindsight, it is difficult to reconcile *Ortho* and *Chef America*. Why, for example, was there only "one possible interpretation" for the word "to" in *Chef America*, whereas there were multiple interpretations for the word "and" in *Ortho*? Perhaps it was the additional factors of the dependent claims being rendered nonsensical and the presence of terms such as "independently" and "together" that carried the day for Ortho.

The court will not deviate from the ordinary meaning when the alternative interpretation would render part of the claim functionally meaningless.

In *Cat Tech LLC v. TubeMaster, Inc*., 528 F.3d 871, 87 U.S.P.Q.2d 1065 (Fed. Cir. 2008), the claim at issue recited "a spacing between adjacent plates having a width not greater than the smallest dimension of a single particle to be loaded into the multi-tube reactor," this spacing "for collecting dust and partial particles." *Id*. at 875. The district court construed this limitation to require "spacing that is not large enough to allow whole particles to fall through." *Id*. at 878. On appeal, Cat Tech argued that the claims do not require that all spaces between plates be smaller than the width of a whole catalyst particle, but rather only that there be one point between plates (a "pinch point") that is of the requisite size. The court rejected this argument, finding "no persuasive evidence" in the record that the word "spacing" has a specially defined meaning in the relevant art. *Id*. at 884. Accordingly, "the plates are 'fixed' or 'arranged' so that the distance between them will not be greater than the width of a whole catalyst particle." *Id*. at 885. Cat Tech's construction of the limitation, by contrast, "renders an important claim limitation — the requirement that there be a spacing narrower than the width of a whole catalyst particle — functionally meaningless." *Id*. According to the court,"[i]t would be pointless to require that one inter-plate space be narrower than a whole catalyst particle if the other inter-plate spaces do not meet this sizing limitation" since "whole catalyst particles would simply fall into the other, wider gaps between the plates." *Id*.

Nothing in the Patent Statute prohibits a claim directed to a chimeric gene from encompassing a plant containing that gene.

In *Monsanto Co. v. David*, 516 F.3d 1009, 85 U.S.P.Q.2d 1963 (Fed. Cir. 2008), Monsanto charged David with infringing its patent, claiming the Roundup Ready® chimeric gene. David argued that its seeds did not infringe Monsanto's patent because the patent's specification lacked the specificity required of a patented plant variety and thus the patent claims are limited to the chimeric gene sequence itself and do not encompass plants and seeds containing that gene. David cited the Supreme Court's decision in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc*.[31] for the proposition that plants themselves can only receive patent protection under either the Plant Patent Act or under a utility patent on a plant variety whereby "[a] utility patent on a gene sequence … does not entitle the holder of that patent to enforce its grant of exclusivity against growers of plant varieties that contain the gene sequence." *Id*. at 1013. The court disagreed with David's reading of *J.E.M*., noting that the Supreme Court expressly "decline[d] to narrow the reach of § 101 where

[30] 358 F.3d 1371, 1373, 69 U.S.P.Q.2d 1857 (Fed. Cir. 2004) (emphasis added).

[31] 534 U.S. 124, 60 U.S.P.Q.2d 1865 (2001).

Congress has given us no indication that it intends this result." *Id*. at 1014 (quoting *J.E.M*., 534 U.S. at 145-46)). Accordingly, the Federal Circuit held that Monsanto's "patent covering the gene sequence is infringed by planting a seed containing the gene sequence because the seed contains the gene." *Id*.

The court construes "pharmaceutically acceptable polymer" to include insoluble hydrophilic polymers despite specification's statement that the polymer "is" a "water-soluble hydrophilic polymer" because one of the generic polymers listed in the specification encompasses both water-soluble and water-insoluble species of polymers.

In *Abbott Labs. v. Sandoz, Inc*., 544 F.3d 1341, 89 U.S.P.Q.2d 1161 (Fed. Cir. 2008), the issue was the proper construction of the claim limitation "pharmaceutically acceptable polymer." The specification stated that "[t]he pharmaceutically acceptable polymer is a water-soluble hydrophilic polymer selected from the group consisting of … methacrylic acid copolymers."[32] *Id*. at 1359. Sandoz argued that since the specification expressly limits "pharmaceutically acceptable polymer" to "a water-soluble hydrophilic polymer," the claims do not encompass any water-insoluble polymer. Abbott argued, however, that the definition of "a pharmaceutically acceptable polymer" expressly includes methacrylic acid copolymers, which are known to encompass both water-soluble and insoluble polymers. Accordingly, Abbott argued that the claims should be construed as encompassing both water-soluble and -insoluble polymers. The district court, and ultimately the Federal Circuit, agreed with Abbott and held that "the existence of water-insoluble polymers from the specifically-mentioned methacrylic acid co-polymer subset actually militates towards a broader construction urged by Abbott that would encompass water-insoluble methacrylic acid co-polymers." *Id*.

A claim reciting detection of "a complex as formed" does not require detection of the complex itself even though all the methods described in the specification detect the complex itself; an applicant is not required to describe every conceivable and possible future embodiment of his invention.

In *Innogenetics, N.V. v. Abbott Labs*., 512 F.3d 1363, 85 U.S.P.Q.2d 1641 (Fed. Cir. 2008), Innogenetics sued Abbott for infringing a claim directed to diagnostic tools that not only detect but also classify hepatitis C virus (HCV) genotypes in a biological sample. The claim required hybridizing nucleic acids with a probe and "detecting a complex as formed with said probe and said nucleic acids." *Id*. at 1368.

Abbott argued that the word "as" limits the claim to detecting hybridized complexes in a contemporaneous manner, thereby excluding its product that detects the formation of the complex after it has been destroyed, and not the actual complex itself. Specifically, Abbott argued that the specification disclosed that the detection of hybrids "may be determined by means of colorimetric, fluorescent, radiometric detection or any other method comprised in the state of the art" and that all these methods related to "contemporaneous detection because the described embodiments all feature detection of an actual complex." *Id*. at 1370 (emphasis omitted). The court was not persuaded. "A plain reading of the claim limitation suggests that it does just what it says — it detects the **formation** of a complex between a probe and nucleic acids of the HCV. Nowhere does the claim language suggest that it only detects the complex itself." *Id*. (emphasis added). The court added that "an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Id*.

The Federal Circuit emphasizes the importance of the prosecution history in construing claims, and holds that prosecution history trumps doctrine of claim differentiation.

In *Regents of the Univ. of Cal. v. DakoCytomation Cal., Inc.,* 517 F.3d 1364, 85 U.S.P.Q.2d 1929 (Fed. Cir. 2008), the Federal Circuit reviewed the district court's construction of the phrase "heterogeneous mixture of labeled unique sequence nucleic acid fragments" as meaning fragments that include only unique sequence fragments, which excluded the accused kits since they contained repetitive sequences in addition to unique fragments. Looking at the prosecution history, the court found that the term "unique sequence" was "clearly added [to the claims] to overcome [an] enablement rejection." *Id*. at 1372-73. By restricting the heterogeneous mixture to labeled probes of unique sequences, the applicants sought to avoid the problem resulting from probes binding to the repetitive sequences, i.e., too much background. Moreover, in prosecuting the application that matured into the '842 patent, the applicants indicated that "[a]ll of the newly added claims are directed"

[32] These are the same claims construed by the court in *Abbott Labs. v. Andrx Pharm., Inc*., 473 F.3d 1196, 81 U.S.P.Q.2d 1289 (Fed. Cir. 2007). There, the Federal Circuit concluded that the use of the term "is" was not setting forth a definition. Furthermore, the court noted that dependent claims further defined the polymer as water-soluble, thereby supporting the broader construction of the independent claim under claim differentiation.

to an embodiment of the invention in which repetitive sequences would be blocked. *Id*. at 1374 (emphasis omitted).

