



Pharmaceutical, Chemical and
Biotech Year in Review 2009

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Introduction

The year 2009 proved to be one of the more eventful years in terms of biotech and pharmaceutical patent practice. On the patentability side, the court continued to develop its post-*KSR* case law regarding the obviousness of compounds and formulations, often finding novel actives valid and new forms of old actives invalid. We saw a very poignant example of the effects of *KSR* in the *Kubin* case, where the court expressly overruled its earlier holding in *Deuel* and found that a protein now renders *prima facie* obvious the specific DNA encoding that protein. The court also continued to provide guidance as to when an invention that is “obvious to try” is merely an obvious selection from a finite number of identified and predictable solutions on the one hand versus a non-obvious selection based on a myriad of possibilities or reliance on a general approach on the other. In developing its post-*KSR* “obvious to try” jurisprudence, the court has reached back to some of its older case law and defined two very specific situations where an invention that is obvious to try is not obvious.

In our opinion, the court also stumbled somewhat in its case law regarding both anticipation and obviousness. For example, the court found anticipation in a situation where the prior art merely suggested making a compound. The court also corrupted the language of *KSR* to justify disregarding a teaching away by treating the unsuccessful teaching as one of the finite number of predictable solutions of the prior art. Perhaps the most disturbing was the court’s treatment of obviousness double patenting, where the court continued to gut the double patenting safe harbor of 35 U.S.C. § 121 by holding that restricted claims filed in an application labeled “continuation” were not entitled to the safe harbor merely because applicant has not called the application

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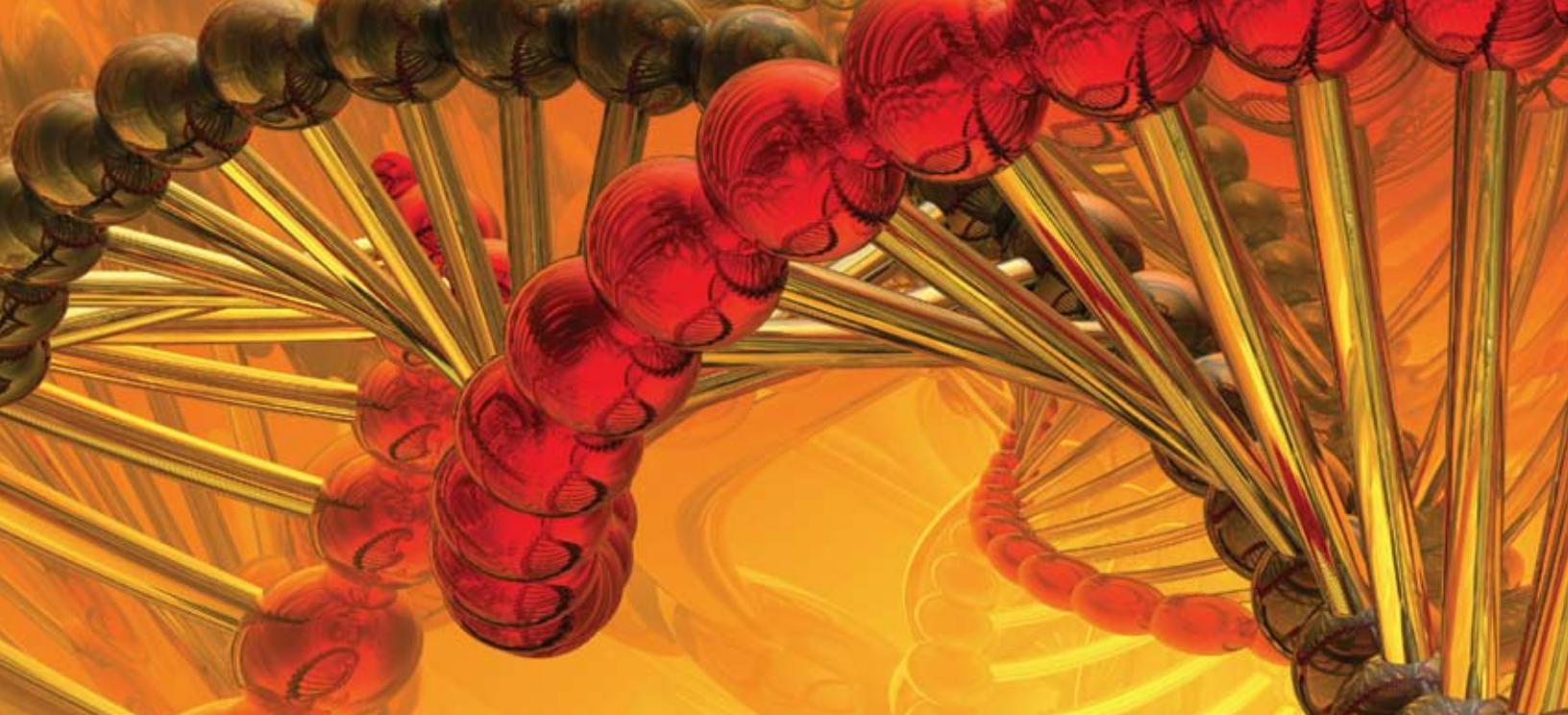


a “divisional.” Similarly disturbing was how the court confused the restriction practice standard for independent or distinct inventions with the standard for obviousness in the context of double patenting. This confusion led the court to hold for the first time that so long as there were alternative processes in existence at the time a divisional is filed, the process claims of the divisional are non-obvious over prior related product claims.

On written description, the court heard *Ariad en banc* and found that 35 U.S.C. § 112, first paragraph includes a separate written description requirement, which came as no surprise to observers. By focusing so intensely on this question, it is our opinion that the court and the interested public have been missing the point. The question is not so much whether there is a separate written description requirement (based on the placement of the comma in the statute according to much of the argument) but rather what the “invention” is that is being described. Sometimes, the “invention” is information (e.g., the discovery of a new receptor whose blockage will have a therapeutically beneficial effect, where it is routine to obtain molecules that will bind that

receptor). Alternatively, sometimes the invention is indeed the structure, such as a compound isolated from a plant having a therapeutic effect, where even a modest change to that structure will dramatically affect the properties of that compound. With the threshold issue of whether there is a separate written description requirement put to rest by *Ariad*, perhaps the court will now be free to focus on the real question of how to apply the written description requirement in particular cases.

Finally, on the infringement side, *Abbott* gave us closure on the question of how to construe product-by-process claims. It came as no surprise to anyone to see this court hold that claims may be construed one way for validity purposes (as products, regardless of the process by which made) and another way for infringement purposes (limited to the process). The court in *Abbott* also expanded the disclosure dedication rule (which holds that subject matter disclosed in a patent but not claimed cannot be captured by the doctrine of equivalents) by applying this rule to disclosure of a crystalline form of a compound that was not disclosed in the patent in suit but in the foreign priority application.



Section 101 Statutory Subject Matter

A method for calibrating the proper dosage of a drug that involved both “administering” and “determining” steps is patent-eligible subject matter under the “transformation” prong of Bilski.

In *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 92 U.S.P.Q.2d 1075 (Fed. Cir. 2009), the Federal Circuit reviewed whether a method of monitoring the administration of a drug satisfied the court’s test for statutory subject matter under *In re Bilski*. The method claims recited steps of:

- (a) “administering” a drug that provides 6-TG to a subject;
- (b) “determining” the levels of the drug’s metabolites, 6-TG and/or 6-MMP, in the subject; and
- (c) comparing the measured metabolite levels to predetermine metabolite levels, “wherein” the measured metabolite levels “indicate a need” to increase or decrease the level of drug to be administered so as to minimize toxicity and maximize efficacy of treatment.

The court framed the issue as whether Prometheus’s claims are “drawn to a fundamental principle or an application of a fundamental principle.” The court referred to its “definitive” *Bilski* test, i.e., that a process is patent-eligible under § 101 if “it is tied to a particular machine or apparatus, or it transforms a particular article into a different state or thing.” Further, this transformation must be “central to the purpose of the claimed

process” and not merely “data gathering.” The court found that the claimed method met the “transformation” prong of *Bilski*, holding that “[w]hen administering a drug such as AZA or 6-MP, the human body necessarily undergoes a transformation. The drugs do not pass through the body untouched without affecting it.” The court held that “[t]he determining step ... is also transformative and central to the claimed methods” because “[d]etermining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation, for those levels cannot be determined by mere inspection.” This transformation is not mere “data-gathering” because “[m]easuring the levels of 6-TG and 6-MMP is what enables possible adjustments to thiopurine drug dosage to be detected for optimizing efficacy or reducing toxicity during a course of treatment.” The court also found that the final “mental step” in the claim of providing a warning based on the results of the prior steps does not detract from the patentability of the “claimed methods as a whole.”

While *Prometheus* should give comfort to patentees who claim therapeutic diagnostic methods, the U.S. Supreme Court is currently reviewing the “machine or transformation” test of *Bilski*. Meanwhile, the Supreme Court has not yet decided Mayo’s petition for certiorari seeking review of this case. If the Supreme Court alters the *Bilski* “machine or transformation” test, the Supreme Court may grant certiorari for purposes of vacating and remanding the *Prometheus* case to the Federal Circuit for reconsideration in view of *Bilski*.



Anticipation/Obviousness

A laminate composed of two layers of “compatible polymeric materials” in terms of softening points is not obvious over prior art showing layers made from the same general classes of materials where such general classes of materials can have different softening points.

In *Süd-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 89 U.S.P.Q.2d 1768 (Fed. Cir. 2009), the court reviewed the validity of a claim requiring that the inner surfaces of the microporous and laminate films be composed of “compatible polymeric materials,” which generally refers to their ability to mix on a molecular scale and their similar softening points. The district court concluded that the prior art films are “compatible” because the prior art reference discloses the same general classes of materials that are identified in the patent, e.g., both films can be made from polyethylene, polypropylene and other polyolefinic materials. The Federal Circuit disagreed, noting that

in concluding that [the prior art] teaches the use of compatible polymeric materials, the district court failed to acknowledge that the specified classes of materials comprise a large number of substances with quite different properties, and that various combinations of those materials can be compatible or incompatible depending on how they are assembled in layers to form the container.

Id. at 1006.

The court found that the prior art “container is formed by heat-sealing a microporous layer with a high softening point to an inner laminate layer with a low softening temperature,” whereas the claimed “container is formed by sealing a microporous layer with a low softening point to an inner laminate layer that also has a low softening temperature.” *Id.* (emphasis omitted). Thus, the district court erred in looking

only to the classes of materials described in the patents and did not examine the softening points of the materials. It therefore failed to recognize that [the prior art] discloses the use of incompatible materials where the ... patent requires compatible materials, and it therefore incorrectly concluded that [prior art] teaches the same container as that claimed in the ... patent.

The court reaffirms that there can be anticipation even when the prior art discloses no utility for the compound and even when that compound is selected from a list of 1,400 other compounds.

In *In re Gleave*, 560 F.3d 1331, 90 U.S.P.Q.2d 1235 (Fed. Cir. 2009), the court reviewed Gleave’s claims directed to anti-sense oligodeoxynucleotides, as well as methods of making them and methods of treating endocrine-regulated cancers by using them to prevent the formation of Insulin-Dependent Growth Factor Binding Protein (“IGFBP”) and particularly IGFBP-2 and IGFBP-5 (Insulin-Dependent Growth Factor Binding Protein (“IGFBP”). The representative claim

required that “substantially all of the oligodeoxynucleotide is complementary to (1) a portion of a gene encoding human IGFBP-2 and (2) a gene encoding human IGFBP-5, and wherein the oligodeoxynucleotide is of sufficient length to act as an antisense inhibitor of human IGFBP-2 and human IGFBP-5.” *Id.* at 1333. The claims were rejected over a reference including a 1,400 member list of every fifteen-base-long sense oligodeoxynucleotide in the IGFBP-2 gene.¹ The reference “also disclosed the general concepts that antisense oligonucleotides are preferably between fifteen and twenty-five bases in length, and that some antisense oligonucleotides may be bispecific (i.e., capable of inhibiting ‘an IGFBP such as IGFBP-2 and/or IGFBP-3’).” *Id.* Finally, the prior art stated “that ‘[a]ntisense oligonucleotides to IGFBP-2 may be selected from molecules capable of interacting with one or more’ of the sense oligonucleotides described in the long list.” *Id.* at 1333-34.

The issue presented on appeal was whether a reference that lists every fifteen-base **sense** oligodeoxynucleotide in a known nucleic acid sequence anticipates or renders obvious claims to specific **antisense** sequences having particular properties. The court began with a discussion of the law, noting that

[a]s long as the reference discloses all of the claim limitations and enables the “subject matter that falls within the scope of the claims at issue,” the reference anticipates—no “actual creation or reduction to practice” is required. This is so despite the fact that the description provided in the anticipating reference might not otherwise entitle its author to a patent.

Id. at 1334 (citations omitted).

The Court finds anticipation of an antisense polynucleotide based on prior art disclosure of sense nucleotides.

Gleave argued that the prior art “does not describe any particular individual antisense species,” because the prior art merely gives the public “ink, formed into strings of letters, without inventive thought and without placing the public in possession of anything new. There is no guidance to make particular selections, and no understanding of which of the targets would be useful, and what the properties of the related antisense would be.”

¹ Interestingly, the reference does not disclose the antisense sequences. Rather, it discloses in example 6 that “antisense oligonucleotides to IGFBP2 may be selected from molecules capable of interacting with one or more of the following sense oligonucleotides.”

Id. at 1335.

The Federal Circuit noted its case law “makes clear that a reference need disclose no independent use or utility to anticipate a claim under § 102.” *Id.*

Here,

Gleave’s claims are to compositions of matter—oligonucleotides—and therefore a reference satisfies the enablement requirement of § 102(b) by showing that one of skill in the art would know how to make the relevant sequences disclosed in [the prior art]. Thus, the fact that [the prior art] provides “no understanding of which of the targets would be useful” is of no import, because Gleave admits that it is well within the skill of an ordinary person in the art to make any oligodeoxynucleotide sequence. As such, [the reference] is an enabling disclosure sufficient to anticipate Gleave’s invention under § 102(b).

Id. at 1335-36 (citation omitted).

The court also rejected Gleave’s argument that no example of an actual antisense oligonucleotide complementary to a sequence in the prior art’s list is shown to have antisense activity

because the simple fact is that Gleave’s composition claims do not require antisense activity either.” The claims at issue merely require the oligodeoxynucleotides to be “of sufficient length to act as an antisense inhibitor of human IGFBP-2 and human IGFBP-5.” ... As explained above, evidence as to whether particular compounds work for their intended purpose is irrelevant to our § 102(b) analysis. Certainly where the claims themselves do not require a particular activity, we have no call to require something more from the anticipating reference.

Id. at 1336.

Selection of claimed compound from among a very large list does not negate anticipation where the art lists all the compounds and such compounds are enabled.

The court next addressed Gleave’s argument that when a listing of specific compounds in the prior art gets long enough, it should be treated as a genus disclosure. The court first distinguished *In re Wiggins*, 397 F.2d 356 (C.C.P.A. 1968), noting that even though the court there found no anticipation where there was a selection among a very large list, the

holding of no anticipation was based on failure to enable the compounds in that list and not on the selection itself.

In this case, Gleave's arguments fail for two reasons. First, [the reference] expressly lists every possible fifteen-base-long oligodeoxynucleotide sequence in IGFBP-2, and under our precedent, this list anticipates Gleave's claims. Second, even if we were to accept Gleave's invitation to treat [the reference] as equivalent to the statement that one "could make antisense that targets IGFBP-2," which we decline to do, a person of ordinary skill in the art equipped with an IGFBP sequence is admittedly capable of envisioning how to make any antisense sequence. Thus, even if we were to adopt Gleave's policy position, Gleave's claims would not be entitled to a patent over [the prior art].

Id. at 1338.

There is an "elephant" in the room in this case that neither Gleave nor the court seems to have addressed: namely, that the oligonucleotides in the reference were not the claimed *antisense* molecules but rather the *sense* molecules from which antisense molecules could be prepared. While no one can argue that one of ordinary skill in the art in possession of the sense sequence was fully enabled to make the corresponding antisense sequence, that is still not **anticipation** of the *antisense* sequence. In other words, the court found anticipation of a molecule that, however obvious, was not actually disclosed in the reference. This may be the low-water mark for anticipation in Federal Circuit jurisprudence. It has certainly been true that precedent does not require a **disclosed** compound to have utility to be anticipatory. It is also certainly true that precedent has found anticipation even when a compound had to be selected from among many compounds in a long list. However, never has anticipation been found for a compound not disclosed explicitly or inherently.

