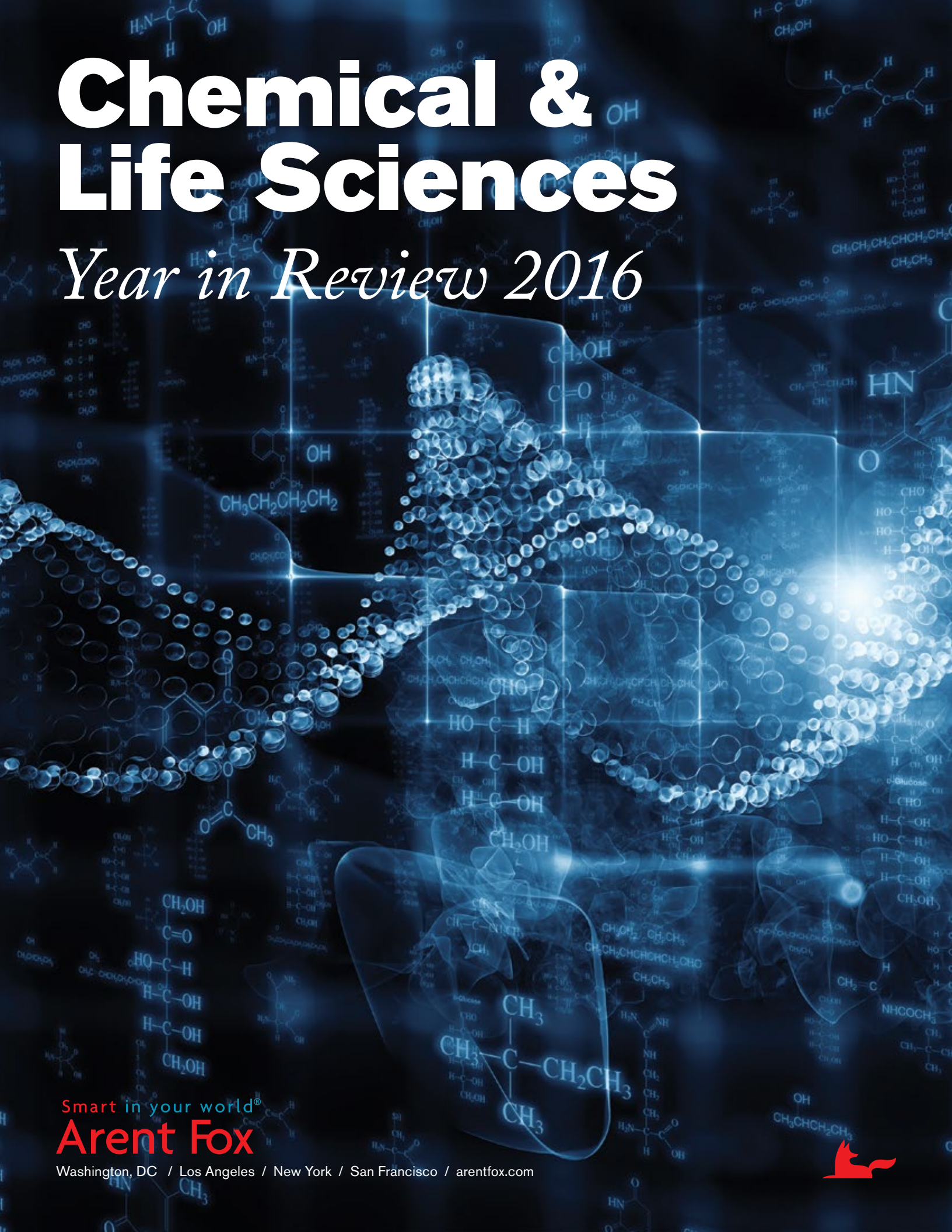
Chemical & Life Sciences

Year in Review 2016



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Introduction

As in previous years, 2016 brought us a combination of both expected and unexpected holdings by the Supreme Court and the Federal Circuit.