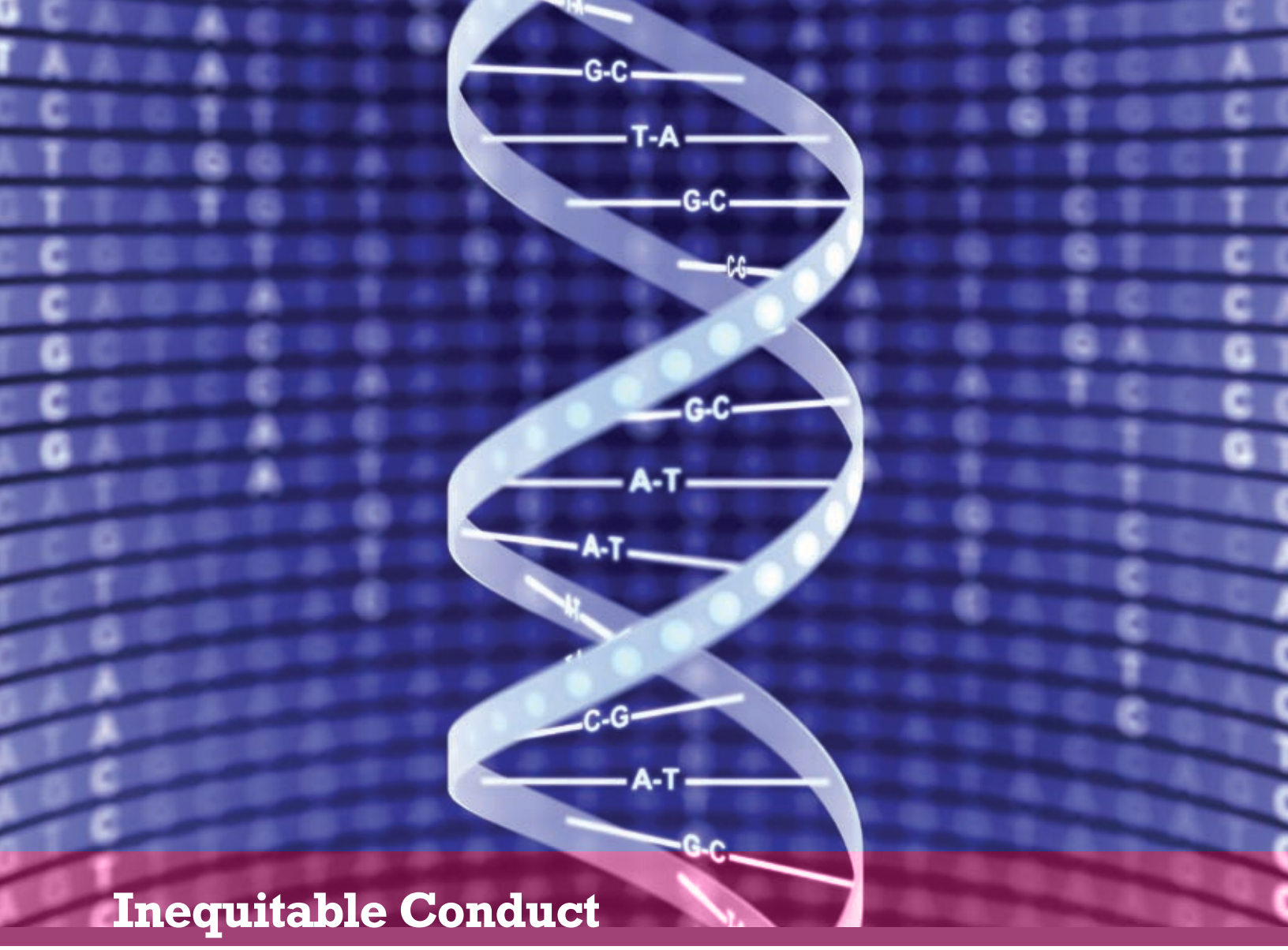
The University of California ("UC") argued for a broader construction of the limitation, pointing out that, since certain dependent claims require inclusion of repetitive sequences, under the doctrine of claim differentiation the independent claims are presumed to be broad enough to include repetitive sequences. The court was not persuaded. "Presumptions are rebuttable. We have held that 'while it is true that dependent claims can aid in interpreting the scope of claims from which they depend, they are only an aid to interpretation and are not conclusive.' " *Id*. at 1375 (citing *N. Am. Vaccine, Inc. v. Am. Cyanamid Co*., 7 F.3d 1571, 1577 (Fed. Cir. 1993)). The court found that, in this case, "the prosecution history overcomes the presumption." *Id*.

The second issue the Federal Circuit addressed was whether the district court erred in construing the limitation "morphologically identifiable cell nucleus," which appears in both the '841 and '479 patents, as "a single cell nucleus that contains the full complement of chromosomal DNA." Id. at 1379. UC argued that the claim merely requires that the nucleus be "capable of being identified by its form or function" and does not require the full set of DNA. *Id*. The court agreed, and adopted UC's construction. "First, the plain language of the claim term suggests that the nucleus must be identifiable by form or structure, and … does not indicate that a full set of chromosomal DNA must be present in the cell nucleus." *Id*. Indeed, the term "morphological" generally refers to form or structure, and not to chromosomal DNA content. "In addition, the prosecution history of the '841 patent reveals that the term … was added to the claim to clarify that the target chromosomal DNA remained in a natural biological structure during in situ hybridization." *Id*. The court could not find any indication in the prosecution history that the term "morphologically identifiable" was added to impose a requirement that the cell nucleus must retain its full complement of chromosomal DNA.

An applicant's motivation in making narrowing amendments is relevant to the doctrine of equivalents analysis, and where such amendments are not directly related to the accused product, the applicant can rebut the presumption of total surrender.

The final issue the court addressed was whether the district court erred in barring UC from asserting that Dako's use of synthetic peptide nucleic acids (PNAs) in its accused products infringed the patent under the doctrine

of equivalents. UC argued that the doctrine of prosecution history estoppel did not apply because the "nucleic acid" limitation was never narrowed during prosecution, and even if the doctrine did apply, any presumption of surrender was overcome because the amendment was merely tangential to the accused equivalent. This time the court agreed with UC. After concluding that the patent claims were amended for a substantial reason related to patentability, and thus subject to a presumption of surrender under *Festo*, the court held that the presumption had indeed been overcome. *Id*. at 1377-78. Specifically, the focus of the applicants' arguments during prosecution centered on the method of blocking, and not on the particular type of nucleic acid that could be used for blocking. "Indeed, the 'nucleic acid' limitation was never narrowed during prosecution and was not at issue." *Id*. Accordingly, UC had "met [its] burden of showing that the amendment did not surrender the equivalent in question because the narrowing amendment was only tangential to the accused PNA equivalent, *i.e*., the peptide nucleic acid." *Id*.



Inequitable Conduct

There is no inequitable conduct in presenting "mere attorney argument" on the lack of relevance of a reference when both the reference and the foreign search report discussing the relevancy of the reference were provided to the PTO.

In *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 85 U.S.P.Q.2d 1641 (Fed. Cir. 2008), Abbott charged Innogenetics with inequitable conduct for advising the PTO that the prior art references "do not relate to the invention and, therefore, further discussion of the same is not necessary," even though one of the references had been found anticipatory in a corresponding European application. *Id*. at 1379. At trial, the prosecuting attorney admitted that such statement was simply boilerplate and that he had actually never reviewed the reference. The Federal Circuit held that this did not amount to inequitable conduct. Specifically, the court noted that Innogenetics submitted both the reference and the international search report, which set forth that the reference was problematic to the EPO. Furthermore, the court held that Innogenetics' attorney's statement that the references do not relate to the invention was "mere attorney argument and our precedent has made clear that an applicant is free to advocate its interpretation of its claims and the teachings of prior art." *Id*.

An inventor's detailed notes taken from a poster presentation are material for purposes of inequitable conduct where they contradict applicant's arguments distinguishing a much less detailed prior art abstract on which the presentation was based.

In *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 85 U.S.P.Q.2d 1582 (Fed. Cir. 2008), Bayer charged Monsanto with infringing its patents directed to transforming plants with a gene for Bt toxin. Monsanto argued that the patents

were unenforceable due to inequitable conduct. Specifically, Monsanto accused Bayer of failing during prosecution to disclose its full knowledge of the subject matter of an abstract from a poster presentation made at a scientific conference. The subject matter of the abstract was production of a chimeric gene comprising an amino terminal portion of Bt toxin fused to a selectable marker protein that could be used to select recombinant cells. The abstract itself, however, was quite vague in terms of the particular *Bt* gene used, the point at which the gene was truncated, and whether the truncated gene was ever successfully formed into a fusion gene construct that expressed toxicity to insects. By contrast, the poster presentation, which a Bayer inventor attended, reported the specific truncation, that the truncated gene encoded a toxic protein, that the truncated gene was successfully employed to create a chimeric gene encoding a fusion protein that expressed a toxic protein in a bacterial system, and that such chimeric gene was successfully inserted into a plant expression vector. *Id*. at 1234-36.

The court agreed with the district court's conclusion "that the poster notes would stand in 'sharp contradiction' to Bayer's argument before the patent examiner, in which Bayer argued that the construct described in the Barnes Abstract was non-toxic and non-enabled." *Id*. at 1239. The court concluded that "[i]n light of these discrepancies between the interpretation of the … Abstract Bayer advocated and the information contained in the [inventor] notes, the … notes clearly and convincingly 'refute, or [are] inconsistent with,' a position the applicant took in opposing the Examiner's argument of unpatentability" and, therefore, "the notes meet the standard for materiality." *Id*. at 1239-40 (last two alterations in original). The court hastened to add, however, that it was not announcing a per se rule "that all internal documents of potential relevance must be submitted to the PTO as a matter of course. Rather, it is the particular circumstances that render the internal documents material in this case." *Id*. at 1240.