The ramifications of this panel's new spin on anticipation could be rather interesting. For example, if the prior art discloses a racemic compound and also discloses, but does not

actually describe or make, one of the optically pure enantiomers of that racemate, will that now be enough to constitute anticipation? This is precisely what happened in last year's *Sanofi-Synthelabo v. Apotex Inc.*² case, where the court rejected that precise reasoning. While it is true that the court in *Apotex* later found that the preparation of the enantiomer there was not enabled, it nonetheless 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.* at 1084. It is difficult to see how this can be reconciled with *Gleave*,

where the court could have equally held that knowledge that antisense molecules may be prepared based on the structure of the sense molecules is not anticipation of a specific antisense molecule that has not been prepared.

Although claimed 3-pyr EHDP and the prior art 2-pyr EHDP are both bisphosphonates differing only as positional isomers of each other, it is still necessary to identify the reason for the modification.

In *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989, 90 U.S.P.Q.2d 1947 (Fed. Cir. 2009), the court reviewed the district court's holding that P&G's patent directed to risedronate, the active ingredient in the commercial product ACTONEL®, was not invalid. The claimed compound was a 3-pyridine ("3-pyr") hydroxy-ethandiphosphonate

("EHDP"), whereas the closest prior art compound was a 2-pyr EHDP. The compounds are related as positional isomers where the EHDP is connected to the #3 carbon of the pyr ring according to the claimed invention, but to the #2 carbon atom of the pyr ring in the prior art. Teva of course argued that as structural isomers, the claimed and prior art compounds were obvious in view of one another.

"In keeping with the flexible nature of the obviousness inquiry,' the court noted, 'the requisite motivation [to modify] can come from any number of sources.' Thus, in addition to structural similarity between the compounds, a *prima facie*

² 550 F.3d 1075, 89 U.S.P.Q.2d 1370 (Fed. Cir. 2008).

case of obviousness may be shown by 'adequate support in the prior art' for the change in structure." *Id.* at 995 (citations omitted) (alteration in original). Citing its earlier *Takeda* case, the court noted that

[a] known compound may suggest its homolog, analog, or isomer because such compounds often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties. ... [However,] it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.

Id. at 995-96 (citing *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007)). Here, P&G established that at the time of the invention, a person having ordinary skill in the art realized that the properties of bisphosphonates could not be anticipated based on their structure because every bisphosphonate compound exhibits its own physical-chemical, biological and therapeutic characteristics, so that each bisphosphonate has to be considered on its own. In support of its argument, P&G synthesized and tested the prior art 2-pyr EHDP, the claimed risedronate (3-pyr EHDP) and 4-pyr EHDP, another structural isomer. Confirming the unpredictability of bisphosphonates, test results for 4-pyr EHDP revealed that it was not active in inhibiting bone resorption despite its close relationship with potent compounds.

The court noted that "[t]o the extent an art is unpredictable, as the chemical arts often are, ... solutions are less likely to be genuinely predictable." *Id.* at 996 (citations omitted) (alteration in original). Here, the court found that there was an insufficient showing that a person of ordinary skill in the art would have had a "reasonable expectation of success" in synthesizing and testing risedronate. The court justified its conclusion in view of *KSR*,³ noting that this was not a case when an obvious modification "leads to the anticipated success," such that the invention is likely the product of ordinary

skill and is obvious under § 103. "Here, the district court's findings indicate that there was no reasonable expectation [at the time of the invention] that risedronate would be a successful compound. Cases following *KSR* have considered whether a given molecular modification would have been carried out as part of routine testing. ... In this case, there is no credible evidence that the structural modification was routine." *Id.* at 996-97.

Unexpected results found where testimony established that researchers could not have predicted the potency of the claimed compound or the fact that the claimed compounds had lower toxicity than those of the prior art.



The court further found that even if Teva could establish a *prima facie* case of obviousness, P&G had introduced sufficient evidence of unexpected results to rebut such a showing. P&G provided testimony that the properties of risedronate were not expected, that researchers did not predict the potency of risedronate and that in a test to determine the lowest dose at which these compounds caused toxic reactions, risedronate outperformed 2-pyr EHDP by a substantial margin. Risedronate also showed no observable toxic effect at a dose higher than that achieved with the 2-pyr EHDP.

The existence of long-felt need depends on whether there is another product at the time applicant files the patent application, not whether there is another product available before commercialization of the product covered by the patent.

In P&G, the district court also found that risedronate satisfied a long-felt unmet need. The court based this conclusion on testimony that the art recognized osteoporosis as a serious disease with inadequate existing treatments. Teva noted that the competing drug alendronate was available before risedronate and therefore risedronate did not in fact meet an unmet need. Citing its earlier *Monarch* case, the Federal Circuit pointed out that determination of whether there is a long-felt need is measured from the date the application is

³ *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

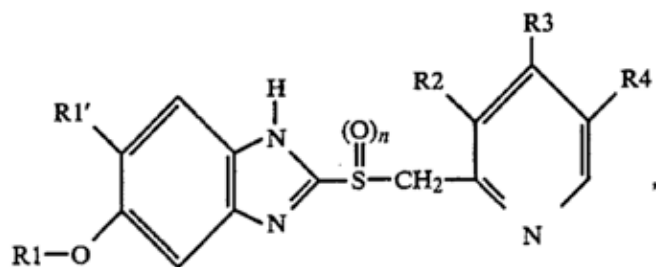
filed, not whether there was a commercial product available before the patented product:

Here, alendronate was not produced until ten years after the filing of the ... patent. Under *Monarch*, we look to the filing date of the challenged invention to assess the presence of a long-felt and unmet need. Accordingly, it was not clear error for the district court to conclude that risedronate met such a need and that secondary considerations supported a finding of non-obviousness.

Id. at 998 (citing *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH* 139 F.3d 877 (Fed. Cir. 1998)).

The court reaffirms that structural obviousness of chemical compounds post-KSR requires initial identification of a “lead compound” but finds that there can be multiple “lead compounds” in view of the Supreme Court’s directive to avoid rigid tests in assessing obviousness.

In *Altana Pharma AG v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 999, 91 U.S.P.Q.2d 1018 (Fed. Cir. 2009), the Federal Circuit reviewed the district court’s denial of a preliminary injunction sought by Altana based on Altana’s failure to establish that it was likely to prevail on the merits as to the validity of its patent. At issue was whether the district court improperly selected “compound 12” as the lead compound for assessing the obviousness of Altana’s claimed compound. Altana’s claimed compound included a methoxy group, $-CH_3O$ at the R3 position, whereas compound 12 provided a methyl group, $-CH_3$, at the R3 position. Teva argued that it would have been obvious to one of ordinary skill in the art to substitute the methyl group of the prior art with the claimed methoxy group.



Altana first argued that the district court improperly allowed Teva to select compound 12 of the prior art as the lead compound when the prior art suggested the availability of numerous other compounds that were at least as promising. The Federal Circuit disagreed, holding that one of skill in the art would have selected a number of compounds disclosed in the prior art patent, including compound 12, as

a starting point for further developments. The court cited (1) the fact that the compounds of the prior art patent, including compound 12, were improvements over the prior art, specifically omeprazole; (2) compound 12 was disclosed as one of the more potent of the 18 compounds of the prior art patent for which data was provided during prosecution; (3) the examiner relied on the compounds of the prior art patent during prosecution; and (4) expert testimony established that one of skill in the art would have selected the eighteen exemplary compounds, including compound 12 of the prior art patent, over omeprazole from which to pursue further development efforts designed to improve the quality and effectiveness of PPIs. *Id.* at 1007-09. The court also found that it was improper to construe the prior art as necessarily limited to a single lead compound, holding that “to the extent Altana suggests that the prior art must point to only a single lead compound for further development efforts, that restrictive view of the lead compound test would present a rigid test similar to the teaching-suggestion-motivation test that the Supreme Court explicitly rejected in *KSR*.” *Id.* at 1008.

A sufficient case of obviousness to evade preliminary injunction found where secondary references suggest desirability of a lower pKa for the compound and that changing a methyl group on a pyridine ring to a methoxy group would achieve such lower pKa.

Having concluded that the district court properly based its obviousness analysis on compound 12 as the “lead compound,” the court then assessed whether Altana’s claimed compound with the methoxy group was obvious in view of the prior art having a methyl group at the same position. The district court determined that the secondary reference taught those skilled in the art that the compound of the primary reference should have a pKa of 4 because such pKa would lead to better stability of the compound within the body. Thus, one of skill in the art would have been motivated to modify the prior art compounds to reduce their pKa to 4. The other secondary reference taught the pKa values of various chemical groups, including methoxy groups, at the 3-position of a simple pyridine ring. Teva argued that the other secondary reference taught that a methoxy group at the 3-position of pyridine ring would have a lower pKa value than if it had a methyl group at that position, as does the compound of the primary reference. The Federal Circuit concluded that this evidence supported the district court’s overriding decision that Teva made out a sufficient case of obviousness to defer the matter for trial on the merits, as opposed to granting the preliminary relief sought by the plaintiffs. *Id.* at 1009.

This case is the third in a series since the *KSR* decision (in addition to *Eisai*⁴ and *Takeda*⁵) where the Federal Circuit has held that an obviousness analysis of a claimed compound begins with identification of a lead compound in the prior art reference followed by a determination of whether the claimed compound is obvious in view of that lead compound. However, this approach is not one that has necessarily trickled its way down to the U.S.P.T.O. (“PTO”), where examiners will still generally comb through a reference in search of the compound that is structurally the closest to that claimed, regardless of whether that compound is one of the preferred or “lead” compounds disclosed in the reference. It will not necessarily be easy to persuade an examiner in such a situation that he or she should withdraw the rejection because the obviousness assessment should be carried out in view of a structurally more remote “lead compound.”

Patentee may not rely on unrecited commercial advantages or the fact that the prior art conducts additional steps to distinguish its method from otherwise anticipatory prior art.

In *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 91 U.S.P.Q.2d 1225 (Fed. Cir. 2009), FMC argued that Ecolab’s claim directed to “[a] method of treating an animal carcass to reduce a microbial population in resulting cut meat” was invalid as anticipated. *Id.* at 1345. The method comprised “applying ... an antimicrobial composition comprising” di-peroxycarboxylic acids having up to 12 carbons and carboxylic acids having up to 18 carbons ... in an amount and time sufficient to reduce the microbial population.” *Id.* The court agreed that FMC showed anticipation through a patent disclosing the same combination of acids as claimed. The court accepted the testimony of Ecolab’s expert that the prior art taught application of the PAA “in an amount and time sufficient to reduce the microbial population,” as claimed because the prior art reported that the muscle surfaces were decontaminated as a result of the PAA treatment. *Id.* at 1347.

Because Ecolab’s claim “is written broadly and is not limited to PAA treatment in a meat processing plant,” the court rejected Ecolab’s argument that its method was distinct from the prior art because Ecolab’s method reduced microbial populations “in the complex setting of a processing plant.” The court also rejected Ecolab’s argument that use of the prior art 3% PAA solution would require undue experimentation in view of Ecolab’s evidence relating to low-concentration

⁴ *Eisai Co. Ltd. v. Dr. Reddy’s Labs., Ltd.*, 553 F.3d 1353, 87 U.S.P.Q.2d 1452 (Fed. Cir. 2008).

⁵ *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 83 U.S.P.Q.2d 1169 (Fed. Cir. 2007).

PAA solutions (0.01-0.025%). Finally, the court rejected Ecolab’s argument that the prior art “does not disclose that the PAA treatment alone is sufficient to reduce the microbial population on a meat surface” because the prior art required “that each of two PAA treatment steps is followed by a trimming step, wherein the PAA-treated surface of the meat is trimmed away and discarded.” *Id.* The court found that

the ... publication disclosed that muscle surfaces were decontaminated by PAA treatment *before* the trimming steps were performed The fact that the [prior art] method discloses additional trimming steps performed under sterile conditions cannot render [the] claim ... valid because [the prior art] discloses all of the claim[s] limitations. Moreover, the publication itself discloses that the meat surface was decontaminated by the PAA treatment prior to any subsequent trimming steps.” *Id.* at 1347-48 (emphasis in original).

Method for spraying PAA as antimicrobial agent onto poultry at pressure of 50 psi obvious in view of art teaching spraying of PAA onto poultry and art teaching such pressures with other agents, as this is merely a combination of familiar elements to yield predictable results.

Also in *Ecolab*, the court addressed the obviousness of a dependent claim reciting treatment of poultry with PAA at a spray pressure of “at least 50 psi.” Although the prior art did not disclose the recited pressure, it did disclose “rapidly spraying” PAA onto poultry in order to sanitize the poultry. Ecolab’s expert acknowledged that the advantages of spraying antimicrobial solution onto meat at a pressure greater than 50 psi (including ensuring sufficient contact between the antimicrobial solution and the bacteria on the meat surface and using the pressure to “vigorously wash” the meat surface) were known in the art. The prior art also disclosed spraying a different antibacterial solution onto meat at a pressure ranging from 20 to 150 psi to provide sufficient force for good cleaning. Because the advantages of spraying antimicrobial solutions onto meat at high pressure were known, and methods for sanitizing meat with PAA were known, the court concluded that “[t]here was an apparent reason to combine these known elements—namely to increase contact between the PAA and the bacteria on the meat surface and to use the pressure to wash additional bacteria off the meat surface during the PAA treatment.” *Id.* at 1350. Thus, “the claims are invalid as obvious because the combination ... is merely [that] of familiar elements to yield predictable results.” *Id.*

The court concludes that *Deuel* was overruled by *KSR* and holds that a prior art peptide renders obvious the gene encoding that peptide.

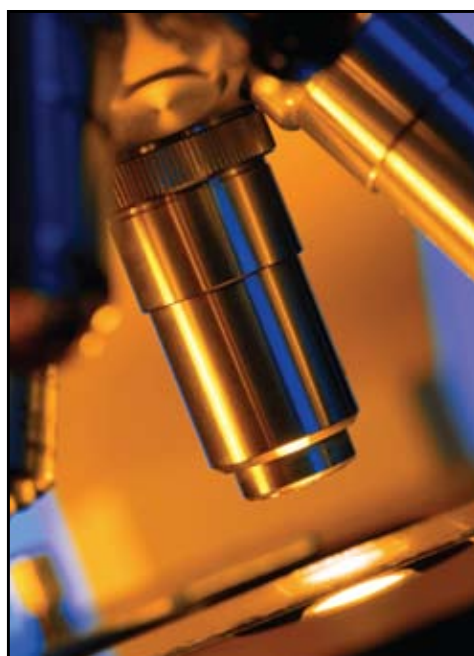
In *In re Kubin*, 561 F.3d 1351, 90 U.S.P.Q.2d 1417 (Fed. Cir. 2009), Kubin appealed the decision of the Board of Appeals, which found claims directed to a gene sequence encoding the NAIL (Natural Killer Cell Activation Inducing Ligand) protein unpatentable for obviousness and for lack of written description. Natural Killer (NK) cells act to fight tumors and viruses, and NAIL is a specific receptor protein on the cell surface involved in the activation of NK cells. The prior art Valiente reference disclosed a protein called “p38,” described as an activation marker found on the surface of NK cells, along with a monoclonal antibody specific for the p38 protein. The court found that p38 and NAIL were the same protein. Valiente also taught that the sequence of p38 could be obtained using “conventional methodologies known to one of skill in the art.” *Id.* at 1354. The court further relied on a reference disclosing the sequence encoding the murine analog of NAIL. Kubin argued that Valiente did not disclose the sequence, nor did it disclose the identical process for obtaining the cDNA of the NAIL protein. The Federal Circuit nevertheless found the invention obvious, stating that the appellant “cannot represent to the public that their claimed gene sequence can be derived and isolated by ‘standard biochemical methods’ discussed in a well-known manual on cloning techniques, while at the same time discounting the relevance of that very manual to the obviousness of their claims.” *Id.* at 1356. Upon holding the claims unpatentable for obviousness, the Federal Circuit declined to reach the issue of written description.