The Supreme Court decided three patent cases in 2016, but the Court's denial of certiorari in *Ariosa v. Sequenom* will have the most lasting impact on the prospects for patenting in the life sciences. The Federal Circuit's *Ariosa* decision—left undisturbed by the Court—precludes patenting most diagnostic methods that rely on generally known techniques, as being drawn to ineligible subject matter under 35 U.S.C. § 101. Combined with the Federal Circuit's decision in *Genetic Techs. v. Merial* that allows adjudicating § 101 eligibility questions on a motion to dismiss, the *Ariosa* decision rapidly changes the landscape for patenting diagnostics and potentially other life sciences inventions.

But there was at least one silver lining for life science patent owners this year. In *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, the Federal Circuit upheld claims to a method of producing hepatocytes, finding that the claims are "directed to" patent eligible subject matter, and although the method steps were individually known, the process of repeating the steps was not routine and conventional.

In two decisions affecting chemical and life science patenting, the Supreme Court weighed in on the standard for willfulness in *Halo*, and the procedures for inter partes review (IPR) in *Cuozzo*. *Halo* overruled the Federal Circuit's Seagate standard of "objective recklessness," making it easier for patent owner to prove willful infringement and obtain treble damage awards. This decision increases the importance of timely non-infringement opinions of counsel for potential infringers.

In *Cuozzo*, the Court blessed the Patent Office's approach to claim construction in an *inter partes* (IPR), and agreed that institution decisions based on slightly different grounds than presented in the petition are not appealable. The Court cast some doubt upon the Federal Circuit's blanket practice of finding anything related to the institution decision non-appealable. As a result, the Federal Circuit granted *en banc* rehearing in *WiFi One, Inc. v. Broadcom Corp.*, where it will reassess its standards for what issues may be appealed to the Federal Circuit in an IPR.

The Federal Circuit largely affirmed the Patent Trial and Appeal Board's decisions whether they related to IPRs or *ex parte* examinations. For example, the court held that the Board has discretion regarding whether to permit new arguments late in an IPR proceeding, and to rely on references showing the "state of the art" even if not cited in the institution decision.

The Federal Circuit also weighed in on several issues of substantive patent law of interest to chemical and life sciences, including anticipation, obviousness, indefiniteness, written description, and claim construction. Most notably for pharmaceutical patent owners, the *en banc* court reversed an earlier panel holding that a contract manufacturer's "sale" of manufacturing services to the patentee presented an on-sale bar.

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At the Supreme Court

In *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131 (2016), the Supreme Court considered two questions regarding *inter partes* reviews ("IPRs") namely (1) does the "No Appeal" rule (making the PTO's determination to institute an IPR final and non-appealable) bar a court from considering whether the PTO wrongly instituted an IPR on grounds not specifically mentioned in the IPR Request; and (2) does the statute permitting PTO issuance of regulations governing IPRs authorize the PTO's claim construction standard of broadest reasonable construction ("BRC") in light of the specification of the patent in which it appears?

The "No appeal" rule making the PTO's determination to institute an IPR final and non-appealable applies even against claims not specifically identified in the IPR Request, where such claims were logically linked to the claims subject to the Request.

Garmin argued that the IPR petition had to specifically mention all claims to which the obviousness argument applied. The government argued that because the claims were "all logically linked and 'rise and fall together,' the 'petition need not simply repeat the same argument expressly when it is so obviously implied.'" *Id.* at 2139. The Government also argued that because Garmin's argument relates to a matter determined during the institution phase of an IPR, judicial review of that decision is precluded by the "No appeal" rule codified in 35 U.S.C. § 314(d), which provides that "[t]he determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable."

The Court agreed with the government, concluding that "the 'No Appeal' provision's language must, at the least, forbid an appeal that attacks a 'determination . . . whether to institute' review by raising this kind of legal question and little more." § 314(d). The Court noted that "a contrary holding would undercut one important congressional objective, namely, giving the PTO significant power to revisit and revise earlier patent grants." *Id.* at 2140. The *Cuozzo* holding in this regard gives the PTAB flexibility in crafting final written decisions including final grounds that go beyond merely repeating verbatim the grounds proposed in the petition.

Court does not preclude review of all appeals of IPR institution decisions, such as where the appeals implicate Constitutional questions, are in excess of statutory jurisdiction or arbitrary and capricious.