Conspicuously absent from the court's opinion is any indication whether the conference and poster presentation attended by the Bayer inventor were in their own right prior art. Presumably had the presentation been prior art, Bayer's failure to disclose it would have been a material omission and the case would have been straightforward. But if the presentation was not prior art, then it is hard to understand its relevance. For example, if the more detailed disclosure on which the inventor made notes had appeared in a reference published ***after*** Bayer's filing date, rather than at a scientific conference, would the court still have found the inventor's notes to be material? One suspects the answer is no. It is noteworthy that nowhere in the court's opinion is there an indication that Bayer improperly characterized the teachings of the abstract itself and, in any event, the examiner had that abstract to review herself. This case is therefore difficult to reconcile with the *Ortho* case reported below, in which the court found no inequitable conduct in a very similar situation.

Determination of whether information is material for purposes of inequitable conduct is made concerning claims pending at the time applicant learns of the information, and not concerning the claims as issued.

Bayer argued that the notes were immaterial because the Bt toxin used by the author of the abstract was not identical to the Bt toxin claimed. Agreeing that the toxins were indeed different, the court nonetheless found that "at the time of the Examiner's rejection, Bayer was not limiting its claim to one species of Bt toxin protein but was broadly claiming a chimeric construct encoding any 60-80 kD N-terminal fragment of a Bt toxin protein. Thus, any species of chimeric gene … within this genus would directly implicate the allowability of Bayer's claims." *Id*. at 1238.

An applicant who only "repeated the disclosure" of the references does not commit inequitable conduct by failing to divulge nonpublic testing that it conducted on compounds disclosed in the references.

In *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc*., 520 F.3d 1358, 86 U.S.P.Q.2d 1196 (Fed. Cir. 2008), Mylan accused Ortho-McNeil ("Ortho") of committing inequitable conduct by failing to disclose to the PTO the results of nonpublic tests it had conducted on prior art compounds. Ortho did submit the references themselves. According to Mylan, Ortho's statements during prosecution that the prior art compounds did not have utility as anticonvulsants were inconsistent with Ortho's own internal data. The court disagreed, holding that Ortho "did not make misrepresentations to the Patent Office during prosecution" and "made no assertions about the compounds themselves, but only repeated the disclosures of the … references." *Id*. at 1363. The court observed that the "references do not disclose any utility. On this point, the applicant is correct." *Id*.

So why was it that it was not material when Ortho withheld its nonpublic information regarding the property of the prior art compound but it was material when Bayer withheld its nonpublic information regarding the prior art chimeric genes? One possible distinction is that Ortho's undisclosed nonpublic information was generated by Ortho itself rather than the author of the reference, whereas Bayer's undisclosed

nonpublic information derived from the author of the reference. Another possible distinction is that Ortho's information supplemented, but was not inconsistent with, the prior art, whereas Bayer's information purportedly contradicted what was stated in the prior art. While such distinctions might provide some comfort, it is still difficult to reconcile these cases. The simple fact is that the notes were not, as held by the court, inconsistent with a position the applicant took in opposing the examiner's argument of unpatentability because the ***applicants' remarks related to the abstract whereas the inventor's notes related to the conference and poster, which were not being distinguished or, for that matter, even alleged to be prior art.*** Accordingly, just as Ortho properly characterized what was taught in the four corners of its prior art, Bayer likewise properly characterized what was taught in the four corners of the abstract.

The court distinguishes* McKesson *decision and finds no inequitable conduct for failing to disclose rejections in co-pending application in view of applicants' belief that claimed compounds were separately patentable over co-pending application, even though applicants ultimately did not pursue that argument.

In *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd*., 533 F.3d 1353, 87 U.S.P.Q.2d 1452 (Fed. Cir. 2008), Teva charged Eisai with inequitable conduct by failing to disclose to the examiner a co-pending application as well as rejections from that application's prosecution that would have applied to the patent-in-suit. Eisai claimed that it failed to cite the rejections in the co-pending application because it considered the claims in the instant application to be separately patentable over those claimed in the other application. The district court "found credible" Eisai's argument and ruled that it had not committed inequitable conduct. "Furthermore, even if a provisional obviousness-type double-patenting rejection might have issued in the prosecution of the [patent-in-suit] due to the co-pending … application, the district court found the materiality of this potential situation low, because applicants routinely overcome this type of rejection … by amending claims or filing a terminal disclaimer." *Id*. at 1360 (quoting from Trial Order). The Federal Circuit affirmed, holding:

> While disclosure of the co-pending … application to the Patent Office during the prosecution of the [patent-in-suit] would have been prudent, Eisai's failure to do so is by no means fatal, for two reasons. First, the district court had ample evidence from which to conclude that the materiality of the … application was low [and] … [s]econd, the record is devoid of any real suggestion of intent to deceive the Patent Office, much less the clear and convincing evidence required to support a finding of inequitable conduct. *Id*. at 1360-61.

There was no inequitable conduct in a case in which the applicant submitted declaration comparing the claimed compound with cited compounds rather than with compound disclosed in related application.

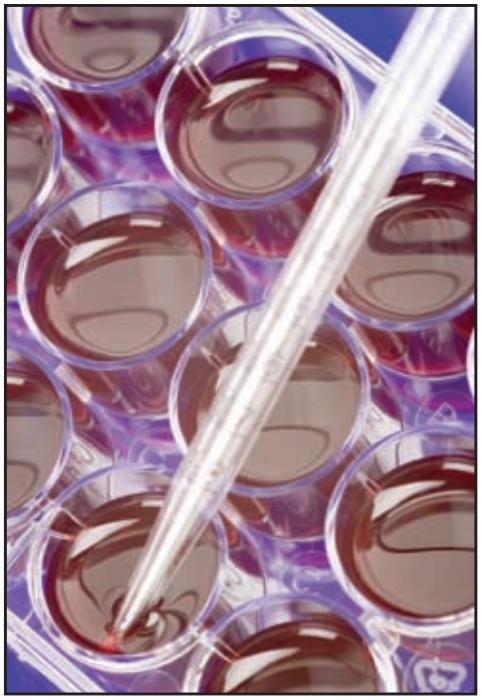
The court also rejected Teva and Dr. Reddy's argument that Eisai committed inequitable conduct by submitting a declaration comparing the claimed compound with two nonprior art compounds but not with the compound disclosed in the co-pending application. The Federal Circuit agreed with the district court's characterization of this argument as "contorted" because the declaration "indisputably showed a comparison" between the claimed compound and the compounds cited by the Examiner demonstrating rabeprazole's superiority." *Id*. at 1362. Noting further that "the materiality of [the related compound] and the patent application claiming it was low," the court concluded that "[t]he data from the … Declaration were relevant to prosecution, but Eisai had no obligation to include additional, unnecessary data such as a comparison to [the related compound]." *Id*. Finally, the court found that Teva and Dr. Reddy "had presented neither direct evidence of deceptive intent nor any evidence to support an inference of materiality." *Id*.

There are few decisions more reviled and feared by patent holders than 2007's *McKesson* decision,[33] which held that applicants have a duty to divulge related co-pending applications as well as the prosecution and prior art cited in those applications, even when those related applications are before the same examiner as the application at issue. There is really no way to reconcile *Eisai* with *McKesson*. Indeed, the *Eisai* panel (Judges Rader, Linn and Prost) did not even try. The silver lining in all this is that *Eisai*, although not overruling *McKesson*, has certainly called into question the reach (if not the rationale) of that earlier decision. Notably, neither of the judges in the *McKesson* majority was on the *Eisai* panel. The take-home message, therefore, may be that the enforceability of a patent may boil down to the luck of the draw in terms of the panel that hears the argument.

Inequitable conduct was found when applicant relied on half-life differences between its claimed compounds and the prior art compounds, yet failed to advise the PTO that such comparison was carried out using different doses of the claimed and prior art compounds.

[33] *McKesson Info. Solutions, Inc. v. Bridge Medic., Inc*., 487 F.3d 897, 82 U.S.P.Q.2d 1865 (Fed. Cir. 2007).

In *Aventis Pharma S.A. v. Amphastar Pharm., Inc*., 525 F.3d 1334, 87 U.S.P.Q.2d 1110 (Fed. Cir. 2008), the court reviewed whether applicants had committed inequitable conduct during prosecution of a patent directed to a composition comprising low molecular weight heparins ("LMWHs"), marketed commercially as Lovenox®. In response to prior art rejections during prosecution, Aventis filed a declaration asserting that its claimed compounds had different half-lives than prior art compounds. Amphastar accused Aventis of committing inequitable conduct by failing to disclose that the half-life studies comparing the claimed and prior art compounds were at different doses. The district court agreed with Amphastar and ruled that Aventis's failure to disclose this information was material since the examiner relied on Aventis's representation that the difference in mean half-life was statistically significant in allowing the application. The court also found that Aventis intended to deceive the PTO since there was no credible explanation for withholding the dosage information of the prior art compounds. The Federal Circuit agreed with the district court as to materiality, but as to intent remanded because "the reasonableness of the comparison at different doses is relevant to determining whether there was an intent to deceive in withholding the dosage of the [prior art] composition." *Id*. at 1342



On remand, the district court again concluded that Aventis had committed inequitable conduct, and Aventis appealed once more. At the Federal Circuit, Aventis argued that it lacked the requisite intent to deceive because it had submitted the half-life comparisons in response to the obviousness rejection rather than to demonstrate a compositional difference to address the anticipation rejection. According to Aventis, while not appropriate for anticipation, it was appropriate to compare different doses "if the purpose is to establish a difference in property," in which case "it is more appropriate to use the 'clinically relevant dose.' " *Id*. at 1344. Aventis argued that the district court had erred by focusing on compositional differences, i.e., anticipation rather than obviousness, and by concluding that the purpose of the half-life comparisons was to show compositional differences in rebuttal to an anticipation rejection. The Federal Circuit rejected this argument, pointing out that Aventis's declaration had failed to distinguish between anticipation and obviousness, and, in any event, the district court had indeed recognized the existence of both the obviousness and anticipation rejections and that the half-life comparisons were, at least in part, intended to show compositional differences. *Id*. at 1346.