In sustaining the board’s obviousness rejection, the court acknowledged the contrary holding of its own 1995 decision of *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995), where “this court reversed the board’s conclusion that a prior art reference teaching a method of gene cloning, together with a reference disclosing a partial amino acid sequence of a protein, rendered DNA molecules encoding the protein obvious.” *Id.* at 1358. The court in *Deuel* had also admonished the Patent Office for applying an inappropriate “obvious to try” standard to determined obviousness. In other words, the prior precedent had firmly held that while isolating the gene sequence of a known protein may be obvious to try when the methods of isolation were well known, that did not imply that the sequence itself was obvious. Though acknowledging the precedent of *Deuel*, the Federal Circuit noted that in the interim period since the *Deuel* decision, the Supreme Court had decided the landmark case of *KSR Int’l*



Co. v. Teleflex, Inc., 550 U.S. 398 (2007), which overruled the Federal Circuit's obvious-to-try jurisprudence. *Id.* at 1358-59.

The Federal Circuit more specifically found that *KSR* resurrected the Federal Circuit's own prior standard on obvious-to-try expressed in the decision of *In re O'Farrell*, 853 F.2d 894, 903, 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988). The court noted that *O'Farrell* addressed two classic situations where an invention that seemed merely obvious to try was nevertheless nonobvious. First, "where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness." *Id.* at 1359. Second, obviousness is not established where "what was [allegedly] 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *Id.* (quoting *O'Farrell*, 853 F.2d at 903). The Federal Circuit found in *Kubin* that the "prior art teaches a protein of interest, a motivation to isolate the gene coding for that protein, and illustrative instructions to use a monoclonal antibody specific to the protein for cloning this gene." *Id.* at 1360. Accordingly, the court held that "a skilled artisan would have had a resoundingly 'reasonable expectation of success' in deriving the claimed invention in light of the teachings of the prior art." *Id.*



Finally, the Federal Circuit addressed Kubin's arguments that the present case was in an unpredictable technology and that the prior art taught away from the invention. With respect to the former, the court found that "these ... results [are] profoundly predictable" and that "in the face of *KSR*, [this court cannot] cling to formalistic rules for obviousness, customize its legal tests for specific scientific fields in ways that deem entire classes of prior art teachings irrelevant, or discount the significant abilities of artisans of ordinary skill in an advanced area of art." *Id.* (quotations omitted). As to the latter "teaching away" argument, the court noted that "[the secondary reference's] quasi-agnostic stance toward the existence of a human homologue of the [murine] gene cannot fairly be seen as dissuading one of ordinary skill in the art from combining [the teachings of the primary and secondary references]."

Id. at 1357. In a somewhat unusual move, the court turned Kubin's argument around, noting that "the disclosure [of the secondary reference], in light [of the teachings of the primary reference] regarding the p38 protein and its role in NK cell activation, would have aroused a skilled artisan's curiosity to isolate the gene coding for p38." *Id.*

The takeaway from *Kubin* for biotechnology patents is that barring a teaching away or a secondary consideration such as unexpected results or commercial success, a DNA is now generally obvious in view of a prior art reference disclosing the protein it expresses. In this respect, the decision on the facts of *Kubin* may fall into the category of bad facts make

bad law. While Kubin argued on appeal that the prior art references did not provide "any guidance for the preparation of cell culture that will serve as a useful source of mRNA for the preparation of a cDNA library," *Id.* at 1356 (citation omitted), Kubin did not submit any declaratory evidence to back up such assertions. Without any evidence to contradict the board's finding, the Federal Circuit simply concluded that these arguments "are diminished by appellants' own disclosure" while referring to the secondary reference as enabling one to obtain the claimed gene by "standard biochemical methods." *Id.* (quotations omitted). In this regard, the court seems to have confused the obviousness of a cloning method, which Kubin acknowledged, with the obviousness of obtaining a suitable

library containing the DNA of interest with which to practice such cloning method. The court's confusion is apparent from the exchange of the court with counsel during oral argument. It goes without saying that patent applicants and owners seeking to rely on the difficulty of isolating a gene to a known protein to support obviousness arguments should ensure that such arguments are supported by evidence that has been made of record.

Because the court found the claim obvious, it did not address the written description rejection of the claim that the board had affirmed. Accordingly, we have the worst of both worlds right now in the area of molecular biology, where very little precision is required for obviousness, but a great deal of precision is required for written description. Keep in mind

that the board in *Kubin* reversed the enablement rejection yet sustained the written description rejection, even though application referred to a specific SEQ ID, albeit one having a region of 80% variation. The hapless applicant here made the unforgivable mistake of following the PTO's own written description guidelines, which the board held it could ignore at its discretion. Thus, at present, an unsequenced protein now renders obvious any DNA encoding that protein, but even providing a SEQ ID for a DNA is not enough to describe that DNA if one includes therein an area of 80% homology. Under this court's current jurisprudence, the "one of ordinary skill in the art" referenced in the obviousness statute, § 103, is indeed a clever person, being able to obtain any DNA given an isolated unsequenced protein. Yet the "person skilled in the art" referenced in the enablement/written description statute, § 112 ¶ 1, cannot even fill in the blanks on an identified SEQ ID. While it is certainly true that obviousness does not make for written description, in molecular biology it is rather hard to defend the position that one could not have envisioned all the molecules in the region of variation.

Where one reference suggests making the claimed micronized drug but another reference teaches away, the Federal Circuit has found obviousness, holding that the the divergent teachings simply represent the "finite number of identified predictable solutions" discussed in KSR.

In *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341, 91 U.S.P.Q.2d 1569 (Fed. Cir. 2009), Bayer claimed a pharmaceutical composition comprising ***micronized*** drospirenone particles in an oral dose form ***exposed to the gastric environment upon dissolution***, the composition being effective for oral contraception in a human female. Although drospirenone was known in the prior art, Bayer relied on the fact that its drospirenone was micronized and exposed to the gastric environment upon dissolution. Bayer argued that it was not obvious to prepare an exposed, i.e., uncoated, micronized composition, because it was believed at the time of the invention that an enteric coating was necessary for protection against the highly acidic gastric environment. In support, Bayer cited the "Nickisch" teaching, which disclosed that drospirenone broke down when exposed to acid *in vitro*, thereby teaching away from allowing exposure to the gastric environment. By contrast, the defendant, Barr, relied on the "Krause" series, which taught that spirorenone, which is structurally very similar to the claimed drospirenone, did not break down before absorption in *in vivo* tests in humans and monkeys, thereby suggesting that exposed drospirenone could be used. Relying on the

spirorenone "analogy" of the Krause series, the district court agreed with Barr that the exposed drospirenone would have been obvious. *Id.* at 1346.

On appeal, Bayer argued that the district court ignored key differences between drospirenone and spirorenone, such that the former isomerizes 40% faster than the latter, and that drospirenone is more soluble and thus could dissolve and isomerize in acid faster. The court concluded that this was irrelevant because the Krause series prior art is not an anticipatory reference. It can be used to show that a drug formulator having ordinary skill had a viable known option to consider with micronized, unprotected drospirenone, and a reasonable expectation that drospirenone would perform similarly (even if not identically) to the spirorenone in the Krause series.

Id. at 1349.

The court then held that the choice between the Krause series and the Nickisch was precisely the "finite number of identified predictable solutions" identified by the Supreme Court in *KSR*⁶:

[A] person having ordinary skill in the art has reached a crossroads where he must choose between two known options: delivery of micronized drospirenone by a normal pill following the spirorenone analogy in the Krause series, or delivery of drospirenone by an enteric-coated pill following the Nickisch teaching that the drug needs to be protected in the stomach. This is a finite number of identified, predictable solutions. The prior art would have funneled the formulator toward these two options; he would not have been required to try all possibilities in a field unreduced by the prior art, thus avoiding the first pitfall of *O'Farrell*. Additionally, the prior art was not vague in pointing toward a general approach or area of exploration, but rather guided the formulator precisely to the use of either a normal pill or an enteric-coated pill, thus avoiding the second pitfall of *O'Farrell*. Because the selection of micronized drospirenone in a normal pill led to the result anticipated by the Krause series, the invention would have been obvious. *Id.* at 1350 (citations omitted).

There are several problems with the court's reasoning here. First, it defies a plain reading of *KSR*. The Supreme Court in *KSR* spoke in terms of "solutions," which in normal parlance would mean a presentation of "viable" alternatives for solving a problem. Accordingly, the Nickisch teaching was in reality

⁶ *KSR Int'l Co.*, 550 U.S. at 421.

a teaching away and not a potential solution as envisioned by *KSR*. Indeed, if a teaching away is now viewed by this court as one of the potential solutions, then it is difficult to envision how a teaching away would ever be persuasive of nonobviousness unless there is absolutely no other art pointing in the other direction. Another problem with the court's approach, as referenced by Judge Newman in her dissent, is that they indeed seem to be playing scientist. *Id.* Here, the teaching away related **to the claimed compound**. By contrast, the suggestion of the invention related to an analogous compound. Finally, it is difficult to reconcile this case with the *P&G* case⁷ reported above. It will be recalled that in *P&G* there was likewise a teaching toward the claimed 3-pyr compound (the fact that the prior art 2-pyr compound had therapeutic activity) and a teaching away from the claimed 3-pyr compound (the fact that the 4-pyr compound prepared by P&G did not have therapeutic activity). In contrast to this case, however, the court viewed such facts in *P&G* as being evidence of the unpredictability of the behavior of the compounds depending on the location of the pyr group. It would seem that the court here could have just as easily concluded from the Krause and Nickisch teachings that there was evidence of unpredictability here as well.

What probably was the controlling distinction between the *P&G* case and the instant case, although the court did not enunciate it, is the fact that P&G claimed a novel active compound whereas Bayer claimed a new form of a known compound. In previous editions of Hunton & Williams' *Year-in-Review* brochures, we have noted that a new form of an old active is rarely upheld by this court, no matter what the facts. By contrast, novel actives, even if positional isomers that would normally have been viewed as obvious, have been upheld.

Advertisement for a nutritional supplement was an enabling anticipatory printed publication even though the advertisement did not prove the effectiveness of the nutritional supplement.

In *Iovate Health Sciences, Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*, 586 F.3d 1376, 92 U.S.P.Q.2d 1672 (Fed. Cir. 2009), the Federal Circuit addressed the question of whether an advertisement for a nutritional supplement was an anticipatory "printed publication" for a claim reciting "[a] method for enhancing muscle performance or recovery from fatigue wherein said method comprises administering a composition comprising a ketoacid and an amino acid wherein said amino acid is cationic or dibasic."

⁷ *Procter & Gamble Co.*, 566 F.3d at 989.

The prior art cited against Iovate was an advertisement describing a supplement containing the recited components to increase muscle strength, size and mass and to help muscles recuperate faster after exercise. The advertisement also described how the product is made and instructed a user on the amount to take.

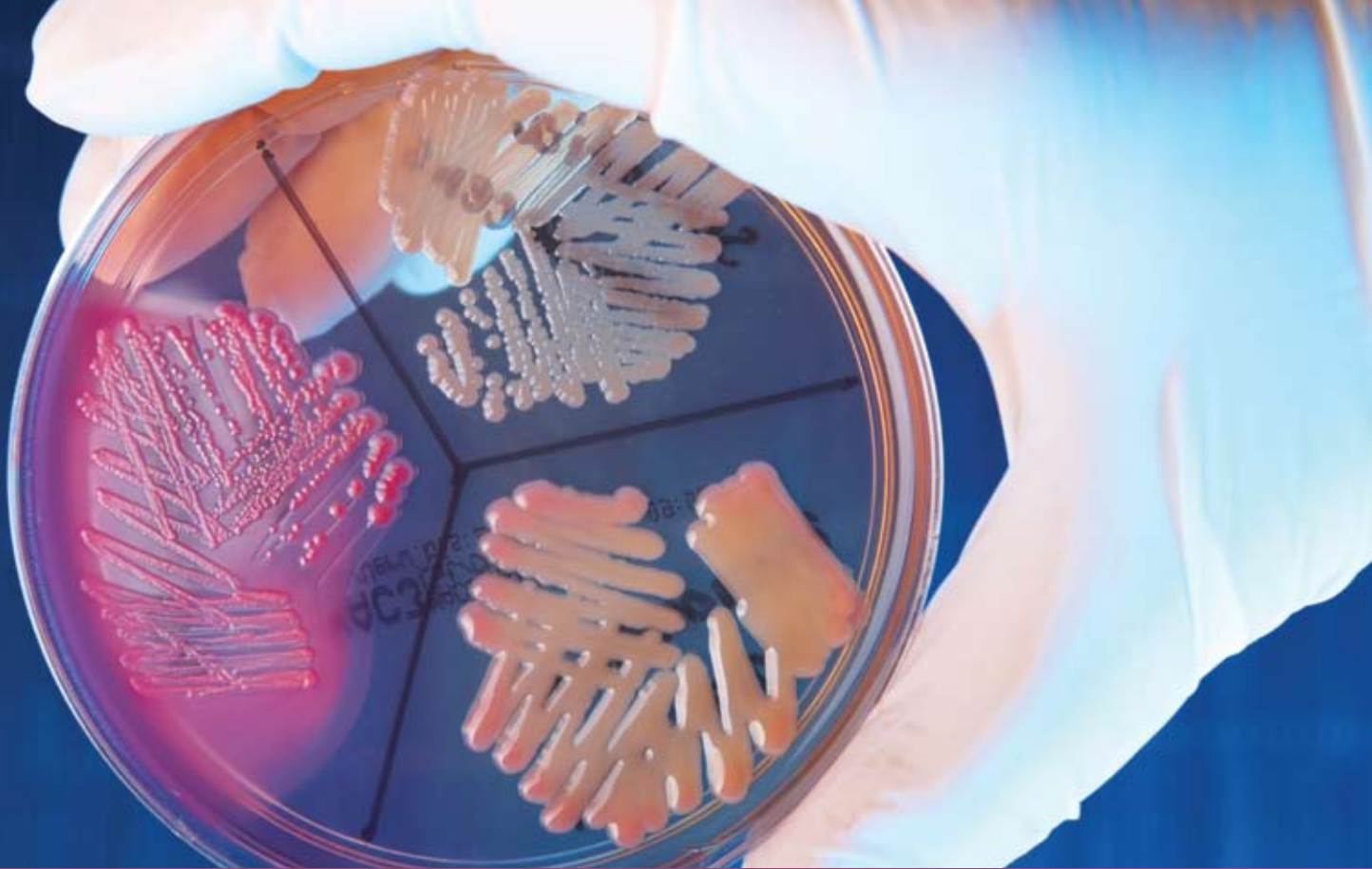
Iovate argued that the advertisement failed (1) to disclose an effective method of "enhancing muscle performance or recovery from fatigue" and (2) to teach an "effective amount" of the components. The court rejected these contentions, holding that the disclosure of increasing muscle strength and helping muscles recuperate faster after exercise anticipates "enhancing muscle performance" and "recovery from fatigue." *Id.* at 1381. The court further found that the claims do not restrict the method to an "effective amount" and, in any event, the prior art discloses such amount. *Id.* The court seemed particularly perturbed by the testimony of Iovate's expert, noting that it "borders on the frivolous" to argue that "those skilled in the art of nutritional supplements used the term 'enhancing muscle performance'—and thus 'increasing the ability of muscle to maintain required or expected force or power output'—to exclude increasing muscle strength." *Id.* Iovate also argued that the advertisement failed to enable the method because the advertisement "lacks any guidance on appropriate ingredient dosages." Bio-Engineered ("BSN") responded that, "because the claims are not directed to any particular concentrations, ratios, or percentages, one of skill in the art could practice the invention by buying the individual ingredients" or "the product itself." *Id.* at 1382. The court agreed with BSN because "all one of ordinary skill in the art would need to do to practice an embodiment of the invention is to mix together the known ingredients listed in the ad and administer the composition as taught by the ad." *Id.* at 1382-83.

Given the Federal Circuit jurisprudence that the level of disclosure necessary to enable an anticipatory reference is lower than that required to support a claim under the first paragraph of 35 U.S.C. § 112, *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1326, 75 U.S.P.Q.2d 1297 (Fed. Cir. 2005) ("proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation"), it is not surprising that an advertisement in *Flex* magazine disclosing every limitation of a method of therapeutic use would be considered sufficient disclosure for purposes of anticipation. It remains to be seen how creative defendants and examiners will become in seeking out unconventional sources of anticipatory prior art to knock out claimed methods of therapeutic use.