However, the Court did not preclude review of appeals that (i) implicate constitutional questions, (ii) depend on other less closely related statutes, or (iii) present other questions of interpretation that reach, in terms of scope and impact well beyond "this section." For example, judicial review may be proper where a petition fails to give "sufficient notice" such that there is a due process problem with the entire proceeding; or the agency acts outside its statutory limits by, for example, canceling a patent claim for indefiniteness under §112 in an IPR. Such "shenanigans" may be properly reviewable because reviewing courts may "set aside agency action" that is "contrary to constitutional right," "in excess of statutory jurisdiction," or "arbitrary [and] capricious." *Id.* at 2155.

The Supreme Court's language apparently softening the "No appeal" rule resulted in a successful *en banc* petition challenging the Federal Circuit's case law that severely restricted judicial review of almost all issues decided on institution of IPR. In *WiFi One, Inc. v. Broadcom Corp.*,[1] the Federal Circuit requested briefing on the following question:

> Should this court overrule *Achates Reference Publishing, Inc. v. Apple Inc.,* 803 F.3d 652 (Fed. Cir. 2015)[2] and hold that judicial review is available for a patent owner to challenge the PTO's determination that the petitioner satisfied the timeliness requirement of 35 U.S.C. § 315(b) governing the filing of petitions for *inter partes* review?

Should the Federal Circuit loosen the "No appeal" rule, Patent Owners would be able to argue the Patent Office erred in instituting IPR where one or more statutory requirements for IPR were not met. For example, as in *Achates*, where the patent owner had filed a civil lawsuit for patent infringement against petitioner, or its privies, more than one year before the petition's filing date in contravention of the one-year time bar of § 315(b). Because this will impact a large number of IPR decisions, an *en banc* reversal in *WiFi One* would be the largest lasting effect of the *Cuozzo* decision.

PTO had authority to mandate the "broadest reasonable construction" standard for IPRs because the statute (1) does not unambiguously dictate a standard and thus leaves a "gap" and (2) expressly allows the PTO to enact reasonable rules for IPRs.

The Court next addressed whether the PTO had the authority to mandate the BRC standard for IPRs. Citing *Chevron*[3], the Court noted that "[w]here a statute is clear, the agency must follow the statute," "[b]ut where a statute leaves a 'gap' or is 'ambigu[ous],' we typically interpret it as granting the agency leeway to enact rules that are reasonable in light of the text, nature, and purpose of the statute." *Cuozzo*, 136 S. Ct. at 2142. Because "[n]o

1 Case No. 2015-1944, -1945, -1946 (Fed. Cir. January 4, 2017) (granting petition for *en banc* review).

2 *Achates* held that the patent owner could not seek review of the PTAB's determination that a petitioner had met the one-year time bar of § 315(b).

3 *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837 (1984)

statutory provision unambiguously directs the agency to use one standard or the other," "[t]he statute contains such a gap." *Id.* Further, the statute expressly grants the PTO to issue regulations governing IPRs, and the BRC regulation governs IPR procedure.

Cuozzo argued that Congress designed IPRs as a "surrogate for court proceedings" and "if Congress intended to create a 'surrogate' for court proceedings, why would Congress not also have intended the agency to use the claim construction standard that district courts apply (namely, the ordinary meaning standard), rather than" BRC? *Id.* at 2143. The Court disagreed, holding that [an IPR] "is less like a judicial proceeding and more like a specialized agency proceeding" in that (i) there is no standing requirement; (ii) the proceeding may continue at PTO and for judicial review after settlement; and (ii) there is a different burden of proof in an IPR versus litigation. *Id.* at 2144.

The BRC standard is a reasonable exercise of PTO rulemaking authority, as it ensures drafting of more precise claims, is supported by past practices in reexaminations and interferences and is not undermined by possibility of inconsistent results with litigation.

The Court next turned to the question whether the PTO's regulation is a reasonable exercise of its rulemaking authority and found that it is. First, the BRC "helps to protect the public" by increasing the possibility that the PTO will find the claim too broad (and deny it) and thus encourage the applicant to draft narrowly, which ensures more precision in claims. *Id.* at 2144-45. Second, it's supported by past practice in interferences and reexaminations. Finally, the BRC is not undermined by possibility of inconsistent results with litigation as this possibility has long been present in the patent system, but the different evidentiary burdens mean that "the possibility of inconsistent results is inherent to Congress' regulatory design." *Id.* at 2146.