Even if the examiner could have figured out from submitted experiments that the applicant used different doses in comparing the claimed and prior art compounds, that does not negate intent to deceive if the data was presented in a misleading way.

Aventis also argued that it had in fact disclosed the dosage information for the patented compound since example 6 "provided half-life data for the patented compound at 60 mg as well as at 40 mg" and "attached the raw half-life data for the patented compound … which showed that the half-life of the patented compound was less at a 60 mg dose than at the 40 mg dose that was used in the comparison with the [prior art] compound." *Id*. at 1348-49. The Federal Circuit disagreed, holding that "[e]ven if we acknowledge that half-life data at other doses for the patented compound were provided to the examiner, the data were provided in a very misleading way." *Id*. at 1349.

No intent to deceive was found based on a misstatement in a provisional filing that was corrected in the nonprovisional or where the accused failed to meet its initial burden that prior art was intentionally withheld, even where patentee's rebuttal was deemed noncredible.

In *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co*., 537 F.3d 1357, 88 U.S.P.Q.2d 1001 (Fed. Cir. 2008), the court addressed whether Star engaged in inequitable conduct in a claim directed to a process of substantially preventing the formation of at least one nitrosamine in a harvested tobacco plant ("tobacco specific nitrosamines" or "TSNAs"). The invention was based on the observation that formation of dangerous nitrosamines could be reduced by providing "an airflow sufficient to substantially prevent an anaerobic condition" around the plant during curing. *Id*. at 1364. The district court inferred an intent to deceive based on (1) that during

prosecution, counsel failed to submit to the PTO a letter disclosing that the probable cause for the absence of TSNA in tobacco cured in China "was their use of the old [radiant heat] flue-curing techniques," which were of course less anaerobic than techniques in which the tobacco was cured with the exhaust of a gas; and (2) that counsel included an inaccurate statement in the provisional application that prior art radiant heat curing produced high levels of TSNAs in American tobacco. *Id*. at 1361-62, 1365 (alteration in original).

The Federal Circuit held that neither omission evinced an intent to deceive. As for the inaccurate statement in the provisional, the court noted that "[w]hile we do not hold that inaccurate statements made in provisional applications cannot evidence an intent to deceive, we note that provisional applications are not examined and that the alleged misrepresentation here was corrected prior to examination of the non-provisional applications. As such, we hold that this statement is not clear and convincing evidence of deceptive intent." *Id*. at 1367 n.7. The Federal Circuit also held that the district court improperly found deceptive intent based on RJR's theory that plaintiffs "conspired" to prevent disclosure of the letter to the PTO by replacing its first prosecuting counsel with new counsel who was purposely kept ignorant of the letter. *Id*. at 1367-68. The court noted that even if Star's explanation that it replaced counsel for performance-related issues was not to be believed, "it remained RJR's burden to prove its allegation regarding the reason for the [first] firm's dismissal. RJR cannot carry its burden simply because Star failed to prove a credible alternative explanation." *Id*. at 1368 (emphasis omitted). Rather, "[t]he patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence." *Id*. The court found that RJR failed to meet that threshold burden that an intent to withhold the letter had anything whatsoever to do with the change of counsel.

Where "actual data" of Cmax were before the PTO, there was no inequitable conduct in representing to the PTO that the data were "statistically significant" in an inventor declaration even in view of later admission by the inventor that no statistical analysis had been carried out.

In *Abbott Labs. v. Sandoz, Inc*., 544 F.3d 1341, 89 U.S.P.Q.2d 1161 (Fed. Cir. 2008), Sandoz charged Abbott with committing inequitable conduct when prosecuting its patent for controlled release antibiotic formulations. During prosecution Abbott had submitted an inventor declaration comparing the Cmax values of the invention with those of a prior art formulation and stating that the difference in Cmax values was "statistically significant[]." *Id*. at 1353. But in litigation the inventor admitted not having actually analyzed the statistical significance of the data and acknowledged that one could not definitively conclude that there in fact was a statistically significant difference in C_{max} values. Nonetheless, the district court found that Sandoz had failed to show materiality, noting that: (1) the actual data were before the PTO and such data did in fact show a lower C_{max} for the inventive formulation; (2) no patent claim required the

extended release formulation to have a statistically significant lower C_{max} than the prior art formulation; and (3) the extended release formulation was in fact pharmacokinetically different from the immediate release suspension formulation. *Id*. at 1354. The court also rejected Sandoz's argument that deceptive intent is inferred from materiality alone, holding that precedent requires independent proof of deceptive intent. *Id*. at 1354-55. On appeal, the Federal Circuit found no abuse of discretion, and affirmed the district court. *Id*. at 1355.

It is interesting to contrast this case with *Aventis*. In particular, it will be recalled that the court in *Aventis* rejected Aventis's argument that its failure to divulge in its declaration that it carried out its comparison of the inventive formulation and the prior art formulation at different doses did not evince an intent to deceive because it had submitted the raw data demonstrating that it had indeed used different doses in the comparison. The court noted that Aventis nonetheless presented such data "in a very misleading way." By contrast, in *Abbott* the court found no intent to deceive by Abbott because, among other things, the raw data were before the examiner even though the inventor had not determined that the reported release values were statistically significant, as represented to the PTO.

Data submitted to FDA showing that the prior art formulation had lower taste perversion than the claimed formulation, which was contrary to information in the patent application, was not "material" under "reasonable examiner" standard because different dosage levels were employed.

Sandoz next challenged Abbott's failure to submit clinical test results, conducted after the application was filed, showing that the prior art immediate release formulation has a lower incidence of taste perversion than the claimed extended release formulation, contrary to statements contained in the patent application. Abbott responded that the tests were from dosages that were not directly comparable, and that they did not change the correctness of the data in the patent application. Agreeing with Abbott, the district court concluded that, although the taste results met the materiality criteria of Rule 56, a reasonable examiner would not have considered the information important in deciding whether to grant the patent because the dosages were not comparable. The district court also observed that Sandoz had presented "no evidence of deliberate withholding of this information in order to deceive the patent examiner." *Id*. The district court again noted that "[m]ateriality is not evidence of intent, which must be established as a separate factual element of a discretionary ruling of inequitable conduct." *Id*. at 1356. The Federal Circuit found no abuse of discretion. *Id*.

Information material to the patentability of a cancelled or withdrawn claim, but not material to the patentability of any remaining claim, need not be submitted.

Sandoz argued that Abbott's alleged inequitable conduct during prosecution of one patent tainted a second patent in which a taste perversion claim had been included before being cancelled in a preliminary amendment. The district court declined to hold the second patent unenforceable based on the canceled claim, citing 37 C.F.R. §1.56(a), which states: "Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application." The district court deemed it "wholly inequitable to hold a patent to be invalid for fraudulent conduct in the prosecution of a claim that was withdrawn before actual prosecution had even begun." *Id*. at 1357. The Federal Circuit affirmed, concluding that the district court did not abuse its discretion. *Id*. at 1358.

There are a number of interesting takeaways from the *Sandoz* case. First, *Sandoz* in conjunction with *Eisai*[34] appear to signal that the Federal Circuit is correcting the excesses in some of the inequitable conduct holdings from 2007, most notably in *McKesson*.[35] Indeed, Judge Newman, who dissented in *McKesson*, wrote the majority opinion in *Sandoz*. Judge Newman even referenced the Supreme Court decision in *Zurko*[36] for the proposition that the PTO is owed greater deference in the context of inequitable conduct such that routine prosecution acts and even mishaps cannot rise to the level of inequitable conduct. *Id*. at 1357-58. For those of us in the trenches of day-to-day prosecution, these cases are a welcome reprieve from the paralyzing uncertainty created in the wake of *McKesson*. A second interesting takeaway is that the court continues to apply its own standard of "materiality," i.e., whether a reasonable examiner would consider the information important in deciding whether to grant the patent rather than the standard set forth in Rule 56.[37] This case perfectly illustrates where information that meets materiality under Rule 56 does not meet the "reasonable examiner" standard used by the Federal Circuit. The final takeaway is that the court continues to reiterate that materiality by itself is insufficient to show intent.