Recitation in the claim of the source of the EPO as “purified from mammalian cells grown in culture” was sufficient to distinguish the claim from naturally occurring EPO because EPO from the claimed recombinant source had a different structure than the naturally occurring product.

In *Amgen, Inc. v. F. Hoffman-La Roche, Ltd.*, 580 F.3d 1340, 92 U.S.P.Q.2d 1289 (Fed. Cir. 2009), the court reviewed the validity of a claim to “[a] pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, **wherein said erythropoietin is purified from mammalian cells grown in culture.**” *Id.* at 1364 (emphasis added). Roche argued that addition of the source limitation (“purified from mammalian cells grown in culture”) could not distinguish the prior art urinary EPO because the EPOs were the same, regardless of source. The court acknowledged that an otherwise old product is not made patentable merely because it is made by a new process. “However, a new product may be patented by reciting source or process limitations so long as the product is new and unobvious.” *Id.* at 1366. Here, the court concluded that the district court did not err in giving weight to the source limitation since “by its plain terms,” the patent “claims a product with a source limitation.” *Id.* at 1367. The next question was “whether the production of EPO by recombinant technology resulted in a new product, so that [the claim] was not anticipated by the urinary EPO” of the prior art. *Id.* Here, the court held that the claimed recombinant EPO with the source limitation was not anticipated because, compared to natural EPO, it had (1) a higher molecular weight, (2) different charge and (3) a different carbohydrate content. *Id.*





Double Patenting

The “two-way” test for double patenting is not applicable where the PTO is not solely responsible for delays in the issuance of the later application.

In *In re Fallaux*, 564 F.3d 1313, 90 U.S.P.Q.2d 1860 (Fed. Cir. 2009), the applicant Fallaux appealed a double patenting rejection of its claims, relying on the “narrow exception” established in *In re Braat*⁸ that the PTO was required to apply a “two-way” test in the double patenting analysis. Under the so-called “two-way” test, both (1) the application claim must be obvious over the earlier patent claim, and (2) the earlier patent claim must be obvious over the later application claim. Typically, the PTO assesses double patenting under the one-way test, looking only to whether a later application claim is obvious over an earlier patent claim and not vice versa. The court established the narrow two-way exception in *Braat* in recognition of the fact “that ‘basic and improvement patents should not be penalized by the rate of progress of the applications through the PTO, a matter over which the applicant does not have complete control’ ” as “‘it is not the applicant’s fault’ that the claims in the reference patent issued first.” *Id.* at 1317-18 (alterations omitted). Here, however, the board

specifically found that the applicant, and not the PTO, dictated the rates of prosecution of the patents in the family, and substantial evidence supports this finding. *Id.* at 1318. The court also made reference to its precedent in *Eli Lilly*⁹, where the court held that the two-way test was not applicable where the PTO was not solely responsible for the delay because the applicant could have presented the claims earlier in one of its parent or grandparent applications. *Id.*

Change in law regarding patent term from seventeen years from issuance to twenty years from filing does not justify application of the two-way test in view of availability of other types of extensions as well as harassment by multiple assignees.

Finally, the court rejected Fallaux’s argument that the court’s precedent refusing to allow applicants to rely on the two-way test are distinguishable because, unlike the applicants in those cases, the applicant here is not seeking an unjustified patent term extension. *Id.* In particular, Fallaux pointed out that the court’s precedent was based on the old law where patents expired seventeen years from issuance such that a

⁸ 937 F.2d 589, 19 U.S.P.Q.2d 1289 (Fed. Cir. 1991).

⁹ *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 U.S.P.Q.2d 1865 (Fed. Cir. 2001).

developments occurring decades after the filing date of the secondary application.

This is one of those cases that cause those enmeshed in the patent system to scratch their heads in puzzlement. The standard enunciated by court (“Product and process claims are patentably distinct if multiple processes for creating a product exist at the time of the invention.”) is one straight out of the MPEP and applied by examiners at the outset of examination, to determine whether inventions are “independent or distinct” under the statute governing restriction practice, 35 U.S.C. § 121. While the existence of other distinct processes may be helpful to an examiner in determining, before conducting a search and with no knowledge of the prior art, whether the claims should be divided by issuing a restriction requirement, it is unclear what purpose this analysis serves in determining whether double patenting exists. Indeed, the “independent or distinct” standard has never been applied in the obviousness double patenting analysis. Thus, the court is confusing the standard for determining if inventions are independent or distinct for the standard for determining if inventions are obvious. After *Takeda*, no matter how obvious a later process patent is over an earlier product patent, the patent owner can escape double patenting simply by showing that there are alternative processes in existence at the time of the second filing. Having created new law out of thin air, it is not surprising that the court found it had to set a new standard regarding applicable dates. Under normal circumstances, it would be speculation to conclude that this misapplication of the law will create a lot of mischief. However, as the next case, *Amgen*, demonstrates, we did not have to wait long to observe the fruits of this court’s error.

An applicant who files its restricted claims in an application labeled as a “continuation” rather than as a “divisional” cannot claim the benefit of the safe harbor against double patenting under 35 USC § 121.

In *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd.*, 580 F.3d 1340, 92 U.S.P.Q.2d 1289 (Fed. Cir. 2009), Amgen asserted its patents covering EPO and Roche counterclaimed for

invalidity based on obviousness-type double patenting. The district court held that the claims of Amgen’s later patents were the subject of a restriction requirement and therefore exempt from double patenting under the safe harbor of § 121. On appeal, Roche argued that § 121 cannot shield the patents because they issued from “continuation” applications to which § 121 is inapplicable and not from “divisional” applications (to which the double patenting protection of § 121 applies exclusively). The Federal Circuit reversed the district court on the double patenting issue: “We conclude that, because the ... applications were filed as continuation — rather than divisional — applications, the ... patents do not receive the benefit of § 121.” *Id.* at 1352. The court referred



to its earlier holding in *Pfizer v. Teva*¹⁰ that the safe harbor applies only to divisionals, and not to divisional CIPs: “The statute on its face applies only to divisional applications, and a continuation application, like a continuation-in-part application, is not a divisional application.” *Id.* at 1353 (footnote omitted). “Because the ’178 and ’179 applications were filed as continuation applications instead of divisional applications, we hold that the ’933, ’422, and ’349 patents do not receive the protections afforded by § 121’s safe harbor.” *Id.* at 1354.

This is a situation of a bad holding leading to a further bad holding. We criticized *Pfizer’s* holding that the safe harbor protection of § 121 against double patenting did not apply to divisional CIPs because the court conveniently disregarded the sentence of

the statute “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.” Clearly, such wording contemplated “divisionals” with new matter, otherwise, it would have been redundant to state “If a divisional is directed solely to subject matter described and claimed in the original application” The court seems to simply have a political agenda directed to minimizing availability of the safe harbor.

Although a patentee may evade a double patenting rejection by showing the existence of alternative methods as

¹⁰ *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353, 86 U.S.P.Q.2d 1001 (Fed. Cir. 2008).

of its second filing, a patent challenger cannot rely on evidence arising after the first filing to show a lack of distinctiveness.

Roche next contended that *Takeda*¹¹ changed the time frame for an obviousness-type double patenting analysis. Roche honed in on the language in the *Takeda* opinion, stating that “the relevant time frame for determining whether a product and process are ‘patentably distinct’ should be at the filing date of the secondary application” and contended that it should therefore be able to rely on evidence up to the filing date of the secondary application to show a lack of patentable distinctiveness in this case.” *Id.* at 1355-56. In Roche’s view, if the patentee is to benefit from art that arises after the invention date, than an accused infringer is likewise benefited. Amgen argued that *Takeda* allows only the patentee an opportunity to rely only on post-invention evidence.

The court sided with Amgen, holding that “Roche’s view that *Takeda* changed the time frame of the obviousness-type double patenting inquiry in all cases collides with 35 U.S.C. § 120[, which provides that a qualifying] ‘application for patent for an invention ... shall have the same effect ... as though filed on the date of the prior application.’” *Id.* at 1356. Citing § 120, the court read *Takeda* to stand for the limited proposition that an applicant can rely only on subsequent developments in the art up to the filing date of the “secondary application” in order to show that alternative processes to make the product render the product and the process for making that product patentably distinct:

We cannot read *Takeda* in the manner for which Roche advocates without violating the plain language of 35 U.S.C. § 120. Section 120 requires that all five of Amgen’s asserted patents ... benefit from the effect of having been filed [on the same date]. That means that Amgen’s patents cannot be invalidated based on art arising after [that date].

Id. at 1357.

Accordingly, the court remanded the case with the understanding that, under *Takeda*, Amgen, if it wishes to do so, can rely on alternative processes for making the products claimed in the ‘933 and ‘422 patents up to their filing dates to prove that the claims of those patents and the claims of the ‘868 and ‘698 patents are patentably distinct.

Later patents claiming processes are not obvious in view of prior patent claiming the starting materials necessary to execute the processes because there was no reasonable expectation of success.

Elsewhere in *Amgen*, the court addressed whether Amgen’s claims were invalid under obviousness-type double patenting. The court found that the claim in the prior ‘008 patent

recites the starting materials necessary to execute the processes recited in the asserted claims of the ‘868 and ‘698 patents. ... [T]he main difference between claim 27 of the ‘008 patent and the asserted claims of the ‘868 and ‘698 patents is the actual production of isolatable glycosylated EPO having the stated *in vivo* biological activities.

Id. at 1361.

The court framed the issue as whether “a person of ordinary skill in the art in possession of the transfected CHO cells would have had a reasonable expectation of success in producing a recoverable amount of *in vivo* biologically active EPO.” *Id.* at 1362. The court concluded that

one of ordinary skill in the art would not have reasonably expected to successfully produce isolatable quantities of glycosylated EPO having the stated biological activities in transfected CHO cells.

Id.

The court was persuaded by the testimony of Amgen’s expert that a person of ordinary skill in the art would not have had a reasonable expectation of success because “(1) an ordinarily skilled artisan would not have known which, if any, host cells would produce EPO with the carbohydrate structures necessary for its *in vivo* function; and (2) no one had successfully produced any recombinant glycoprotein with *in vivo* bioactivity where the carbohydrate structures were important for biological activity.” *Id.* at 1363 (footnote omitted). Roche’s argument that Amgen’s inventor personally harbored a reasonable expectation of success was rejected because an inventor’s “personal expectations are not conclusive of an ordinarily skilled artisan’s reasonable expectations.” *Id.*

¹¹ *Takeda Pharm. Co. v. Doll*, 561 F.3d 1372, 90 U.S.P.Q.2d 1496 (Fed. Cir. 2009).



Written Description

A priority application disclosing unicellular strains of *Thraustochytrium* and *Schizochytrium* and “consolidation” of “cells from several reactors” provides adequate written description to support a claim directed to mixtures of these two microorganisms, despite the absence of a working example.

In *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 92 U.S.P.Q.2d 1148 (Fed. Cir. 2009), the accused infringer Lonza argued that Martek’s claims reciting extracting lipids from “microorganisms of the genus *Thraustochytrium*, microorganisms of the genus *Schizochytrium* **and mixtures thereof**” were not entitled to the priority date of the 1988 application because such application did not provide an adequate written description for “mixtures.” Martek’s expert noted that (1) “the 1988 application discloses unicellular fungal strains of the *Thraustochytrium* and *Schizochytrium* genera as useful for practicing the invention” and (2) the 1988 application discloses “cells from several reactors consolidated into one reactor,” which “describes the process of mixing strains of the *Thraustochytrium* and *Schizochytrium* genera.” *Id.* at 1370. The court found this testimony to provide the requisite “substantial evidence” to support adequate written description.

Id. The court expressly rejected Lonza’s argument that there was no adequate written description because “the 1988 application contains no working examples that consolidate cells from different strains,” finding that “a patent claim is not necessarily invalid for lack of written description just because it is broader than the specific examples disclosed.” *Id.* at 1371.

The court also rejected Lonza’s argument that “the 1988 application teaches away from the requirement ... that cells of the *Thraustochytrium* and *Schizochytrium* genera be *grown* together, rather than simply mixed together after each strain is grown in a separate reactor” in view of “[t]he application’s disclosure that *Thraustochytrium* strains respond more favorably to phosphate than *Schizochytrium* strains” The court noted that “the fact that the working examples disclose different preferred growth conditions for [the different] cells ... does not teach away from growing strains of the two genera together. In fact, the application describes growth conditions generally suitable for all disclosed strains, rather than specifically useful for any particular strain ... thus indicating that the disclosed strains share growth attributes and may be cultured together.” *Id.*

The court also found that “the 1988 application adequately describes combining extracted lipids with a food material” as claimed. *Id.* at 1372. The court noted that “[t]he application discloses that ‘[t]he cells can also be broken or lysed and the lipids extracted into vegetable or other edible oil’ ” and “that vegetable and edible oils are understood to be ‘food materials,’ and thus, the 1988 application discloses combining the extracted lipids with food materials, as recited in claim 1.” *Id.* (citations omitted). The court further noted that “the 1988 application discloses ‘the production of lipids with high concentrations of omega-3 highly unsaturated fatty acids suitable for human and animal consumption as *food additives.*’ ” *Id.* (citations omitted).

Even though claimed method did not recite compounds, the claim still failed to meet the written description requirement because there still must be a description of some way to perform the claimed method.

In *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 90 U.S.P.Q.2d 1549 (Fed. Cir. 2009), the court addressed whether Ariad’s claim directed to methods comprising the step of reducing NF-kB activity had adequate written description. The invention was based on the applicant’s discovery of NF-kB transcription factor and an appreciation that reduction of its activity could ameliorate the harmful symptoms of diseases that trigger NF-kB activation. Lilly argued that the asserted claims are not supported by written description because the specification fails to adequately disclose how the claimed reduction of NF-kB activity is achieved. Ariad argued that it need not disclose a compound because the claim itself was a method claim that did not recite compounds. The court rejected Ariad’s argument, holding that “[r]egardless of whether the asserted claims recite a compound, Ariad still must describe some way of performing the claimed methods, and Ariad admits that the specification suggests only the use of the three classes of molecules to achieve NF-kB reduction.” *Id.* at 1373. By not “sufficiently disclosing molecules capable of reducing NF-kB activity,” Ariad did not “satisfy the inventor’s obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed.” *Id.* (citation omitted) (quotations omitted).