Supreme Court overrules Federal Circuit's Seagate test for enhanced damages, concluding that a showing of objective recklessness is unduly rigid because it encumbers a district court's discretion and can excuse some of the worst infringers from liability for enhanced damages.

In *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 136 S. Ct. 1923 (2016), the Supreme Court reviewed the Federal Circuit's two part *Seagate*[4] test regarding the award of enhanced patent damages where the patentee must show by clear and convincing evidence that (1) "the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent;" and (2) the risk of infringement "was either known or so obvious that it should have been known to the accused infringer." The Federal Circuit affirmed the district court's determination that Halo failed to show "objective recklessness" under the first step of *Seagate*.

On review, the Supreme Court noted that 35 U.S.C. § 284 provides simply that "the court may increase the damages up to three times the amount found or assessed," which contains no explicit limit or condition. Furthermore, although the word "may" clearly connotes discretion, the Court found the Federal Circuit's test unduly rigid because it impermissibly encumbers the district court's discretion and "can have the effect of insulating some of the worst patent infringers from any liability for enhanced damages." *Id.* at 1932. In the context of such deliberate wrongdoing, the Court concluded that "it is not clear why an independent showing of objective recklessness should be a prerequisite to enhanced damages." *Id.* Culpability is generally measured against knowledge of an actor at the time of the challenged conduct, but *Seagate* impermissibly excused liability even where an infringer had no reason to suppose his conduct was arguably defensible. *Id.* at 1933.

As Section 284 imposes no specific evidentiary burden for proving recklessness for enhanced damages, the "preponderance of the evidence" standard applies, and not the "clear and convincing" standard.

The Court also rejected the use of the "clear and convincing" evidence standard to prove recklessness, noting that Section 284 imposes no specific evidentiary burden, much less such a high one. Further, the Court found the fact that Congress expressly erected a higher standard of proof elsewhere in the Patent Act, but not in §284, to be telling and that nothing in historical practice supports a heightened standard. Noting that patent-infringement litigation has always been governed by a preponderance of the evidence standard, the Court concluded that enhanced damages are no exception. *Id.* at 1934.

What's the practical effect of *Halo*? Under *Seagate*, one could avoid enhanced damages simply by generating a post-litigation opinion of invalidity and/or non-infringement (the "objective prong" of *Seagate*). Now, the Court determines willfulness based on the infringer's knowledge at the time of infringement. No longer will an infringer avoid willfulness by simply generating a non-infringement or invalidity opinion well after becoming aware of a potential infringement. After *Halo*, those aware of patents they potentially infringe should obtain an opinion of invalidity and/or non-infringement before engaging in the activity or, shortly after learning of the patent.

Subject Eligibility

Patent eligibility under 35 U.S.C. § 101 may be adjudicated on a Rule 12(b)(6) motion to dismiss, even before a formal claim construction in certain cases.

4 *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (*en banc*).

In *Genetic Technologies Ltd. v. Merial LLC*, 818 F.3d 1369 (Fed. Cir. 2016), the court reviewed the eligibility of Genetic Technologies' ("GT's") claims directed to a method for detection of at least one coding region allele of a multi-allelic genetic locus. GT discovered that certain DNA sequences in coding regions (exons) of certain genes are correlated with non-coding regions (introns) within the same gene, different genes, or the genome that are not part of any gene. The method sets forth two steps:

1. Amplifying the genomic DNA in the ***non-coding region*** using a primer pair to produce an amplified DNA sequence characteristic of said allele; and

2. Analyzing the amplified DNA sequence to detect the allele.

At the district court, defendants moved to dismiss under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim, arguing that the GT's patent claims covered ineligible subject matter under 35 U.S.C. § 101. The district court granted the motion, holding that the claim is invalid for claiming a law of nature as "it merely informs a relevant audience about certain laws of nature, even newly-discovered ones, and any additional steps collectively consist only of well-understood, routine, conventional activity already engaged in by the scientific community." *Id.* at 1373. On review, the Federal Circuit concluded that it was proper to find ineligibility on a Motion to Dismiss: "We have repeatedly recognized that in many cases it is possible and proper to determine patent eligibility under 35 U.S.C. § 101 on a Rule 12(b)(6) motion." *Id.* In so holding, the court noted that such eligibility determination "can proceed even before a formal claim construction," such as where "there is no claim construction dispute relevant to the eligibility issue." *Id.* at 1374.