[34] *Eisai Co. Ltd. v. Dr. Reddy's Lab*s., 533 F.3d 1353, 87 U.S.P.Q.2d 1452 (Fed. Circ. 2008).
[35] 487 F.3d 897, 82 U.S.P.Q.2d 1865 (Fed. Cir. 2007).
[36] *Dickinson v. Zurko*, 527 U.S. 150, 50 U.S.P.Q.2d 1930 (1999).
[37] 37 C.F.R. § 1.56 (2008).

Declaratory Judgement/Hatch-Waxman

A court finding infringement is authorized to reset the date of ANDA approval even when the FDA approved the ANDA because of the passage of the 30-month stay period without a finding of infringement or granting a preliminary injunction.

In *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 86 U.S.P.Q.2d 1196 (Fed. Cir. 2008), the court was faced with a situation in which (1) a generic manufacturer files an ANDA with a paragraph IV certification; (2) the patent holder obtains a 30-month stay; (3) the 30 months pass without a preliminary injunction or determination of infringement such that the ANDA is approved by operation of law; but (4) after approval, a court finds infringement. Although the statute, 35 U.S.C. § 271(e)(4)(A), is silent on this eventuality, the Federal Circuit held that "the statute, as informed by its legislative history, supports the district court's action of resetting the effective date." *Id*. at 1366. In so holding, the court rejected Mylan's contention that because the statute lays out two specific situations in which the court may reset the effective date of an ANDA approval different from the one at issue, the court had no authority to reset the date in this situation. "[T]he district court correctly discerned that the [specific situations] do not limit the authority of the district court to reset the effective date in circumstances similar to those statutorily listed as indeed suggested by the legislative history for the provision." *Id*.

An ANDA filer can establish declaratory judgment jurisdiction even in a situation in which the patentee has unilaterally granted it a covenant not to sue.

In *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 86 U.S.P.Q. 2d 1289 (Fed. Cir. 2008), the court addressed whether Caraco, who was the second generic manufacturer to file an ANDA against two Orange Book-listed Forest patents directed to the antidepressant Lexapro®, could avail itself of a declaratory judgment action against Forest. Forest sued Caraco on only one of the listed patents, while granting it a covenant not to sue on the other listed patent. According to Forest, this deprived Caraco of a "case or controversy" for the second patent. The district court agreed with Forest. On appeal, Caraco argued that in the Hatch-Waxman context a case or controversy existed despite Forest's covenant not to sue. In particular, Caraco noted that as the second ANDA filer it was forestalled from marketing generic Lexapro® until the first ANDA filer, Ivax, exhausted its 180-day exclusivity period. Under the statute, the only two things that could start Ivax's 180-day exclusivity period were: (1) Ivax's commencement of marketing; or (2)

successful judgments of invalidity and/or noninfringement against both Forest patents. The problem here was that Ivax unsuccessfully challenged the first patent, and was therefore enjoined until the patent's expiration in 2012, and Ivax never challenged the second patent. Accordingly, only a successful challenge by Caraco or another party of both patents (including the one for which Forest granted a covenant not to sue) could break the logjam. *Id*. at 1286-90.

The Federal Circuit began by reiterating that, "[f]ollowing *MedImmune*, proving a reasonable apprehension of suit is only one of many ways a patentee can satisfy the Supreme Court's more general all-the-circumstances test to establish that an action presents a justiciable Article III controversy." *Id*. at 1291. The court found that there was present the "injury-in-fact" requisite for standing, namely "a restraint on the free exploitation of non-infringing goods," *id*. (internal quotations and citation omitted), which the court held to be "exactly the type of injury-in-fact that is sufficient to establish Article III standing under our caselaw." *Id*. at 1292 (citing *Teva Pharms*., 482 F.3d at 1345); *see also id*. at 1293-94 ("In claiming that it has been denied the right to sell non-infringing generic drugs, Caraco has alleged precisely the type of injury that the Declaratory Judgment Act is designed to remedy."). The court found "causal connection" in that Forest's listing of its patent in the FDA's Orange Book effectively delayed FDA approval of Caraco's ANDA. The court found the injury was "redressable" because a favorable judgment would eliminate the delay. *Id*. at 1293. As for "ripeness," the court found the issues were fit for judicial decision and there would be hardship to the parties if the court withheld judicial consideration, noting that further factual development was not needed (1) because Caraco had a complete generic drug product that has been submitted to the FDA for approval, *id*. at 1295, and (2) if Caraco's drug did not infringe Forest's patent, then withholding court consideration of Caraco's suit would have the immediate and substantial impact of delaying FDA approval of Caraco's ANDA. *Id*. at 1295-96.

The final question in *Caraco* was whether Forest's covenant not to sue Caraco on the patent at issue rendered Caraco's declaratory judgment action moot. The court concluded that it did not, acknowledging that although Forest's covenant not to sue eliminated any reasonable apprehension of suit, that was no longer the test, particularly in suits under the Hatch-Waxman Act. *Id*. at 1296. "[I]n the Hatch-Waxman context, regardless of a covenant not to sue, a generic drug manufacturer cannot enter the market without FDA approval." *Id*. Accordingly, Forest's covenant not to sue did not eliminate the controversy with Caraco; only a judgment of infringement or noninfringement (or possibly a consent decree of noninfringement) could resolve the controversy. *Id*. at 1297.[38]

A second ANDA filer's stipulation of validity of an Orange Book-listed patent and patentee's covenant not to sue on its other listed patents precludes the second filer from seeking a declaratory judgment for the other two Orange Book-listed patents even though a favorable judgment would result in an earlier triggering of the first ANDA filer's 180-day exclusivity period.

In *Janssen Pharmaceutica, N.V. v. Apotex, Inc*., 540 F.3d 1353, 88 U.S.P.Q.2d 1079 (Fed. Cir. 2008), Apotex filed an ANDA with a paragraph (iii) certification as to Janssen's first Orange Book patent covering risperidone (thereby agreeing not to market its product until after expiration of the first patent) and paragraph (iv) certifications as to two other patents covering risperidone solutions and methods for their preparation. Before Apotex's ANDA filing, Teva likewise filed an ANDA with the same certifications. Because Janssen never asserted its other two patents against Teva, and since Teva was the first ANDA filer, Teva was entitled to market its product with a 180-day exclusivity period upon expiration of the first patent. Apotex, however, sought declaratory judgment of noninfringement against Janssen's other two patents and, citing *Caraco*,[39] refused to withdraw that request even after Janssen provided it with a covenant not to sue on those other two patents. Apotex did stipulate as to the validity of the first patent.

In support of the court's declaratory judgment jurisdiction over the other two patents, Apotex argued that a finding of invalidity or noninfringement would permit a "prompt launch" of product by Apotex immediately upon expiration of Janssen's first patent as opposed to waiting at least 180 days after the first patent's expiration, corresponding to Teva's exclusivity period.[40] *Id*. at 1357-60. Apotex cited *Caraco* for the proposi-

[38] Earlier in its analysis, the court suggested, but expressly refrained from holding, that a consent decree might have mooted the controversy: "Although we do not so decide, it appears that if Forest would submit to a consent decree that the drug described in Caraco's ANDA does not infringe the '941 patent, such a decree would redress Caraco's alleged injury-in-fact just as well as any other court judgment. Thus, if Forest's objective in granting the covenant not to sue on the '941 patent was to avoid costly litigation with Caraco, this might be the best approach to resolve the controversy between the parties." *Id*. at 1293 n.11.

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

[40] The commercial launch trigger was the only one available to Teva to start its 180-day exclusivity. Teva could not rely on the judgment trigger because it agreed to wait for the expiration of the first patent and failed to obtain a favorable court judgment on the other two patents. By contrast, a declaratory judgment would have permitted Apotex to seek a favorable court judgment that the other two patents are invalid or

tion that despite the existence of a covenant not to sue, a declaratory judgment claim brought under the Hatch-Waxman Act presents a justiciable Article III controversy. *Id*. at 1360.

The Federal Circuit found that Apotex did not satisfy the requirements for declaratory judgment jurisdiction. It held that because Apotex "stipulated to the validity of the [first] patent," even if it successfully invalidated Janssen's other two patents, it still could not obtain FDA approval until the first patent expired. *Id*. Thus, "Apotex is being excluded from the market by Teva's 180-day exclusivity period — a period which Teva is entitled to under the Hatch-Waxman Act." *Id*. at 1361. Unlike *Caraco*, "Apotex's inability to promptly launch its generic risperidone product because of Teva's 180-day exclusivity period is not a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act." *Id*.

Fear that the first ANDA filer will indefinitely delay its 180-day marketing exclusivity period after expiration of the patent is not sufficiently "definite and concrete" or "real and substantial" to give rise to a justiciable Article III controversy.