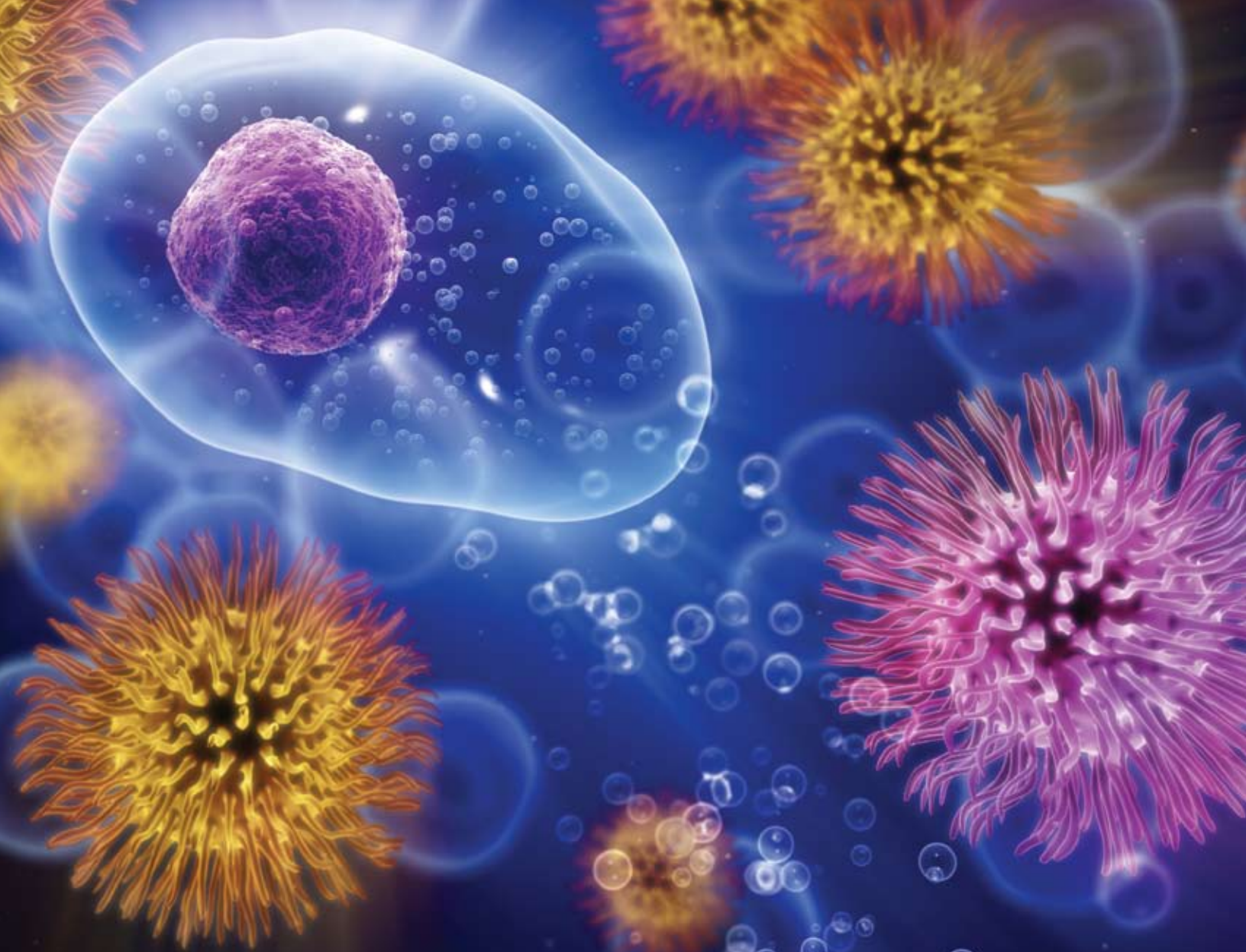
The court reviewed each of the three classes of compounds generally disclosed by Ariad and found inadequate written description regarding all of them. The description of the “specific inhibitor” was inadequate because only one molecule, I-B, was disclosed but the figure disclosing the sequence of DNA that encodes I-B was not in the priority application.

Testimony that I-B existed as of the priority filing and could be isolated was considered insufficient as “a vague functional description and an invitation for further research,” which “does not constitute written disclosure of a specific inhibitor.” *Id.* at 1374.

The court likewise found inadequate written description of the “dominantly interfering molecules” since the specification provided no examples and further disclosed requirements for such molecules that the patent itself did not disclose as being met, leaving one skilled in the art in the dark. The court also found it insufficient that skilled workers actually practiced this teaching soon after the priority application was filed, since a written description analysis occurs as of the filing date sought. *Id.* at 1375. As for the “decoy molecules, the court acknowledged that the specification proposes example structures but found that this “does not answer the question of whether the specification adequately describes using those molecules to reduce NF-kB activity.” *Id.* Here, the specification disclosed only that by using decoy molecules, “NF-kB ‘would bind the decoy’ and thereby, ‘negative regulation can be effected.’ ” *Id.* (citation omitted). While such prophetic examples are routinely used in chemical arts and can be sufficient to satisfy the written description requirement, the disclosure here “is not so much an ‘example’ as it is a mere mention of a desired outcome. ... [T]here is no descriptive link between the table of decoy molecules and reducing NF-kB activity.” *Id.*

The *en banc* decision was recently issued¹², and to no one’s surprise, the court found that there is indeed a separate written description requirement. As discussed above, one of the problems is that the current written description jurisprudence is too simplistic in its application because it ignores the fact that the “invention” that must be described sometimes is and sometimes is not tied to structure. For example, in the area of therapeutically effective small molecules, even very small changes in structure can cause drastic changes in efficacy, such that broad functional descriptions are not adequate. On the other hand, in molecular biology it is often the case that the invention resides not so much in chemical structure but rather in information, the possession of which provides the necessary structures. For example, if a researcher discovers a key receptor and finds that blockage of that receptor will result in a reduction of 50% of a type of cancer, the invention is actually the discovery of that key nexus. In such instance, it would be appropriate to grant claims to any molecule that binds to that receptor, subject to the usual *Wands* criteria for enablement, because any graduate student could find compounds that bind with little experimentation.

¹² *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.* (Fed. Cir. 2010) (*en banc*)



Enablement

It was improper for the district court to find nonenablement for dependent claims limited to 22 qualifying microorganism species based on finding of nonenablement for the independent claim encompassing from 10,000 qualifying species.

In *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 92 U.S.P.Q.2d 1148 (Fed. Cir. 2009), the court reviewed the district court’s holding that all of Martek’s claims were invalid for lack of enablement. Martek asserted that the district court erred by considering only the limitations of independent claim 1 and failing to specifically address the additional limitations of dependent claims 4 and 5. Whereas claim 1

recited a process including the step of extracting lipids from “euryhaline organisms” having specified properties, claim 4 additionally required that the “euryhaline microorganisms are microorganisms of the order Thraustochytriales” and claim 5 additionally required that the “euryhaline microorganisms are selected from the group consisting of Thraustochytrium, Schizochytrium, and mixtures thereof.” *Id.* at 1378.

Noting that “the district court focused exclusively on element (a) of claim 1, which is directed to growing euryhaline organisms that have stated characteristics,” the Federal Circuit reversed the district court’s grant of JMOL as to claims 4 and 5 “because Lonza failed to present any evidence—much

less clear and convincing evidence—that one of ordinary skill in the art must perform undue experimentation to practice claims 4 and 5.” *Id.* at 1378, 1379. The court noted that “there are relatively few potential species that may meet the limitations of claims 4 and 5, as compared to the large number of potential species that may meet the limitations of claim 1.” *Id.* at 1379. The court found that the testimony of Lonza’s expert as to claim 1

regarding the amount of experimentation necessary to select a qualifying species from 10,000 possibilities—is far less relevant and persuasive when considering the selection of a qualifying species from only 22 possibilities [for the dependent claims.] Thus, the evidence supports the jury’s implicit finding that one need not perform undue experimentation to practice claims 4 and 5, as well as the jury’s ultimate conclusion that Lonza failed to prove invalidity of those claims by clear and convincing evidence.

Id.

“Analytic reasoning” is not sufficient by itself to establish utility of a therapeutic method in the absence of human trials, animal tests or in vitro experiments, even though such reasoning was correct.

In *In re ‘318 Patent Infringement Litig.*, 583 F.3d 1317, 92 U.S.P.Q.2d 1385 (Fed. Cir. 2009). The court reviewed the enablement of a claim directed to a “method of treating Alzheimer’s disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof.” *Id.* at 1320.

The district court found that the specification did not demonstrate utility because relevant animal testing experiments were “not finished . . . by the time the ‘318 patent was allowed” and the specification provided only “minimal disclosure” of utility. The district court alternatively found that the specification and claims did not “teach one of skill in the art how to use the claimed method” because the application “only surmise[d] how the claimed method could be used” without providing sufficient galantamine dosage information.

Id. at 1323 (citations omitted) (alterations in original).

The Federal circuit affirmed. The court noted that patent applications claiming new methods of treatment are typically supported by test results, but that “human trials are not required for a therapeutic invention to be patentable.” *Id.* at 1324. Rather, “results from animal tests or *in vitro* experiments may be sufficient to satisfy the utility requirement.” *Id.* at 1324-25 (footnote omitted). Here, however, the patentee Janssen provided “neither *in vitro* test results nor animal test results involving the use of galantamine to treat Alzheimer’s-like conditions.” *Id.* Janssen argued that *in vitro* or animal test results were not necessary here because it could establish utility “by analytic reasoning.” *Id.* at 1326. To this end, Janssen relied on testimony by an expert stating “that the specification ‘connected the dots’ for galantamine as a potential Alzheimer’s disease treatment, [by teaching that] galanthamine in humans [was a] safe and well tolerated cholinesterase inhibitor [having] selective nicotinic effects, and very modest muscarinic receptor side effects” combined with the fact that “nicotinic receptors in the brain are involved with the ability to learn . . . (unlike prior art treatments, which had primarily affected muscarinic receptors).” *Id.* (citations omitted) (alterations omitted).

The court rejected this argument, finding that these “insights” “are nowhere described in the specification. Nor was there evidence that someone skilled in the art would infer galantamine’s utility from the specification, even if such inferences could substitute for an explicit description of utility.” *Id.* The court further noted that the inventor herself testified that when she submitted this patent, she “certainly wasn’t sure, and a lot of other people weren’t sure that cholinesterase inhibitors [a category of agents that includes galantamine.] would ever work.” *Id.* at 1327 (citation omitted) (alterations in original). The court concluded that “the specification, even read in the light of the knowledge of those skilled in the art, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis. That is not sufficient.” *Id.*

This case presents an interesting review of a case where an applicant’s speculation turned out to be right. From a practitioner’s point of view, this case by itself does not particularly offend. What causes some pause, however, is the dual standard relating to similar disclosures in the prior art, which, especially after *KSR*,¹³ are likely to be viewed as anticipatory.

¹³ *KSR Int’l Co.*, 550 U.S. at 398.



Indefiniteness

Construction of claim reciting human EPO as including EPOs “such as” the 165 amino acid EPO isolated from human urine in the example does not render the claim indefinite even though the original application disclosed a 166 amino acid human EPO in the figure.

In *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd.*, 580 F.3d 1340, 92 U.S.P.Q.2d 1289 (Fed. Cir. 2009), the court addressed Roche’s contention that the term “human erythropoietin”

(“EPO”) was indefinite because the district court construed it as encompassing an EPO “such as” the amino acid sequence of EPO isolated from human urine in the example (which was determined to be 165 amino acids after the filing date) even though the sequence disclosed in the figure with the original filing was 166 amino acids. Roche cited this discrepancy as demonstrating that “[a]t the time of the invention ... no one knew the amino acid sequence of human EPO.” *Id.* at 1371. Roche asserted that “[t]o make the term definite,

[the court should] confin[e the] meaning to the specific 166 amino acid sequence disclosed in [the figure].” *Id.* The Federal Circuit disagreed, holding that “[w]hile [the figure] discloses a 166 amino acid sequence of human EPO, neither the claim nor the specification defines human EPO in terms of that figure.” *Id.* The court also accepted the testimony of Amgen’s expert that the example and the figure “would have reasonably apprised a person of ordinary skill of the scope of human EPO” and that “the human EPO produced according to [the example] would have had 165 amino acids.” *Id.* at 1372. The court acknowledged that

an ordinary skilled artisan did not know at the time, and the patent did not explain, that [the example] would produce, or that urinary EPO possessed, the amino acid sequence disclosed in [the figure] less the C-terminal amino acid. That does not mean, however, that an ordinarily skilled artisan at the time of the invention would not have known the scope of human EPO in claim 1.

Id. (citation omitted).

A product defined in a product-by-process claim is not necessarily limited to a product produced by the recited process steps.

Roche also argued that the court’s construction of the claimed source limitation “purified from mammalian cells grown in culture” rendered the claims indefinite. Roche pointed out that the district court construed the source limitations to exclude prior art urinary EPO but failed to “identify which structures distinguish unanticipated recombinant EPO from urinary EPO, and these structures are not defined in the claims.” *Id.* Roche argued that “[t]he implicit exclusion of urinary EPO from the asserted product claims makes it impossible ... to discern the boundaries of the claims.” *Id.* at 1373. The court acknowledged that “the district court found that the asserted claims were not anticipated by urinary EPO because recombinant EPO and urinary EPO are structurally and functionally distinct” and that “those structural and functional distinctions are not stated on the face of the claims.” *Id.* The Federal Circuit then drew the rather interesting conclusion that

[t]hat does not mean, however, that the court implicitly *construed* the source limitations to include those structural and functional differences. Rather, the court construed the source as a limitation of the asserted claims and *found* that the source imparted structural and functional features not possessed by EPO purified from urine. The structural and functional differences were therefore relevant to the court’s finding that recombinant EPO was a new product claimed with reference to the source from which it was obtained.

Id. (citation omitted).

The court thereby held that “[c]ontrary to Roche’s assertions, findings of fact that go to the question of validity of product-by-process claims do not automatically become part of the claim construction.” *Id.*

The court in this case certainly started with correct doctrine as set forth in *Abbott*, namely that product-by-process claims are properly construed one way for infringement purposes (as reading only on products made by the process recited in the claim) but another way for validity purposes (as reading on prior art making the same product even if by a different process). However, the only reason this works is because the definition of a product does not necessarily lock in the definition of the process that produces that product. Accordingly, it is reasonable for validity purposes to construe the claim as encompassing the same product even if made by an alternative process. The converse is not true. In particular, unlike a product, specific process steps in a claim do lock in the definition of the product that those process steps produce. Accordingly, it is nonsensical for a court to first conclude for validity that a particular process limitation locks in a structure but then to turn around for the infringement analysis and conclude that such structure is not dictated by the recited steps. How can the exact same process steps produce two different products, regardless of whether the court is reviewing the claims for validity or for infringement? The court’s blind adherence to *Abbott*’s doctrine of dual treatment led it to conclude that the recitation of source required structure for validity but that same recitation of source did not impose the same structural requirement for infringement.



Proving Infringement

One who alleges infringement of a claim containing functional limitations is not required to perform actual tests or experiments on the accused product or method, so long as testimony establishing infringement is scientifically based rather than merely conclusory.

In *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 92, U.S.P.Q.2d 1148 (Fed. Cir. 2009), the court reviewed whether Martek provided sufficient evidence of infringement for a claim, reciting “the culture medium containing the non-chloride sodium salt as the primary source of sodium results in reduced fermentor corrosion compared to the culture medium containing sodium chloride as the primary source of sodium.” Lonza asserted that Martek failed to prove infringement by failing to conduct comparative testing to demonstrate that Lonza’s culture medium causes less chemical wear as compared to a culture medium containing sodium chloride (NaCl) as the primary source of sodium. Martek presented testimony concluding that Lonza’s culture medium — which contains NaOH as the primary sodium source — causes less corrosion as compared to the hypothetical culture medium — which contains NaCl as the primary sodium source. However, Martek did not conduct actual comparative tests, but rather relied on its experts’ calculations showing that Lonza’s medium contained less chloride than a hypothetical NaCl medium and that “the literature is quite clear’ regarding the

corrosive effects of chlorides on stainless steels. ... ‘And it’s just not a rule of thumb, it’s a scientific fact that if you increase the chloride concentrations in any aqueous medium as far as stainless steel is concerned, you will cause more corrosion.’” *Id.* at 1373 (citations omitted).

Lonza argued that the court’s decision was contrary to its decision in *Kim v. ConAgra Foods, Inc.*,¹⁴ where the court found no infringement of a “consisting essentially of” product claim because the patentee failed to present “any examinations or tests of the actual accused products” even though the accused product contained the same ingredients as recited in the claim.¹⁵ The court in the instant case noted that “unlike *Kim*[,] Martek did not rely on conclusory expert testimony to demonstrate that Lonza’s medium reduces corrosion” but “presented testimony from two experts, each of whom conceptually analyzed the accused process and testified that it must meet the functional claim limitation based on the composition of Lonza’s culture medium and the known effects of chloride concentration on stainless steel corrosion.” *Id.* at 1374. The court further noted that *Kim* “did not articulate a general rule requiring one who alleges infringement of a claim containing functional limitations to perform actual tests or experiments on the accused product or method.” *Id.*

¹⁴ 465 F.3d 1312, 80 U.S.P.Q.2d 1495 (Fed. Cir. 2006).

¹⁵ *Id.* at 1320.



Claim Construction

Intrinsic and extrinsic evidence supported construction of term “non-chloride sodium salt” as encompassing NaOH despite selected passages from prosecution history that supported contrary conclusion but were not sufficient to amount to a clear and unmistakable disavowal.