The claimed correlation between variations in the non-coding regions and allele presence in the coding regions is no more than a consequence of the naturally occurring linkages in the DNA sequence and thus a law of nature under the first step of the Alice test.

Applying the first step of the two-step test of *Alice*[5], the court found the claim to be directed to one of the patent-ineligible concepts, a law of nature, in reciting "the relationship between non-coding and coding sequences in linkage disequilibrium and the tendency of such non-coding DNA sequences to be representative of the linked coding sequences." *Id.* The claim thus covers "any comparison, for any purpose, of any non-coding region sequence known to be linked with a coding region allele at a multi-allelic locus" and "does not limit its scope to methods of detecting any particular alleles linked to any particular non-coding sequences." *Id.* at 1374-1375. The court viewed GT's claims as being similar to those found to recite laws of nature in *Mayo*[6], agreeing with the district court that just as the relationship at issue in *Mayo* was entirely a consequence of the body's natural processes for metabolizing thiopurine, so too is the correlation here (between variations in the non-coding regions and allele presence in the coding regions) a consequence of the naturally occurring linkages in the DNA sequence. The court also found the claim similar to that found ineligible in *Ariosa*[7] in that both involved "newly discovered information about human biology" involving "no creation or alteration of DNA sequences." *Id.* at 1376. Thus, "[t]he similarity of [the claim] to the claims evaluated in *Mayo* and *Ariosa* requires the conclusion that [the claim] is directed to a law of nature." *Id.*

Because the steps of genomic DNA amplification and analysis of the amplified genomic DNA were both conventional, their combination with the recited law of nature does not add "significantly more" to transform the claim into a patent-eligible application.

Applying the second step of *Alice*, the court found that the claim did not add "significantly more" to transform the abstract idea or law of nature into a patent-eligible application. "The first claimed step of 'amplifying' genomic DNA with a primer pair was indisputably well known, routine, and conventional in the field of molecular biology." *Id.* at 1377. "The second physical implementation step, 'analyzing' amplified DNA to provide a user with information about the amplified DNA, including its sequence, was also clearly well known, routine, and conventional at the time the … patent was filed." *Id.* "Thus the physical steps of DNA amplification and analysis of the amplified DNA to provide a user with the sequence of the non-coding region do not, individually or in combination, provide sufficient inventive concept to render [the claim] patent eligible." *Id.* As such, the court found GT's claims "directly comparable to the claims invalidated in *Ariosa*." *Id.* at 1378.

Even though the claimed analysis step is performed upon man-made DNA (amplified intron DNA) and is novel, the step did not make the claim eligible because it is merely a mental process step setting forth a routine comparison that can be performed by the human mind.

GT also argued that because its claimed analysis step is "performed upon the amplified, i.e., man-made, non-coding DNA to detect the coding region allele," and because "no one had before analyzed man-made non-coding DNA in order to detect a coding region allele," the claim recited significantly more than the discovery of the linkage disequilibrium between coding and non-coding regions or the observation of using a non-coding polymorphism to learn about a coding region allele. *Id.* The court disagreed, finding that the step of detecting the allele (in the sense of examining the non-coding region to detect an allele in the coding region) was a mental process step that provides the claim with a purpose

5 *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S.Ct. 2347 (2014).

6 *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

7 *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

but does not create the requisite inventive concept, because "it merely sets forth a routine comparison that can be performed by the human mind." *Id.* The court noted that the claims in *Mayo*, *In re BRCA*[8], and *Ariosa* similarly included such mental comparison steps which did not provide the requisite "significantly more" to transform the law of nature into a patent eligible process.

On the heels of *Ariosa,* decided in 2015, this case seems to further confirm a point of view at the Federal Circuit that a combination of a natural phenomenon or correlation with so-called "conventional" steps does not amount to the "significantly more" required in the second part of the *Mayo* or *Alice* tests to transform the process into a patent-eligible one. In so deciding, the Federal Circuit glosses over a key distinction between *Mayo* on the one hand, and *Ariosa* and *Genetic Technologies* on the other hand. In *Mayo*, all of the recited process steps were "conventional" in that the prior art had administered the drug to a patient and had measured levels of the drug's metabolite in a patient's bloodstream, the only difference being the natural correlation. By contrast, in both *Ariosa* and *Genetic Technologies*, the claimed methods included active steps that were not "conventional" since no one had ever carried out the step of amplifying fetal DNA from a mother's plasma or serum before Sequenom, and no one had ever amplified introns associated with an allele before GT. But this distinction is lost on the court. Moreover, one could further argue that both *Ariosa* and *Genetic Technologies* involve inventions where the process steps do not become obvious until the natural phenomena is recognized. However, at the time of the invention, if one did not know about the correlation between genomic intron DNA and the presence of an allele, it would not have been obvious to amplify the selected portion of an intron and determine its presence. We detail these and other arguments in an *amicus* brief that we filed in *Ariosa*.[9]