The court also rejected Apotex's argument that its product launch could be indefinitely delayed because "Teva does not have to commercially launch immediately after the expiration of the [first] patent." *Id*. at 1362. The court found that there was no "basis to conclude that Teva will, or is likely to, delay in bringing its generic product to market in the future," and thus the dispute was not sufficiently "definite and concrete" or "real and substantial" to give rise to a justiciable Article III case or controversy. *Id*. at 1363. Finally, the court rejected Apotex's argument that Janssen's covenant not to sue was deficient since it failed to protect Apotex's affiliates, suppliers and downstream customers. The court found that "[t]he covenant expressly gives Apotex protection from suit for 'manufacture [and/or] having manufactured' the claimed product," which "expressly covers all suppliers and affiliates involved in the manufacturing process," and which "protects all of Apotex's customers without any distinction between direct and downstream customers." *Id*. (second alteration in original).

Even post-*MedImmune*, a "case or controversy" requires a real and immediate injury or threat of future injury that is an objective standard that cannot be met by a purely subjective or speculative fear of future harm; a history of past lawsuits between the parties and a patentee's refusal to sign a covenant not to sue does not rise to a "case or controversy."

In *Prasco, LLC v. Medicis Pharm. Corp*, 537 F.3d 1329, 87 U.S.P.Q.2d 1675 (Fed. Cir. 2008), the court again addressed the scope of declaratory judgment jurisdiction in view of *MedImmune*[41] and concluded that this particular case did not present an Article III "case or controversy." Prasco made a generic benzoyl peroxide cleansing product OSCION™ for which it sought a declaratory judgment of noninfringement against several Medicis patents. At the time that Prasco filed its declaratory judgment action, it had not yet begun marketing OSCION™, but had devoted substantial efforts to development and marketing plans. Prasco based its alleged Article III jurisdiction on (1) Medicis's marking of its own TRIAZ® products with the numbers of the four patents-in-suit; (2) a previous infringement suit brought by Medicis against Prasco involving a different patent and cleanser product; and (3) Medicis's refusal to grant Prasco a covenant not to sue under the four patents. In addition, Prasco sent a sample of OSCION™ and an ingredient list to Medicis. *Id*. at 1334-35.

The court began by reiterating the post-*MedImmune* standard for establishing declaratory judgment jurisdiction. It noted that, "[w]hile the Supreme Court rejected the reasonable apprehension of suit test as the sole test for jurisdiction, it did not completely do away with the relevance of a reasonable apprehension of suit. Rather, following *MedImmune*, proving a reasonable apprehension of suit is one of multiple ways that a declaratory judgment plaintiff can satisfy the more general all-the-circumstances test to establish that an action presents a justiciable Article III controversy." *Id*. at 1336 (citing *Caraco*, 527 F.3d at 1291). The court added that "*MedImmune* clarified that an injury-in-fact sufficient to create an actual controversy can exist even when there is no apprehension of suit, [but] it did not change the bedrock rule that a case or controversy must be based on a real and immediate injury or threat of future injury that is caused by the defendants — an objective standard that cannot be met by a purely subjective or speculative fear of future harm." *Id*. at 1339 (emphasis omitted).

Considering the "totality of the circumstances," the court held that Prasco did not allege a controversy of sufficient "'immediacy and reality' to create a justiciable controversy." *Id*. at 1338. The court explained that "([t]he mere existence of a potentially adverse patent does not cause an injury nor create an imminent risk of an injury; absent action by the

noninfringed, thereby starting Teva's 180-day exclusivity period through the judgment trigger both before expiration of the first patent and before Teva could even commercialize the product.

[41] *MedImmune, Inc. v. Genentech, Inc.,* 127 S. Ct. 764, 81 U.S.P.Q.2d 1225 (2007).

patentee, 'a potential competitor … is legally free to market its product in the face of an adversely-held patent.)" *Id*. (citation omitted) (omission in original). The court rejected Prasco's argument that it was suffering "'paralyzing uncertainty' from fear that Medicis will bring an infringement suit against it." *Id*. Indeed, the court observed that Prasco had already launched its OSCION™ product and noted that "a fear of future harm that is only subjective is not an injury or threat of injury caused by the defendant that can be the basis of an Article III case or controversy …. Rather, 'it is the reality of the threat of … injury that is relevant to the standing inquiry, not the plaintiff's subjective apprehensions.' " *Id*. at 1338-39 (citation omitted) (omission in original).

The court also rejected each of Prasco's rationales for declaratory judgment jurisdiction. The court regarded Medicis's marking of its products as "irrelevant to the question of whether Medicis' [sic] believes OSCION™ infringes the applicable patents or will attempt to interfere with Prasco's business on the basis of an allegation of infringement." *Id*. at 1340-41. As for Medicis's past history of enforcing patent rights against Prasco, the court held that "one prior suit concerning different products covered by unrelated patents is not the type of pattern of prior conduct that makes reasonable an assumption that Medicis will also take action against Prasco regarding its new product." *Id*. at 1341. Finally, Medicis's failure to sign a covenant not to sue Prasco, although a factor weighing in favor of declaratory judgment jurisdiction, was deemed insufficient in and of itself because a "patentee has no obligation to spend the time and money to test a competitors' product nor to make a definitive determination, at the time and place of the competitors' choosing, that it will never bring an infringement suit." *Id*.

After* MedImmune*, the second prong of the Federal Circuit's test for declaratory judgment jurisdiction, i.e., whether there has been "meaningful preparation" to conduct potentially infringing activity, remains a necessary element in assessing jurisdiction.

In *Cat Tech LLC v. TubeMaster, Inc*., 528 F.3d 871, 87 U.S.P.Q.2d 1065 (Fed. Cir. 2008), the court addressed whether the district court had jurisdiction to issue a declaratory judgment of noninfringement as to TubeMaster's configurations 1, 2 and 4, in a process for loading catalyst into multitube chemical reactors after Cat Tech sued TubeMaster for infringement for TubeMaster's configuration 3. While acknowledging that the Supreme Court in *MedImmune*[42] "rejected the first prong of our declaratory judgment standard, concluding that the 'reasonable apprehension of suit test' was unduly restrictive," the court noted that "[t]his court has yet to fully consider *MedImmune's* impact on [the second] prong"

[42] *Id*.

of its declaratory judgment standard, and found that "whether there has been meaningful preparation to conduct potentially infringing activity remains an important element in the totality of circumstances which must be considered in determining whether a declaratory judgment is appropriate." *Id*. at 879, 880. Accordingly, "[i]f a declaratory judgment plaintiff has not taken significant, concrete steps to conduct infringing activity, the dispute is neither 'immediate' nor 'real' and the requirements for justiciability have not been met." *Id*. at 880.

Whether there has been meaningful preparation to invoke declaratory judgment jurisdiction requires "immediacy," i.e., the accused devices must be substantially ready for sale, and "reality," i.e., the technology must be "substantially fixed."

The court found "immediacy" because "TubeMaster has taken significant, concrete steps to conduct loading activity with configurations 1, 2 and 4." *Id*. at 881. The court noted that "[b]ecause TubeMaster's loading device designs are customized" for each customer, it could "take no further steps toward manufacturing its … devices until it receives an order from a customer with the appropriate dimensions." *Id*. at 881-82. The court also noted that "TubeMaster has already successfully manufactured and delivered a loading device using configuration 3." *Id*. at 882. Accordingly, "constitutionally mandated immediacy requirements have been satisfied because once the threat of liability to Cat Tech has been lifted, it appears likely that TubeMaster can expeditiously solicit and fill orders for loading devices using configurations 1, 2 and 4." *Id*. As for "reality," the court found the relevant question to be "the extent to which the technology in question is 'substantially fixed' as opposed to 'fluid and indeterminate' at the time declaratory relief is sought." *Id*. (citation omitted). Here, the court concluded that "TubeMaster's technology is 'substantially fixed,' " because its "four basic loading device designs are designed 'to cover virtually all of the reactor configurations that might be encountered at customers' facilities.' " *Id*. Accordingly, the court concluded that "the dispute with Cat Tech is 'real,' not hypothetical, because it appears likely that, once the cloud of liability for infringement is eliminated, the accused products can be produced without significant design change." *Id*. at 882-83. The court also found that "reality" did not require the preparation of sales literature or some disclosure of products to potential customers so long as "there is cogent evidence that a declaratory plaintiff has made meaningful preparation to conduct potentially infringing activity." *Id*. at 883.

Section 271(e)(4)(A) gives court postexpiration jurisdiction over a patent, even where there is no claim for damages, in cases in which the FDA grants the patent holder an additional six months of pediatric exclusivity.