Lonza also argued that the district court misconstrued the claim term “non-chloride sodium salt” by allowing that term to encompass sodium hydroxide (NaOH). The Federal Circuit disagreed, holding that

the district court’s claim construction comports with the intrinsic and extrinsic evidence of record in this case. ... First, although the specification does not discuss NaOH, the prosecution history explicitly states that NaOH is a non-chloride sodium salt—a clear indication that the applicant used the term “non-chloride sodium salt” in a manner broad enough to encompass NaOH. Moreover, Martek presented extrinsic evidence to support its position in the form of two treatises, each of which teaches that NaOH can be considered a salt.

Id. at 1377 (citation omitted).

Lonza argued that Martek disclaimed coverage of NaOH during prosecution. The court acknowledged that the

“selected statements spanning two pages of prosecution history ... arguably support Lonza’s assertion,” but found nonetheless that “those statements are undercut considerably by additional statements recited in the same two pages of prosecution history relied upon by Lonza.” *Id.* Accordingly, “under this court’s precedent, Martek committed no clear and unmistakable disavowal of claim scope.” *Id.*

Court concludes that humans are animals

Also in *Martek*, Martek argued that the district court improperly excluded humans when it construed claims reciting methods for achieving high concentrations of omega-3 HUFA in an “animal” to mean “any member of the kingdom *Animalia*, except humans.” The Federal Circuit noted that “[w]hen a patentee explicitly defines a claim term in the patent specification, the patentee’s definition controls.” *Id.* at 1380 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc)). “Here, Martek explicitly defined the term ‘animal’ in the ... patent: ‘The term “animal” means any organism belonging to the kingdom *Animalia*.’ That definition controls. Thus, because it is undisputed that humans are members of the kingdom *Animalia*, it was error for the district court to limit the claim term ‘animal’ to exclude humans.” *Id.* (citation omitted). The court rejected Lonza’s assertion that the disclosure and enumeration of preferred nonhuman animals constitutes a clear and manifest disavowal of human animals. The court

also rejected Lonza's assertion that references to "raising" and "feeding" animals was a disavowal. The court concluded:

Under our precedent, because the patent does not clearly disclaim coverage of humans, it would be erroneous to limit the claims to certain types of animals that the inventor anticipated would prove useful in the invention. That is especially true in the present case because the patent expressly defines the claim term "animal" broadly enough to encompass humans and discloses uses of the claimed invention applicable to humans.

Id. at 1382.

A patentee who erroneously argued that its solution "consisting essentially of" peracetic acid antimicrobial agent excludes additional antimicrobial agents did not disavow coverage of such additional agents where the examiner rejected that argument and allowed the claim on other grounds.

In *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 91 U.S.P.Q.2d 1225 (Fed. Cir. 2009), Ecolab argued that its solution, which included peracetic acid ("PAA") and two additional antimicrobial agents, did not infringe FMC's claim that recited "an aqueous peracetic acid solution, which consists essentially of a sanitizing concentration of at least 100 ppm peracetic acid." According to Ecolab, FMC disclaimed solutions containing antimicrobial agents in addition to PAA by arguing, in response to a prior art rejection, that its invention uses sanitizing solutions containing PAA as the only antimicrobial agent.

However, the examiner rejected FMC's argument and indicated that the claims reciting a composition "which consists essentially of" PAA are not limited to compositions containing PAA as the sole antimicrobial agent. Following the examiner's clarification, FMC never repeated the allegedly disclaiming statements and instead offered alternative reasons to overcome the prior art, which it eventually did. The Federal Circuit found that

a reasonable reader of this prosecution history could conclude that FMC's initial statements that PAA is the sole antimicrobial agent ... were hyperbolic or errone-

ous, that the Examiner corrected FMC's error ... , that FMC recognized its error and never again repeated or relied upon the erroneous rationale, and that the claims were allowed for reasons independent of the allegedly disclaiming statements.

Id. at 1343.

Thus, FMC's statements "simply are not clear and unmistakable enough to invoke the doctrine of prosecution history disclaimer." *Id.*

Even though the specification defined the term "sanitize" in "a method for sanitizing fowl" as requiring making the fowl "safe for human consumption," the court found the claim ambiguous and concluded that the fowl needed to be safe for consumption only after cooking, not immediately after the sanitizing method.



Ecolab also argued that its product did not infringe because the patent claimed "a method for sanitizing fowl," and stated in the specification that the term "sanitize" denotes a bacterial population reduction to a level that is "safe for human handling and consumption." By contrast, Ecolab's process for treating raw poultry does not and cannot make it safe for human consumption; cooking is required. The court found that "the definition of 'sanitize' is ambiguous in that it does not indicate when consumption is to take place—the definition does not indicate whether the consumption would occur immediately after application of PAA or ... at a later time after the meat is cooked."

Id. at 1345. The court resolved the ambiguity by looking to the admission made by Ecolab's expert that in-plant inspectors examine poultry that has been treated with PAA to determine if it is "fit for human consumption" and concluded that "[s]urely the inspectors do not require poultry to be 'fit for human consumption' in its uncooked state." *Id.* Ecolab argued that the court, in the *Chef America*¹⁶ case, construed a claim reciting heating a dough "to" 400° to 800° F. literally even though it was clear that patentee had intended to recite heating the dough "at" 400° to 800° F. lest the dough burn

¹⁶ *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 69 U.S.P.Q.2d 1857 (Fed. Cir. 2004).

to a crisp. Thus, as the court held *Chef America* to the literal words of its claim despite a nonsensical result from such construction, so should it hold FMC to the literal definition of “sanitize” as meaning “fit for human consumption” even though raw poultry “sanitized” by the FMC process is not fit for consumption until cooked. The court rejected the analogy, holding that the language here was ambiguous, while that in *Chef America* was not. *Id.*

This issue likewise arose in *Ortho-McNeil Pharm., Inc. v. Mylan Labs*, 520 F.3d 1358, 86 U.S.P.Q. 2d 1196 (Fed. Cir. 2008), where the court considered the term “and” to mean “or” in the context of the definition of alternative substitutions for a substituted ring. While it is easy to recite the court’s black letter doctrine that it will only deviate from a superficially nonsensical construction if there is an ambiguity, the cases offer little help to determine whether a term is ambiguous in the first place.

Product-by-process claims are limited to the recited process steps for purposes of determining infringement.

The Federal Circuit this year in *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 90 U.S.P.Q.2d 1769 (Fed Cir. 2009), resolved the long-standing controversy over whether process terms in product-by-process claims serve as a limitation in determining infringement.

Abbott’s patent included five claims to crystalline cefdinir, a pharmaceutical sold under the trade name Omnicef®. Cefdinir exists in two crystalline forms — Crystal A and Crystal B. The patent’s independent claim was directed to crystalline cefdinir defined by seven powder X-ray diffraction angle peaks. The dependent claims were directed to crystalline cefdinir without any PXRD peak limitations, but with descriptions of processes used to obtain the crystalline cefdinir. Abbott’s product Omnicef® involved the Crystal A form of cefdinir. The Food and Drug Administration had approved ANDAs for a generic form of cefdinir based in bulk on the Crystal B form with minor amounts of Crystal A form. The appeal at the Federal Circuit resulted from decisions granting partial summary judgment of no infringement under the doctrine of equivalents and no infringement of the dependent product-by-process claims 2–5. Notably, the question of whether the independent product claim 1, which was limited to the Crystal A form, could be literally infringed by a product that contains mostly Crystal B form and only minor amounts of Crystal A form was not at issue in this appeal.

The court limits claims to “crystalline” cefdinir to “Crystal A,” so as to exclude “Crystal B,” citing the specific reference in the specification to the “A” form and removal of reference to the “B” form in going from the priority to the U.S. application.

First the court addressed the district court’s determination that the term “crystalline” as used in each of the patent claims was limited strictly to Crystal A form of cefdinir. Although the court acknowledged that limiting the term “crystalline” to the Crystal A form arguably rendered the peak limitations of independent claim 1 redundant, the court noted that the specification “refers several times” to Crystal A form to distinguish the invention and offers no suggestion that the recited process could produce non-Crystal A compounds, even though other forms such as Crystal B were known in the art. *Id.* at 1289. The court further noted the fact that the Japanese priority application disclosed both Crystal A and Crystal B forms of cefdinir, but all mention of the Crystal B form was omitted from specification of the patent at issue.

The court expands the disclosure dedication rule to encompass subject matter that was known to the patentee at the time of filing by virtue of its inclusion in the priority document but not claimed to preclude application of the doctrine of equivalents.

Moreover, according to the court, the inventor clearly and intentionally disavowed claim scope beyond that of Crystal A form by submitting a declaration showing comparative testing of the Crystal A form relative to known prior art. By interpreting the term “crystalline” of each of the asserted claims to require the Crystal A form of cefdinir, and noting that Crystal B form was known at the time of the invention, the court found that Abbott could not recapture coverage of the Crystal B form of cefdinir under the doctrine of equivalents. The court stated that “[a]lternatively ... this case seems to fit within the dedication doctrine” as “[t]he patent applicant clearly knew of the Crystal B forms of the claimed invention because it claimed and disclosed them in its Japanese priority application.” The notion that the disclosure dedication doctrine is met for subject matter “known” to the patentee is remarkable, because, in the past, the disclosure dedication rule barred application of the doctrine of equivalents only when the specification disclosed the allegedly equivalent subject matter that was literally excluded by the claims. Now the priority application appears to be a valid source of disclosed subject matter for purpose of limiting the doctrine of equivalents. Whether the test is what was known to the patentee apart from what

was described in the specification or the priority application remains to be seen.

Having determined that the accused products could not infringe any of the claims under the doctrine of equivalents, the court turned to the more important question of literal infringement of the product-by-process claims. The dependent claims all recited particular process steps that were admittedly not performed in making the accused product. The court's prior decisions on product-by-process interpretation were split between Judge Newman's 1991 decision in *Scripps Clinic & Research Foundation v. Genentech, Inc.*,¹⁷ which held that product-by-process claims did not necessarily require practice of the recited process steps for purposes of infringement, and Judge Rader's 1992 opinion in *Atlantic Thermoplastics Co. v. Faytex Corp.*,¹⁸ which held that infringement required the accused to practice all of the claimed method steps of a product-by-process claim. Judge Rader in *Atlantic Thermoplastics* held that the Federal Circuit was not bound by the *Scripps Clinic* decision because that decision was in conflict with several prior Supreme Court decisions. The denial of *en banc* review of *Atlantic Thermoplastics* drew several passionate dissents from Judges Rich, Lourie and Newman. Judge Rich in dissent strongly criticized Judge Rader's disregard for the *Scripps Clinic* precedent, stating, "This is not only insulting to the *Scripps* panel [Chief Judge Markey, Judge Newman and a visiting judge], it is mutiny. It is heresy. It is illegal."¹⁹

After nearly two decades of limbo created by the conflicting panel decisions of *Atlantic Thermoplastics* and *Scripps Clinic*, the *Abbott* case finally presented the Federal Circuit with an opportunity to clarify the law on product-by-process claims.

Judge Rader wrote the panel opinion in *Abbott*, but in an unusual procedural maneuver, the question of product-by-process infringement was considered *en banc* before issuing the panel opinion. This time, the Federal Circuit *en banc* court expressly overruled the *Scripps* decision, holding that it conflicted with prior Supreme Court precedent. *Id.* at 1293. Reminiscent of the denial of *en banc* review in *Atlantic Thermoplastics*, Judges Lourie and Newman lodged vigorous dissents from the *en banc* decision. While agreeing that "there is substantial Supreme Court precedent that holds that product-by-process claims require use of the recited process for there to be infringement," Judge Lourie in dissent noted that "many of those cases applied overly broad language to fact situations involving old products or used vague language

¹⁷ 927 F.2d 1565, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991).

¹⁸ 974 F.2d 1279, 23 U.S.P.Q.2d 1801 (Fed. Cir. 1992).

¹⁹ *Id.* at 1281 (Rich, J., dissenting from the denial of rehearing *en banc*).

that makes it difficult to determine whether the products were old or new." *Id.* at 1320 (Lourie, J., dissenting from *en banc* Section III.A.2.). In addition to disagreeing with the panel's interpretation of Supreme Court precedent on product-by-process claims, Judge Newman lashed out at the court for procedural violations, stating, "The *en banc* court has received no briefing and held no argument, although the Federal Rules so require." *Id.* at 1301 (Newman, J., dissenting from *en banc* Section III.A.2.). In the end, *Abbott v. Sandoz* establishes as binding Federal Circuit precedent that product-by-process claims are only infringed by a showing that the process steps recited therein are carried out by the accused infringer.

Having found product-by-process claims limited to the process steps for infringement purposes, the court then proceeds to alter the plain meaning of "obtainable" to "obtained by" in order to limit the claims to the process steps.

The product-by-process claims at issue in *Abbott* used the phrase "obtainable by" to introduce the process limitations, which arguably provides an express indication that the claim should be read broadly, such that the recited process steps are optional. Despite the broad claim language, the court held that "a patentee's use of the word 'obtainable' rather than 'obtained by' cannot give it a free pass to escape the ambit of the product-by-process claiming doctrine." *Id.* at 1296. In response to *Abbott's* argument that it was attempting to give meaning to the word "obtainable," the court stated that *Abbott* "instead seeks to have this court render meaningless the explicit process limitations that the applicant chose to define its invention." *Id.* at 1295. Therefore, the Federal Circuit held that *Abbott's* dependent product-by-process claims were not literally infringed by the accused products, which were made by processes differing from those recited in the claims.

Patent applicants who utilize process limitations in their product claims should take heed of the *Abbott* decision. Whatever uncertainty existed in the past, *Abbott* clearly establishes that, despite the wording, product-by-process claims will be read as process claims for purposes of infringement. Further, *Abbott* reinforced the dichotomy that product-by-process claims are not limited by the process terms recited therein during examination under *In re Thorpe*.²⁰ The patentee who utilizes product-by-process language is now certain to face the worst of both worlds: during prosecution, when the claimed process language is given little consideration

²⁰ 777 F.2d 695, 227 U.S.P.Q.2d 964 (Fed. Cir. 1985).

in defining over the prior art, and during litigation, when the same language is interpreted narrowly to the advantage of the accused infringer. Given the court's uncompromising position on product-by-process language, patentees and applicants should avoid process language in product claims if at all possible.

The court construes claim requiring purification of EPO "from mammalian cells grown in culture" as reading on EPO indirectly produced from mammalian cells and on EPO with a missing hydrogen that was pegylated.

In *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd.*, 580 F.3d 1340, 92 U.S.P.Q.2d 1289 (Fed. Cir. 2009), the court assessed whether Roche infringed Amgen's product-by-process claim to "[a] pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, **wherein said erythropoietin is purified from mammalian cells grown in culture.**" *Id.* at 1364 (emphasis added). Roche argued that its product, MIRCERA®, does not infringe the claims because (1) it is made in a cell-free reaction and is thereby not produced and purified from mammalian cells and (2) once formed, MIRCERA® is a novel, intact molecule that no longer contains human EPO because it loses a hydrogen when reacted with polyethylene glycol ("PEG").

The court rejected both arguments. As for the source limitation, the court found that "MIRCERA® also comprises EPO produced in and purified from mammalian cells, thereby satisfying the source limitations of the asserted claims." *Id.* at 1376. The court found that Roche fundamentally misread the claims "to require that MIRCERA® be produced in, and purified from, mammalian cells and have a cell-produced structure. Yet, all that these claims require is that MIRCERA® comprise EPO produced in and purified from mammalian cells." *Id.* at 1376-77 (footnote omitted). "That MIRCERA® itself can only be produced outside a cell is irrelevant to the source limitations. Consequently, the court properly declined to instruct the jury that the source limitation requires MIRCERA® to be cell-produced." *Id.* at 1377.

As for the structure, Amgen argued that the source limitations do not exclude the attachment of further structure, such as PEG, to human EPO because the source limitations pertain to the source of human EPO, not MIRCERA®, and that they do not preclude the addition of other materials. Amgen also argued that the removal of a single hydrogen atom from epoetin beta does not change the fact that MIRCERA® contains the sequence of amino acids that defines human EPO in the



claims. Citing its claim construction that EPO is “[a] protein having the amino acid sequence of human erythropoietin, **such as the amino acid sequence of EPO isolated from human urine**,” *Id.* at 1376 (citations omitted) (emphasis added) (alteration in original), as well as expert testimony and Roche’s own statements to the FDA, the court agreed with Amgen. *Id.* at 1374. “Roche’s argument that human EPO no longer exists ‘as a matter of chemistry’ once it reacts with a PEG molecule is unpersuasive because the record shows that the human EPO component exists in the final product and confers its structural and functional properties onto MIRCERA®.” *Id.* at 1376. The court thus held that “the attachment of a PEG molecule is the addition of an element, which cannot negate infringement, as opposed to a fundamental chemical transformation, which might save MIRCERA® from infringement.” *Id.*

Because product-by-process claims can be construed one way for infringement and another way for validity, the structural features imposed on the product by the process steps need not be present in the accused product.