The Supreme Court, however, denied certiorari in both *Ariosa* and *Genetic Technologies*, leaving the Federal Circuit's decisions in place.

A method for producing hepatocytes capable of surviving multiple freeze/thaw cycles is not "directed to" a natural law under first step of Alice/Mayo inquiry.

In *Rapid Litigation Management Ltd. v. CellzDirect, Inc.,* 827 F.3d 1042 (Fed. Cir. 2016), the court reviewed the eligibility of claims to a method of *producing* hepatocytes capable of being frozen and thawed at least two times comprising:

1. Subjecting previously frozen and thawed cells to density gradient fractionation to separate viable cells from non-viable ones;
2. Recovering the viable cells; and
3. Refreezing the viable cells without requiring a density gradient step after thawing the hepatocytes for the second time; wherein the resulting hepatocyte preparation can be thawed and used immediately, exhibiting 70% viability after the second thaw.

The invention relates to the discovery that some fraction of hepatocytes are capable of surviving multiple freeze-thaw cycles. The prior art taught that hepatocytes could not be frozen multiple times. Applying the Supreme Court's two-step framework for determining patent eligibility, the district court concluded that (1) the patent is directed to an ineligible law of nature: the discovery that hepatocytes are capable of surviving multiple freeze-thaw cycles; and (2) the patented process lacks the requisite inventive concept because, upon discovering the cells' capability of surviving multiple freeze-thaw cycles, the inventors simply "reapplied a well-understood freezing process." *Id.* at 1046.

On review, the Federal Circuit concluded that the claims are not simply directed to a natural law, i.e., the ability of hepatocytes to survive multiple freeze-thaw cycles. Rather, the claims are directed to "a new and useful laboratory technique for preserving hepatocytes," which "is precisely the type of claim that is eligible for patenting." *Id.* at 1048. The court further explained:

> The inventors certainly discovered the cells' ability to survive multiple freeze-thaw cycles, but that is not where they stopped, nor is it what they patented. Rather, "as the first party with knowledge of" the cells' ability, they were "in an excellent position to claim applications of that knowledge." That is precisely what they did. They employed their natural discovery to create a new and improved way of preserving hepatocyte cells for later use.

Id. (citations omitted).

It is not enough for step (i) of Alice or Mayo to merely identify a patent ineligible concept such as a law of nature underlying the claim; rather court must determine whether the patent-ineligible concept is what the claim is "directed to."

The defendant argued the court's analysis improperly shoehorned the step two analysis into step one: that focusing on the claims' application of the cells' ability to survive multiple freeze-thaw cycles in a new preservation process properly falls under step two's inquiry into "whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* at 1050. The court disagreed, noting that "it is not enough to merely identify a patent-ineligible concept underlying the claim; we must determine

8 *In re BRCA1- & BRCA2-Based Hereditary Cancer Test*, 774 F.3d 755 (Fed.Cir. 2014).

9 http://bit.ly/1XMEnzA

whether that patent-ineligible concept is what the claim is "directed to." *Id.* Here, the patent does not simply claim hepatocytes' ability to survive multiple freeze-thaw cycles, but "instead claims a 'method of producing a desired preparation of multi-cryopreserved hepatocytes.'" *Id.* "This new and improved technique, for producing a tangible and useful result, falls squarely outside those categories of inventions that are 'directed to' patent-ineligible concepts." *Id.*

Court distinguishes claims "directed to" a patent ineligible concept, i.e., amounting to nothing more than observing and identifying the ineligible concept itself, versus a new and useful method, i.e., preserving hepatocyte cells.