In *In re Omeprazole Patent Litigation*, 536 F.3d 1361, 87 U.S.P.Q.2d 1865 (Fed. Cir. 2008), the district court refused to dismiss Astra's infringement suit against Impax for lack of jurisdiction after Astra's patents expired, and despite Astra's no longer having any claims for damages, because the FDA had granted Astra an additional six-month period of pediatric market exclusivity. The district court held that "it had the authority to enforce Astra's right to market exclusivity under the authority of [35 U.S.C. § 271(e)(4)(A) and under its general equitable authority." *Id*. at 1367. The Federal Circuit agreed that "section 271(e)(4)(A) [provides] a post-expiration remedy for infringement under section 271(e)(2)," noting that "[s]ubparagraph (A) … provides an additional type of relief after a finding of infringement under section 271(e)(2) by requiring the district court to 'order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.' " *Id*.

In sum, the Federal Circuit has spent the past year refashioning the test for declaratory judgment jurisdiction. As the cases discussed above demonstrate, in the wake of *MedImmune*, the bar for establishing a justiciable controversy for declaratory judgment jurisdiction has been lowered. No longer must a plaintiff show a reasonable apprehension of suit. Now it suffices simply to allege a substantial controversy and an injury or threat of injury. A patentee can trigger declaratory judgment jurisdiction by, for example, creating a reasonable apprehension of suit, demanding the right to royalty payments, or creating a barrier to the regulatory approval of a product. Moreover, a patentee can no longer unilaterally destroy jurisdiction, such as by granting the accused infringer a covenant not to sue.

However, as the *Prasco* case demonstrates, there are limits on the court's new, more lenient standard for declaratory judgment jurisdiction. Subjective fear of being sued is not enough; the fear must still be objectively reasonable. Moreover, a patentee's prior litigious conduct and refusal to sign a covenant not to sue, while factors to be considered, are not sufficient, alone or in combination, to create jurisdiction. Nor is the patentee's practice of marking products with its patent numbers sufficient. The controversy has to be "real" and "immediate."

Miscellaneous Cases

Accused formulation not "so far changed in principle" from the patented formulation so as to invoke reverse doctrine of equivalents where defendant relied on extrinsic, rather than intrinsic, evidence, to establish the "principle" of the invention.

In *Roche Palo Alto LLC v. Apotex Inc.*, 531 F.3d 1372, 87 U.S.P.Q.2d 1308 (Fed. Cir. 2008), the court addressed the applicability of the reverse doctrine of equivalents to Roche's claim directed to an ophthalmologic drug formulation "comprising" several components in combination with "an ethoxylated alkyl phenol that conforms generally to the formula: $C_8H_{17}C_6H_4(OCH_2\text{-}CH_2)_nOH$ where *n* has an average value of 40 [O_{40}] in a stabilizing amount between 0.001% and 1.0% wt/vol." *Id*. at 1375. Apotex filed ANDAs with paragraph IV certifications alleging that its generic version of the drug would not infringe under the reverse doctrine of equivalents. Apotex cited *Graver Tank*[43] for the proposition that its formulation was "so far changed in principle from a patented article that it performs the same or similar

[43] *Graver Tank & Mfg. Co. v. Linde Air Prods. Co*., 339 U.S. 605, 128 U.S.P.Q. 557 (1961).

function in a substantially different way, but nevertheless falls within the literal words of the claim." *Id*. at 1377.

Apotex argued that the "principle" of Roche's patent "is the use of O_{40} in an amount sufficient to cause the formation of micelles and thereby provide robust stability to the formulation by preventing interactions between KT and BAC." *Id*. at 1378. Even though micelles were not mentioned in the claims, specification or prosecution history, Apotex cited Roche's reliance on a declaration "demonstrating the unexpected results of formulations containing O_{40}" and argued that this established the "principle" of the invention "since a person of ordinary skill in the art knows that O_{40} stabilizes the formulation by forming micelles." *Id*. By contrast, Apotex argued, "the concentration of O_{40} in [its] formulation is far below the concentration required to form micelles" and thus the Apotex "formulation is stabilized by a completely different ingredient and mechanism, and functions in a 'substantially different way' from the formulation claimed in the … patent."

The court rejected Apotex's arguments, holding that it failed to "properly establish the principle of the … patent," which, according to the court, "is determined in light of the specification, prosecution history, and the prior art," and not by an expert declaration. *Id*. The court found that "there is no support in the claims or specification for micelle formation or for robust stabilization of the formulation by prevention of KT/BAC interactions." *Id*. Nor was there evidence "that the examiner, in allowing the claims, attributed the unexpected results of O_{40} to its superiority in forming micelles." *Id*. Accordingly, the "intrinsic evidence is … inconsistent with Apotex's proffered 'principle' of the … invention." *Id*.

The safe harbor provision of 271(e) does not extend to a system or apparatus that measures the characteristics of devices that are subject to FDA approval, but which is itself not subject to FDA approval.

In *Proveris Scientific Corp. v. Innovasystems, Inc*., 536 F.3d 1256, 87 U.S.P.Q.2d 1602 (Fed. Cir. 2008), Proveris sued Innova over its patented system and apparatus for characterizing aerosol sprays commonly used in nasal spray pumps and inhalers. The device sold by the accused infringer, Innovasystems, was likewise used to measure the physical parameters of aerosol sprays used in nasal spray drug delivery systems. Although Innova's devices were not themselves subject to FDA approval, the nasal spray delivery systems measured with the devices were subject to FDA approval. Innova thereby invoked the safe harbor provision of the Hatch-Waxman Act, arguing that its activities were "immunized" since its devices were "used by third parties solely for the development and submission of information to the FDA." *Id.* at 1260. The court disagreed, noting that one of the purposes of the Act was to eliminate "the *de facto* extension of effective patent life at the end of the patent term … caused by the FDA premarket approval process." *Id*. at 1265. Here, the court found that Innova's device "is not subject to FDA premarket approval" and that Innova therefore, "faces no regulatory barriers to market entry upon patent expiration." *Id*. As a result, Innova is not properly "a party who, prior to enactment of the Hatch-Waxman Act, could be said to have been adversely affected," and thus falls outside "the category of entities for whom the safe harbor provision was designed to provide relief." *Id*.

This decision makes sense. It prevents, for example, an accused infringer using a patented test tube in the course of the FDA approval process for a new compound and invoking the safe harbor. Of course, the Federal Circuit may find it challenging to reconcile this result with that in *Merck v. Integra*,[44] in which the Supreme Court held that the use of a patented reagent in the course of the FDA approval process for a new compound is entitled to the safe harbor. Perhaps the difference is that in *Merck* the accused infringer ultimately planned to make a submission to the FDA, while Innova only sold its device to others who might make such submissions.

District court holds that PTO improperly calculated extension of term by applying "double counting" provision of statute to situations in which different types of delays did not occur on the same day.

In *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 88 U.S.P.Q.2d 1538 (D.D.C. 2008), the U.S. District Court for the District of Columbia held that the PTO has been incorrectly calculating patent term adjustment ("PTA"). Section 154 provides for adjustments of patent term to replace some of the time lost to prosecution delay, including: (1) a one-day extension of term for every day that issuance is delayed due to the USPTO failure to comply with certain statutory deadlines, e.g., a delay beyond 14 months before issuance of the first official action ("A delays"); (2) a one-day term extension for every day after the three-year anniversary of filing the application for the patent to issue ("B delays"); and (3) a one-day term extension for

[44] *Merk KGaA v. Integra Lifesciences I, Ltd*., 545 U.S. 193, 74 U.S.P.Q.2d 1801 (2005).

every day of delay caused by an interference, a secrecy order or an appeal ("C delays").[45]

The *Wyeth* decision involved "A" and "B" delays. Under the statute, if "A delays" and "B delays" overlap, "the period of any adjustment granted … shall not exceed the actual number of days the issuance of the patent was delayed."[46] The purpose of this section is to prevent "double-counting" of periods of delay. *See id*. at 139. According to the USPTO's interpretation of this section, however, any "A delay" overlaps with any "B delay," and thus an applicant can get credit only for an "A delay" or a "B delay," whichever is larger, but never for both. *Id*. at 140. The district court disagreed. It concluded that periods of time "overlap" only if they occur on the same day. *Id*. at 141. Therefore, if an "A delay" and a "B delay" occur on different days, then a patentee may obtain an extension of A + B days. The USPTO has since appealed the district court's decision, and the case is now before the Federal Circuit. Until the Federal Circuit resolves this issue, however, the *Wyeth* decision is controlling law. Pending patent applications most affected by this decision are those having both "A delays" (i.e., administrative delays) and "B delays" (i.e., pendency exceeding three years). In such cases, one must determine whether any "A" and "B" periods "overlap," i.e., occur on the same day. Any overlapping delays are counted only once for purposes of PTA.

[45] 35 U.S.C. § 154 (2000).
[46] *Id*. § 154(b)(2)(A).