Elsewhere in *Amgen*, Roche argued that the court incorrectly construed the claims one way for purposes of validity but a different way for purposes of infringement. In the context of validity, the court construed the source limitation of the claimed EPO (“wherein said erythropoietin is purified from mammalian cells grown in culture”) as imparting novel structure over urinary EPO. In the context of infringement, however, the district court did not require the accused EPO product to possess the novel structures that distinguished the claimed EPO based on source from the prior art EPO. Roche argued that because the court did not require Amgen to show for infringement that Roche’s product possessed novel structures that distinguish Amgen’s recombinant EPO from the prior art urinary EPO, the court should not have required Roche to prove for anticipation that the source limitation does not impart novel structure onto EPO. The court rejected Roche’s argument, noting

[f]or product-by-process claims, that which anticipates if earlier does not necessarily infringe if later because a product in the prior art made by a different process can anticipate a product-by-process claim, but an accused product made by a different process cannot infringe a product-by-process claim. Similarly, that which infringes if later does not necessarily anticipate if earlier because an accused product may meet each limitation in a claim, but not possess features imparted by a process limitation that might distinguish the claimed invention from the prior art.

Id. at 1370.



Here, “to prove invalidity, Roche had to show that recombinant EPO was the same as urinary EPO,” which Roche did not do “because urinary EPO and recombinant EPO were structurally and functionally different.” *Id.* “To prove infringement, Amgen had to show that MIRCERA® comprises EPO made recombinantly,” which it did. *Id.* “Importantly, Amgen was not required to show that MIRCERA® was also structurally and functionally different from urinary EPO. In other words ... the court correctly did not require MIRCERA® ... to differ from urinary EPO.” *Id.*

This holding is quite disturbing, since the court is saying that even if Roche’s product were structurally identical to the prior art urinary EPO, it could still infringe a valid claim pro-

vided that Roche’s product was made by the process steps recited in the product-by-process claim. This may be the first time in patent jurisprudence that a court has stated that a prior art teaching infringes a claim but cannot invalidate a claim. The good news is that the court’s misstatement will probably inflict minimal, if any, real damage for the simple reason that it would seem well-nigh impossible to say that the process steps impose a structural distinction on the one hand for patentability purposes but that those exact same process steps carried out in an infringing teaching could be indistinguishable from the prior art.

Even though the claim related to production of crude and un-pegylated EPO having different physical and chemical properties from the refined pegylated EPO imported into the U.S., the court finds no material change, and thus infringement under 271(g), because the product still contains an intact EPO structure, which still functions in the same way.

Because Roche manufactured MIRCERA® overseas, the court also had to review infringement based on 35 U.S.C. § 271(g), which makes the importation into the United States of a product made by a process patented in the United States an act of infringement unless such product is “materially changed by subsequent processes” prior to importation. Roche argued that MIRCERA® is materially changed because (1) “[c]omparing unadministerable crude EPO [as produced by the claim] to FDA-approved MIRCERA® evidences a ‘material change,’” and (2) “due to the attached PEG molecule, MIRCERA® possesses different structures and properties than Amgen’s EPO” and in particular “thousands more atoms, hundreds of new bonds, a significantly higher molecular weight, a different charge, and improved pharmacokinetic properties.” *Id.* at 1377-78. Amgen argued that human EPO in MIRCERA® has the same structure and function as EPO recited in the claims of the patents. The court agreed that human EPO in MIRCERA® is not “materially changed” by pegylation because “we do not read the scope of the asserted claims as limited to production of crude EPO.” *Id.* at 1378. The court acknowledged that “MIRCERA®, unlike crude EPO, is suitable for administration to patients” and that there are “structural and functional differences (e.g., size, molecular weight, half-life, atomic composition) between MIRCERA® and EPO produced by the processes recited in the asserted claims” but found that these differences were not material. *Id.* at 1378-79. However, here, “Amgen presented evidence that the structural and functional differences were not material because MIRCERA® still contains EPO, the structure of EPO remains intact, MIRCERA® binds to the EPO receptor, and MIRCERA® retains its claimed ability to increase the production of reticulocytes and red blood cells.” *Id.* at 1379. Thus, “[t]he record reflects ... that MIRCERA® and human EPO stimulate erythropoiesis similarly.” *Id.*

Neither the specification nor the file history evinces “unmistakable disavowal” from ordinary meaning of “adipose-derived” cells as a cell derived from fat tissue, even though the specification and prosecution distinguished such cells from “mesenchymal stem cells.”

In *University of Pittsburgh v. Hedrick*, 573 F.3d 1290, 91 U.S.P.Q.2d 1423 (Fed. Cir. 2009), the court reviewed an inventorship dispute filed by the University of Pittsburgh seeking to remove a number of the named inventors from the “REBAR” group²¹ in a patent claiming an “adipose-derived stem cell that can differentiate into two or more of the group consisting of a bone cell, a cartilage cell, a nerve cell, or a muscle cell.”

The dispute hinged on the claim construction of the term “adipose-derived.” Although both parties agreed that its plain meaning is a cell “derived from fat tissue,” REBAR argued that the plain meaning needed to be narrowed to exclude prior art mesenchymal stem cells (“MSCs”) that are obtainable from bone marrow tissue but travel to fat tissue. Although acknowledging that the specification distinguishes between MSCs and adipose-derived stem cells, the court found that “the specification does not say that the cells are a separate species from [MSCs] collected from bone marrow as the REBAR researchers argue” *Id.* at 1297. The court noted that merely because “other similar prior art cells are described differently than the inventive cells does not rise to an intent to deviate from the meaning of the terms describing the inventive cells.” *Id.*

The court also rejected any “unmistakable disavowal” of the ordinary meaning in the prosecution history. *Id.* REBAR argued that the Pittsburgh inventors “clearly and unambiguously disclaimed any construction of adipose-derived that could read on prior-art [MSCs] when they overcame a rejection of claims by introducing the term adipose-derived.” *Id.* REBAR cited the interview summary record where the Pittsburgh inventors “agreed that a submission to distinguish between adipose derived stem cell and bone marrow derived stem cell will be submitted.” *Id.* (quotations omitted). Such submission was made and the examiner then agreed that the “adipose-derived stem cells are distinct from the mesenchymal stem cells” of the prior art. *Id.* (quotations omitted). The court concluded that

[t]his is not a disavowal, [finding that] [t]he examiner’s summary is certainly terse, and its terseness does not allow a definition of any claim terms. It does not state why the adipose-derived stem cells in the invention are distinct from [MSCs], and thus does not explicitly characterize the invention at all, let alone in a specific manner to overcome prior art. *Id.*

²¹ Regenerative Bioengineering and Research (“REBAR”) laboratory.



Inventorship

Although reduction to practice requires proof that the invention works to a scientific certainty, conception does not; accordingly, later groups' demonstration of scientific certainty did not entitle them to inventorship and some "holes" in conception may be filled with knowledge of a skilled artisan.

Having concluded that the claim language did not require a distinction between adipose-derived cells and MSCs, the court found that the REBAR group was not properly included as inventors. The court rejected REBAR's argument that the Pittsburgh inventor's evidence was "highly speculative" and that the REBAR inventor's work was required to "know" that

the invention contained every limitation of each claim at the time of conception. *Id.* at 1299. The court noted that

[k]nowledge in the context of a possessed, isolated biological construct does not mean proof to a scientific certainty that the construct is exactly what a scientist believes it is. ... [Rather,] [p]roof that the invention works to a scientific certainty is reduction to practice. Therefore, because the district court found evidence that [the Pittsburgh inventors] had formed a definite and permanent idea of the cells' inventive qualities, and had in fact observed them, it is immaterial that their knowledge was not scientifically certain and that the REBAR researchers helped them gain such scientific certainty.

Id.

Finally, the court disagreed with REBAR that “the district court erred by filling in holes in [the] conception with knowledge that a skilled artisan would have had at the time when no corroborating evidence of their own knowledge was produced.” *Id.* The court found that, under the “rule of reason” analysis,

[e]vidence need not always expressly show possession of the invention to corroborate conception, and a court may properly weigh evidence that a claimed attribute is merely an obvious property of a greater discovery at issue. Here, the greater discovery is that stem cells can be derived from adipose tissue. It was not improper for the district court to recognize that skilled artisans at the time of the alleged conception would have known the obvious properties that these stem cells self-renew for at least 15 passages as in claim 6, that the cells contain cell-surface bound intracellular signaling moieties for claim 9, and secreted hormones for claim 10, and to credit Katz with having the firm and definite idea that these properties existed in his cells.

Id. (citation omitted).

An abandoned patent application is not sufficient corroboration of prior inventorship, which requires evidence in addition to an inventor’s own statements and documents.

In *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 92 U.S.P.Q.2d 1148 (Fed. Cir. 2009), the accused infringer, Lonza, argued that the claimed invention was not patent-eligible because it was previously made by another inventor, Dr. Long. The court noted that “[b]ecause Lonza sought to introduce the testimony of an alleged prior inventor under § 102(g) for the purpose of invalidating a patent, Lonza was required to produce evidence corroborating Dr. Long’s testimony.” *Id.* at 1374. As corroboration, Lonza offered: (1) Dr. Long’s 1987 abandoned patent application and (2) evidence that the examples originally disclosed in that abandoned application were later reproduced, generating the results described in the application. The court noted that “[a]n alleged prior inventor ‘must provide independent corroborating evidence in addition to his own statements and documents,’ such as ‘testimony of a witness, other than [the] inventor, to the actual reduction to practice or ... evidence of surrounding facts and circumstances independent of information received from the inventor.’” *Id.* at 1375 (cita-

tions omitted) (last alteration in original). Here, the proffered abandoned patent application was insufficient to corroborate Dr. Long’s testimony because “while an abandoned patent application is evidence of conception, it is insufficient to corroborate testimony that an alleged prior inventor reduced the invention to practice.” *Id.*

Although evidence corroborating the inventor’s appreciation that the compressed region of a detergent tablet “dissolved more quickly than the non-compressed region” was a close call, it was supported by substantial evidence.

In *Henkel Corp. v. Procter & Gamble Co.*, 560 F.3d 1286, 90 U.S.P.Q.2d 1119 (Fed. Cir. 2009), the Federal Circuit considered for the second time, after a remand, whether the junior party Henkel or the senior party P&G was entitled to priority for a count directed to a detergent composition tablet requiring that the compressed region of the tablet dissolve “at a faster rate than said non-compressed portion on a weight by weight basis.” *Id.* at 1288. In its original review, the court reversed the board’s holding that Henkel had failed to establish a reduction to practice of the count by failing to provide proofs with specific dissolution rates, noting that the count itself did not recite a specific dissolution rate. On second review, the court affirmed the board’s award of priority to P&G, based on the testimony of the inventor that he appreciated, before the critical date, that the compressed region of the tablet dissolved more quickly than the non-compressed region. The court noted that it was a “close call” whether the report relied upon by P&G corroborated the inventor’s appreciation of a more rapid dissolution of the core region. *Id.* at 1290. The board agreed with P&G that the statement in the corroborating report that “the loss of performance [in a “dimple” tablet] could be a result of ‘slower release of NB-base from the dimple vs. regular tablets [,]’ [was] an appreciation that the compressed region (i.e., the ‘regular’ region) of the dimple tablet dissolved at a faster rate than the non-compressed region (i.e., the ‘dimple’ region).” *Id.* (citations omitted). Nonetheless, the Federal Circuit found equally plausible Henkel’s interpretation of the report as implying “a potentially slower release of the untabletable active ingredient from the dimple inert carrier than the release of the same active ingredient tableted in a regular tablet, i.e., a single-region tablet.” *Id.* (quotations omitted). The court found that “the Board’s interpretation is supported by substantial evidence.”



Inequitable Conduct

Material errors in sequence listing figure did not rise to level of inequitable conduct due to lack of intent to deceive in view of plausible explanations that applicants engaged in an honest but imperfect attempt to correct mistakes.

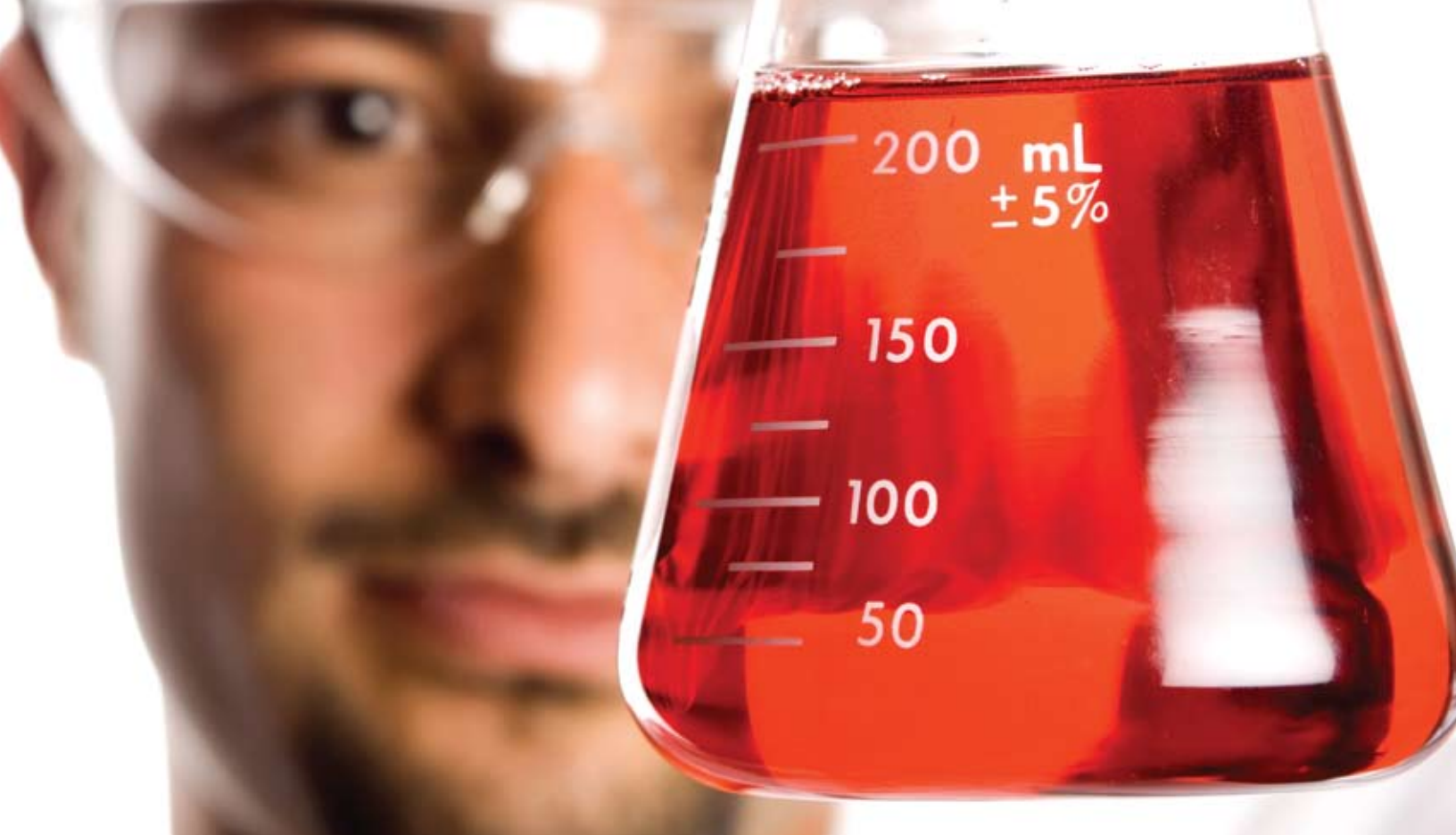
In *Ariad Pharm. Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 90 U.S.P.Q.2d 1549 (Fed. Cir. 2009), Lilly alleged that Ariad committed inequitable conduct in failing to disclose admittedly material errors in a sequence listing figure as well as the fact that the sequence was from a chicken as opposed to a mouse. The court found that there was no intent to deceive. *Id.* at 1378. One of the counsel never knew of the errors. Although Ariad's employee knew, there was no evidence of an intent to conceal the errors, given that she disclosed the errors to her attorneys and justifiably expected that her attorneys would determine the legal significance of them and take appropriate action. Although another counsel also knew of the errors, the district court credited testimony that she was following her firm's standard practice to make the correction only after the PTO indicated the claims were allowable. The fact that knowledge of the errors was lost when counsel left for another firm did not rise to the level of intent to deceive. The court held that the fact that the incorrect figure was left in an application that issued as a patent is simply not

sufficiently suspicious that it should contribute to a finding of intent. ... [given] that the parties involved endeavored to correct [the] figure ... throughout the family of applications. These actions do not signal a nefarious plot to leave [the] figure. ... in the one application that would lead to the patent asserted; rather, they signal an honest but imperfect attempt to correct mistakes.