The court found the claims to be "immediately distinguishable from those we have found patent ineligible in cases since *Mayo* and *Alice*," where "we found claims 'directed to' a patent-ineligible concept when they amounted to nothing more than observing or identifying the ineligible concept itself." *Id.* at 1048. Thus, in *Genetic Technologies*, "the claim amounted to nothing other than identifying 'information about a patient's natural genetic makeup.'" *Id.* Although the claims in *Ariosa,* directed to the identification of the existence and location of fetal cffDNA in maternal serum or plasma, were written as process claims, they were ineligible as being "directed to" the patent-ineligible cffDNA itself. By contrast:

> The end result of the patent claims is not simply an observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles. Rather, the claims are directed to a new and useful method of preserving hepatocyte cells. Indeed, the claims recite a "method of *producing* a desired preparation of multi-cryopreserved hepatocytes." Through the recited steps, the patented invention achieves a better way of preserving hepatocytes. The '929 patent claims are like thousands of others that recite processes to achieve a desired outcome, e.g., methods of producing things, or methods of treating disease.

Id. at 1048-1049 (citation omitted) (emphasis in original).

Even if the claims are "directed to" a law of nature, the recited steps are sufficient to transform the process into an inventive application, under step (ii) of Mayo/Alice, because they apply the law of nature to achieve a new and improved hepatocyte preservation process.

The court also found that even if the claims were "directed to" a law of nature (hepatocytes' natural ability to survive multiple freeze-thaw cycles), thereby requiring the court to proceed to step two, "we would find the claims patent-eligible at that point as well" because "[u]nder step two, claims that are 'directed to' a patent-ineligible concept, yet also 'improve[] an existing technological process,' are sufficient to 'transform[] the process into an inventive application' of the patent-ineligible concept." *Id.* at 1050. Here, the claims "do precisely that: they recite an improved process for preserving hepatocytes for later use," and provide benefits such as elimination of unacceptable losses of viability and an ability to pool samples for later use. *Id.* Thus, "[t]he claimed method is patent eligible because it applies the discovery that hepatocytes can be twice frozen to achieve a new and useful preservation process." *Id.* at 1050-1051.

Under step (ii) of Mayo/Alice, the claim terms must be considered as a whole, both individually and as an ordered combination, such that a new combination of steps in a process, combined with a law of nature, may be patentable even if the individual steps were well known.

Significantly, merely because "each of the claims' individual steps (freezing, thawing, and separating) were known independently in the art does not make the claim unpatentable." *Id.* at 1051. The court acknowledged *Mayo's* holding that a claim that recites only "well-understood, routine, conventional activity already engaged in by the scientific community" will not be patent eligible. However, "in *Mayo*, the claims failed step two because the steps of administering the drug, measuring metabolite levels, and adjusting dosage were already being performed by those in the field; adding knowledge of the natural law was insufficient to render the claims patent eligible." *Id.* Similarly, "in *Ariosa*, the steps of preparing, amplifying, and detecting genetic sequences were already being done; performing those same steps on a newly discovered, naturally-occurring substrate (cffDNA in maternal plasma or serum) did not rise to the level of an inventive concept." *Id.* The court explained that, "in examining claims under step two, we must view them as a whole, considering their elements both individually and as an ordered combination." *Id.* (citing *Alice*). "Thus, 'a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.'" *Id.* (citing *Diamond v. Diehr*, 101 S.Ct. 1048, (1981)).

Here, "[t]he individual steps of freezing and thawing were well known, but a process of preserving hepatocytes by repeating those steps was itself far from routine and conventional" as the prior art only disclosed methods having one freeze-thaw cycle and taught away from multiple freezing steps as the prior art taught that cells could be frozen only once and then had to be used or discarded. *Id.* The court noted that "[r]epeating a step that the art taught should be performed only once can hardly be considered routine or conventional … even though it was the inventor's discovery of something natural that led them to do so." *Id.*