Conclusion

This year proved to be one in which the court restored a sense of balance to its review of novel compositions and compounds. This is a welcome change from the past several years, when almost no biotech or pharmaceutical patent survived the court's invalidity or unenforceability axe. Given the patent bar's initial fears that *KSR's*[47] rejection of a rigid "teaching-suggestion-motivation" ("TSM") test reduced the threshold necessary to establish a *prima facie* case of obviousness, there is some irony in this turn of events. Pre-*KSR*, the court seemed intent on invalidating every patent it reviewed just to prove that the TSM test was not too lenient for patentees. By contrast, after *KSR* the spate of invalidations ceased. This cannot be a coincidence. While we can only speculate, it may very well be that the court felt compelled pre-*KSR* to prove to the Supreme Court that its TSM test was not too lenient. Indeed, its pre-*KSR* decisions are replete with references to the TSM test being flexible and that a teaching, suggestion or motivation need not be explicitly found in the prior art. In nearly every instance, invalidation resulted. By contrast, after *KSR* the court no longer felt compelled to defend itself and adopted a more balanced analysis.

Interestingly, it now appears the PTO's Board of Patent Appeals and Interferences is somewhat in front of the Federal Circuit in lowering the *prima facie* obviousness bar. In *Kubin,*[48] to be decided this year, the Federal Circuit will signal whether the PTO has perhaps gone too far.

Similarly, in the area of inequitable conduct, the Federal Circuit seems to have returned to a more balanced approach. Nevertheless there are some loose ends that the court will need to address in the coming year, such as reconciling

[47] *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385 (2007).

[48] *Ex parte Kubin*, 83 U.S.P.Q.2d 1410 (Bd. Pat. App. & Int. 2007).

McKesson[49] and *Eisai.*[50] We predict that in 2009 the court will develop a new approach to inequitable conduct. We already have seen our first hints of this in *Star Scientific*[51] case relating to the burdens, as well as in Judge Rader's dissent in *Sanofi-Aventis.*[52]

Another positive development in 2008 was the large number of post-*MedImmune*[53] cases clarifying the upper and lower reaches of the new declaratory judgment paradigm. Parties have pushed the envelope post-*MedImmune* to expand declaratory judgment jurisdiction. The court has responded by pushing back, signaling that while a plaintiff need not show reasonable apprehension of suit, it must still satisfy the constitutional minimum of standing, i.e., an injury traceable to the patentee that can be remedied by a favorable decision.

If there was one area of disappointment, it was in the court's resurrection of *Eli Lilly*'s written description doctrine. As we stated earlier, the court needs to abandon its fixation with pictures based on a twentieth-century small molecule mindset that simply cannot be applied in molecular biology. Indeed, it is in the areas that are most pioneering, involving the development of whole new pathways and approaches to treating diseases, where the misguided application of this doctrine is hurting science and promoting incrementalism.

[49] *McKesson Info. Solutions, Inc. v. Bridge Medic., Inc*., 487 F.3d 897, 82 U.S.P.Q.2d 1865 (Fed. Cir. 2007).
[50] *Eisai Co., Ltd. v. Dr. Reddy's Labs*., 533 F.3d 1353, 87 U.S.P.Q.2d 1452 (Fed. Cir. 2008).
[51] *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 88 U.S.P.Q.2d 1001 (Fed. Cir. 2008).
[52] *Sanofi-Synthelabo v. Apotex, Inc*., 550 F.3d 1075, 89 U.S.P.Q.2d 1370 (Fed. Cir. 2008).
[53] *Medimmune, Inc. v. Genentech, Inc*., 127 S.Ct. 764, 81 U.S.P.Q.2d 1225 (2007).

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- Author, Is it harder to enforce Pharmaceutical Patents? *The National Law Journal* (2006)
- Author, "Patent Interferences: An Overview of Practice under the New Rules," *IP Litigator*, Volume 11, No. 5 (2005)
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- Author, "Can Old Products Now be Patented Based on Newly Discovered Properties?" (2003)
- Author, "Federal Circuit Raises the Bar on the Written Description Requirement as Applied to Biotech Inventions" (2002)
- Author, "Better to Describe Than Provide: Federal Circuit. Adopts One-Size-Fits-All Approach to Genetic Inventions" (2002)
- Author, "Justices to Decide Validity of Utility Patents on Sexually Reproduced Plants" (2001)

Speeches

- Speaker, Interferences at the Federal Circuit, Intellectual Property Owners Meeting, Washington, D.C. (2008)
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- Speaker, Practicing Under New Interference Rules, AIPLA Midwinter Meeting, Orlando, FL (2005)
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- Speaker, File Wrapper Estoppel after Festo, Greater Richmond Patent Law Association, Richmond, Virginia (2003)
- Speaker, Developments in Interference Practice, General Electric Annual Retreats; Crotonville, New York (2002-2003)
- Speaker, Application of Written Description and Utility Guidelines to Pharmaceutical Inventions, New Jersey Intellectual Property Law Association, Woodbridge, New Jersey (2002)
- Speaker, Recent Developments in Intellectual Property Practice, General Electric Annual Retreat, Newport, Rhode Island (1999)
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- Opinion counsel for numerous pharmaceutical and biotech companies. Prepared formal opinions on variety of issues, including patent validity, enforceability, and infringement.
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- Coauthor, “Federal Circuit hits pharmaceutical patentees hard,” *The National Law Journal* (2008)
- Author and Presenter, “A Crash Course in Better Legal Writing” (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 Journal* 1856 (2008)
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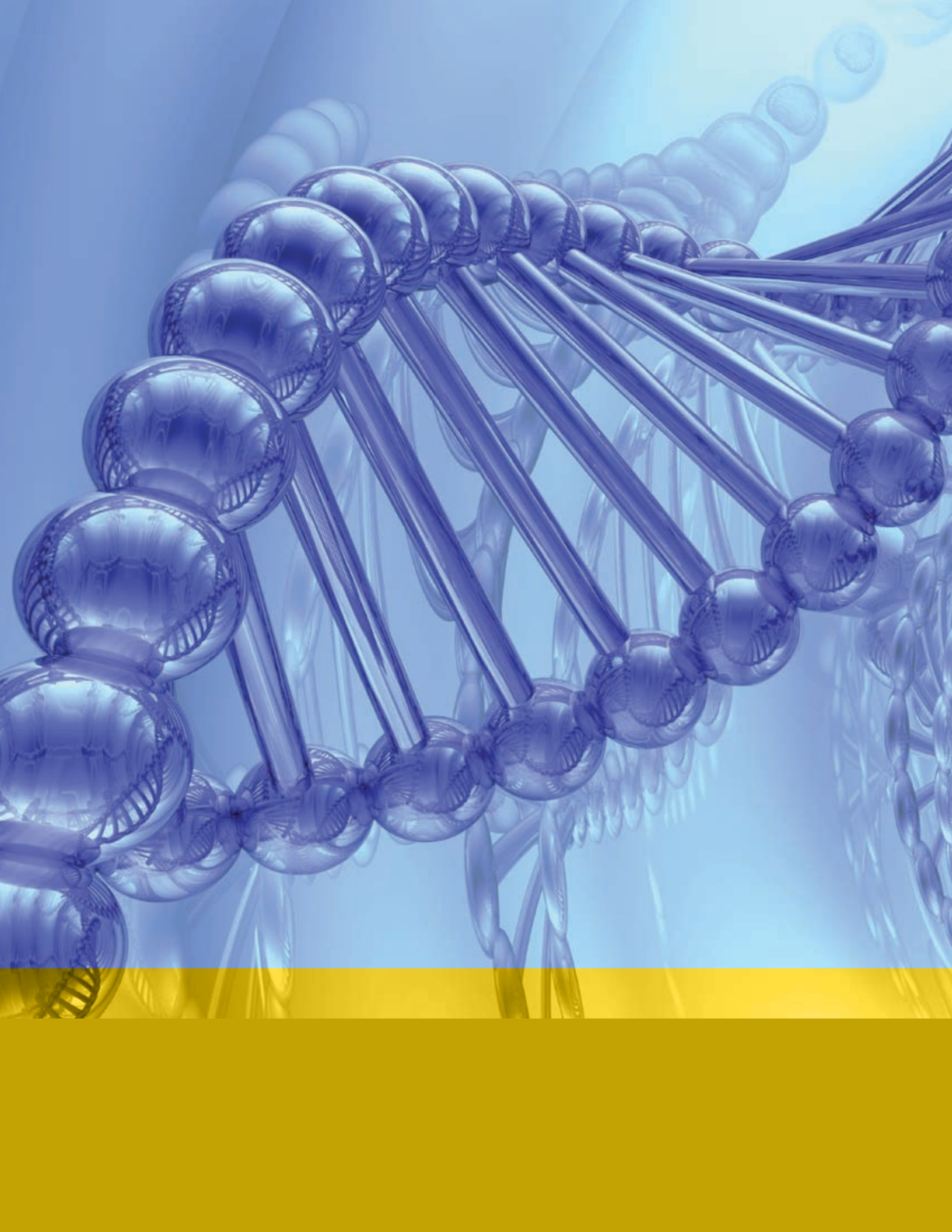

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