Id. at 1379.

Although references published after the application filing date could be material to the issue of inherency, the court finds no intent to deceive, even in view of the inventor's knowledge of their relevancy, given that his reasons for nonsubmission were plausible, albeit legally incorrect.

Also, in *Ariad*, Lilly further argued that four nondisclosed references authored by one of the inventors, although published after the filing date of the patent in suit, were material as relevant to the issue of whether certain claims are anticipated by compounds known in the prior art. Lilly argued that Ariad intentionally concealed the references, pointing to the testimony of the inventor that he knew the references were relevant to the subject matter of the application. See *Id.* "[The inventor]—who is a scientist and not a patent lawyer—was apparently aware of his duty to disclose, and also aware that it could be inappropriate to submit material that might 'inundate' the U.S.P.T.O.'" *Id.* The court found that his reasons for not submitting the references are plausible, even if ultimately legally incorrect, and that Lilly failed to show that deceptive intent was the better explanation for his behavior. Lilly also failed to show that the inventor had any knowledge of how the statements about the effect of prior art compounds on NF- κ B activity made in the references could impact the application or that he appreciated the inherent anticipation theory to which the references allegedly pertained. Finally, the court found that Lilly also failed to show the inventor's knowledge of the historical uses of the prior art compounds. The court noted that Lilly could not prove deceptive intent by clear and convincing evidence simply by relying on the materiality of the errors. See *Id.* 1379-80.



Hatch- Waxman

Because the district court has discretion in ANDA litigation to shorten or extend the thirty-month stay based on a party's failure to reasonably cooperate, extension of stay was justified where ANDA filer changed its formulation late in the litigation.

In *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 557 F.3d 1346, 89 U.S.P.Q.2d 1921 (Fed. Cir. 2009), the Federal Circuit addressed the question of the degree of discretion held by district courts to either shorten or extend the thirty-month stay in ANDA litigation. Here, the district court extended the thirty-month statutory stay. The court found that the ANDA filer, Teva, had recast its product more than eighteen months after it provided the original sample to the patent holder, Eli Lilly, and only eight months before trial was set to commence. The court found that this entitled Eli Lilly, in preparation for trial, to have sufficient opportunity to identify the nature and composition of the raloxifene product as Teva intends for it to be sold. *Id.* at 1352. Relying on Teva's alteration of its proposed generic raloxifene HCL tablets late in the litigation, in particular a change in the particle size manufacturing specification of the active ingredient and the method of measuring particle size, in addition to Teva's delivery of its

changed samples to Lilly past the district court's discovery deadline, the Federal Circuit concluded that the district court acted within its discretion to adjust the statutory thirty-month stay. *Id.* at 1350. The court held that Section 355(j)(5)(B) (iii) "grants district courts the discretion to adjust the statutory thirty-month stay of ANDAs if 'either party to the action failed to reasonably cooperate in expediting the action.'" *Id.* (citation omitted). The court agreed that "[t]rial courts, thus, may shorten or extend the thirty-month statutory period based on the parties' uncooperative discovery practices before the court." *Id.*

The safe harbor statute applies to process patents in actions at the ITC under § 337, when the imported product is used for the exempt purposes of § 271(e)(1).

In *Amgen, Inc. v. International Trade Commission*, 565 F.3d 846, 90 U.S.P.Q.2d 1843 (Fed. Cir. 2009), Amgen filed a complaint at the International Trade Commission ("ITC") arguing that certain recombinant EPO products imported by Roche into the U.S. infringed Amgen's patents. Roche argued noninfringement by operation of the "safe harbor" statute, 35 U.S.C. § 271(e)(1), "because the imported

EPO is used only for the statutorily exempt purpose of the development and submission of information under a federal law regulating the manufacture, sale, and use of drugs.” *Id.* at 848. The ITC agreed. Amgen appealed on the ground that the safe harbor “does not apply to Tariff Act violations based on foreign practice of patented processes.” *Id.* Amgen argued that the “statute does not bar the exclusion of such importation, reasoning that the § 271(e)(1) reference to importing ‘a patented invention’ is necessarily limited to importation of product, for a process cannot be imported. ... Thus, Amgen argue[d] that an importation that is exempt under § 271(e)(1) of the Patent Act may nonetheless be unlawful under § 337 of the Tariff Act.” *Id.* at 850, 851.

The Federal Circuit agreed with the ITC and Roche, holding that “the safe harbor provided by § 271(e)(1) applies in proceedings under the Tariff Act relating to process patents as well as product patents, for imported product that is used for exempt purposes.” *Id.* at 848. The court concluded that such result was “in consonance with congressional policy as set forth in enactment of § 271(g), and as elaborated by the Supreme Court in its applications of the safe harbor statute.” *Id.* at 851. The court noted that

[i]n both *Merck*²² and *Eli Lilly*²³, the Court stressed the congressional purpose of removing patent-based barriers to proceeding with federal regulatory approval of medical products. This purpose and its application in precedent weigh heavily against selectively withholding the § 271(e)(1) exemption depending on whether the infringement action is in the district court or the International Trade Commission.

Id. at 851-52.

Each activity alleged to be exempt under the FDA safe harbor must be evaluated separately and the fact that a given activity occurs while the FDA approval process is pending does not automatically exempt that activity.

²² *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

²³ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

Amgen next argued that even if the safe harbor statute applies to process patents in ITC proceedings, “at least some of the EPO imported by Roche is not exempt because its actual use was not ‘reasonably related to the development and submission of information under [the FDCA],’ § 271(e)(1).” *Id.* at 852. The Federal Circuit agreed with Amgen, noting that the ITC “appears to have assumed that all otherwise infringing activities are exempt if conducted during the period before regulatory approval is granted. That assumption is incorrect, for the Court in *Merck* confirmed that ‘[e]ach of the accused activities must be evaluated separately to determine whether the exemption applies.’” *Id.* (citation omitted). In particular, the court found “that commercial and marketing studies are more clearly subject to separate evaluation for application of the exemption.” *Id.*

Here, at least some of Roche’s activities were not related at all to obtaining regulatory approval, such as its carrying out of studies after the Biologics License Application (“BLA”) information had been submitted to the FDA. As a BLA occurs only after complete data have been obtained, analyzed and presented to the FDA, by definition it cannot be directed to obtaining information for regulatory approval. The court agreed, noting that

the Court in *Merck* set careful boundaries to the exemption, requiring separate review of all studies for which the exemption was claimed. Roche does not appear to dispute that some imported product was used to conduct Roche’s marketing department’s recommended studies for purposes of brand recognition and not for FDA approval, and the record does not discuss whether any of the post-BLA work was supplemental to the BLA and intended for submission to the FDA, thereby subject to exemption.

The court thereby held that “[t]o the extent that the Commission held all importation and all uses exempt while FDA approval was pending, the safe harbor statute does not so provide.” *Id.* to 853.

Conclusion

In 2009, the Intellectual Property Owners Association wrote an open letter to the Obama administration urging it to appoint judges who actually have a background in patent law. Looking back at the year, it is not hard to understand why. For the first time ever, the court, in *Gleeve*, invalidated a claim as anticipated based on the mere suggestion that the claimed compounds could be made. In another first, the court in *Takeda* applied the rules for independent or distinct inventions used in restriction practice to a double-patenting situation. Then, in a classic example of championing form over substance, the court in *Roche* held that an application filed with restricted, nonelected claims was not entitled to the safe harbor protection 35 U.S.C. § 121 simply because it was inadvertently styled a “continuation,” rather than a “divisional” application. This the court did even in view of the applicable MPEP provision indicating that it was irrelevant whether an applicant styled a continuing application as a continuation or divisional.

That same court in *P&G* left everybody scratching their heads when it held that process steps could impart structure on a product for validity purposes, but not necessarily for infringement purposes. In *P&G* and *Bayer*, cases involving similar fact patterns in which one reference pointed toward the claimed invention and another taught away from it, the court reached two seemingly contradictory conclusions regarding obviousness and went as far as to say that a teaching away was actually one of the finite “solutions” envisioned by *KSR*. In *Abbott*, the court sitting *en banc* deviated from established appellate practice and disregarded prior Federal Circuit precedent by relying on Supreme Court precedent that arguably did not address the question at hand. The court also endorsed an expansion of the disclosure

dedication rule to a situation where the excluded embodiment was not even disclosed in the application at issue, such that the applicant could not have claimed it even had it wanted. In *Kubin*, the court confused the obviousness of a particular cloning technique with the obviousness of finding a suitable library for carrying out that cloning technique.

2009 continued an alarming trend in which the Federal Circuit continues to deviate substantially from bedrock principles of patent law and issue inconsistent panel opinions. If the court were a professional sports team, we would recommend it start the new season by “focusing on fundamentals.”



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- Extensive preparation and presentation of speeches both for clients and outside organizations concerning developments in intellectual property law.
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Speeches

- Speaker, Practicing Under New Interference Rules, AIPLA Midwinter Meeting, Orlando, FL, 2005
- Speaker, Strategic Use of Patent Interferences, American Intellectual Property Law Association Mid-Winter Meeting, Orlando, Florida, 01/27/05
- Speaker, File Wrapper Estoppel after Festo, Greater Richmond Patent Law Association, Richmond, Virginia, 01/01/03
- 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
- Speaker, Developments in Biotech and Pharmaceutical Practice at the Patent Office, Courts, and FDA, Association of Industrial Pharmacists Annual Meeting, Paris, France, 1997, 2000

Publications

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Awards and Professional Recognition

- Listed as one of 25 top intellectual property and technology attorneys in the December 2000 issue of *Virginia Business* magazine
- Listed as one of Washington, DC's Best Lawyers for Intellectual Property Law, *Washington Post*, 2010

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Practice includes representation of technology-based companies of all sizes in areas involving intellectual property with particular emphasis on patent procurement, enforcement, and counseling.

Relevant Experience

- Represents clients in a variety of technologies, including: chemical compounds compositions and processes, pharmaceuticals, polymers, medical devices, food science, and bioprocess technology.
- Prepares and prosecutes patent applications before the United States Patent & Trademark Office and foreign patent offices. Experience counseling clients and preparing opinions involving patent infringement, validity, and freedom to operate issues in a variety of technologies. Experience with interference proceedings in the United States Patent & Trademark Office and patent litigation in federal courts.
- Prior to joining Hunton & Williams, Mr. Vockrodt served as a patent examiner in the United States Patent & Trademark Office where he worked on patent applications related to integrated circuits, semiconductor lasers, liquid crystal displays, thin film transistors, semiconductor manufacturing processes, and semiconductor processing equipment. While at the Patent Office, he served at the Board of Appeals and Interferences assisting administrative patent judges with the disposition of ex parte appeals.
- While serving as a law clerk in the United States International Trade Commission (ITC), Office of Unfair Import Investigations, Mr. Vockrodt assisted staff investigative attorneys at the institution, pre-trial, and trial stages of ITC litigation.

Background

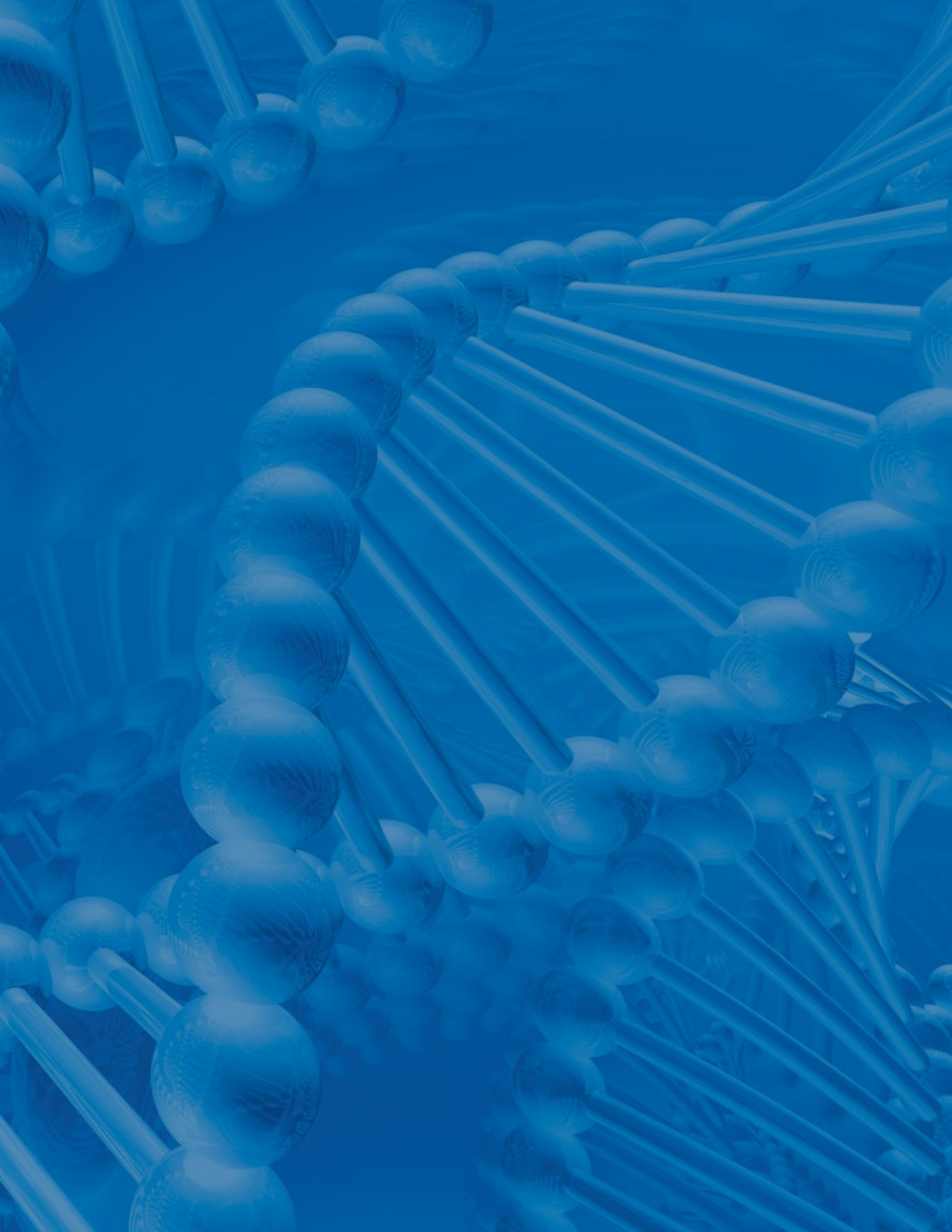
- Law Clerk, U.S. International Trade Commission, Office of Unfair Import Investigations, Summer 2004.
- Patent Examiner, U.S. Patent and Trademark Office, 1999-2004. Externship, Board of Appeals and Interferences, U.S. Patent and Trademark Office, Spring 2004.

Membership

- Registered to practice before the U.S. Patent and Trademark Office
- Member, Maryland State Bar
- Member, District of Columbia Bar

Education

- J.D., George Washington University Law School, member of the Moot Court Board, recipient of the American Bar Association/Bureau of National Affairs Award in Intellectual Property, winner of the best overall competitor, best brief and first place team in the George Washington Law School intellectual property moot court competition, 2005
- B.S., University of Arizona, Chemical Engineering, 1999





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