There are three interesting takeaways from this case. First, the court makes a distinction, for purposes of applying step (i) of the *Mayo/Alice* test, between a claim reciting a law of nature versus a claim "directed to" the law of nature. Thus, even though the claim under review included a law of nature—the ability of hepatocytes

to remain viable after multiple freeze/thaw cycles–the court found step (i) unsatisfied because this was not what the claim was "directed to." The second takeaway is the court's clarification that a process is not ineligible merely because it combines conventional steps (e.g., freezing and thawing cells) with a law of nature. Rather, in examining claims under step (ii), the claims must be viewed "as a whole, considering their elements both individually and as an ordered combination," such that "a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made." *Id.* Third, the court, in *dicta*, indicated that "methods of treating disease," like "methods of producing things," are patent eligible. This statement confirms that *Mayo* does not extend to claims "directed to" methods of treatment–a position that appears contrary to several recent district court and Patent Trial and Appeal decisions.[10]

What remains a mystery is the distinction the court makes between *Mayo*, *Ariosa*, *Genetic Technologies*, and this case. In *Mayo*, the individual steps and combination of steps were conventional, the only point of novelty being the correlation recited in a "wherein" clause. By contrast, *Ariosa* and *Genetic Technologies* seem much more similar to the present case, as no one had ever carried out the recited step of amplifying fetal DNA in a mother's serum or plasma (*Ariosa*), or amplified an intron correlated to an allele as done (*Genetic Technologies*). As such, the steps in *Ariosa* and *Genetic Technologies* were "conventional" but, like the present case, the combination of those steps with the natural law was not obvious. For example, without knowledge in the prior art that fetal DNA is contained in maternal serum or plasma, how could it have been obvious to amplify it? For the moment, the court has found a distinction between non-obvious combinations of steps with a natural law for diagnosis versus non-obvious combinations of steps with a natural law for making a new product. This raises the issue of whether one seeking to claim diagnostics should try to style a claim as a method of making? For example, perhaps Sequenom should have claimed "a method of making amplicons from fetal DNA from maternal plasma or serum?"

10 *See, e.g.*, *Boehringer Ingelheim Pharms., Inc. v. HEC Pharm Co.*, No. 15-cv-5982 (D.N.J. Dec. 7, 2016) ("A method of treating and/or preventing metabolic diseases in a patient … comprising orally administering to the patient a DPP-IV inhibitor wherein the contraindication is selected from the group consisting of: renal disease, renal impairment or renal dysfunction, unstable or acute congestive heart failure, acute or chronic metabolic acidosis, and hereditary galactose intolerance."); *Ex parte Atwood*, Appeal No. 2015-001611 (Bd. Pat. App. & Int. Aug. 16, 2016) ("A method for administering treatment to a patient at risk for developing Alzheimer's disease (AD) or a patient diagnosed with AD … comprising: (a) treating a sample from the patient with reagents that detect a single nucleotide polymorphism ... and (b) administering AD treatment to the patient if ... the patient is determined to be homozygous for [an allele]"); *Ex parte Chettier*, Appeal No. 2016-003639 (Bd. Pat. App. & Int. Aug. 25, 2016) (reh'g denied Jan. 13, 2017) ("A method comprising applying at least one DDD condition therapeutic to a patient based on at least one DDD altered risk associated biological marker determined to be present in said patient."); *Ex parte Chamberlain*, Appeal No. 2014-009849 (Bd. Pat. App. & Int. Jan. 20, 2017) ("A method of treating a human individual having a bone disorder, the method comprising: determining in a nucleic acid sample obtained from the individual, the presence of a TT genotype at a single nucleotide polymorphism … and administering a bisphosphonate to the individual if the TT genotype is present.").

On-Sale Bar

A contract manufacturer's sale of manufacturing services to an inventor does not constitute an invalidating sale under pre-AIA 35 U.S.C. § 102(b) where neither title to embodiments of the claimed invention nor the right to market the same passes to the contract manufacturer.

In *Meds. Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016), the *en banc* court considered the circumstances under which a product is "on sale" under pre-AIA 35 U.S.C. § 102(b).

The Medicine Company ("TMC") owns patents covering the drug bivalirudin (Angiomax®). TMC obtained pharmaceutical batches of the drug from a supplier, Ben Venue Laboratories ("BVL"). After receiving two batches from BVL with levels of Asp9-bivalirudin impurity that exceeded the FDA's approved maximum of 1.5%, TMC developed methods to minimize the impurity and obtained patents directed to such methods. However, more than one year before filing its patent applications, TMC hired BVL to prepare three batches of bivalirudin using an embodiment of the patented product-by-process, for which BVL invoiced TMC and released the batch for commercial and clinical packaging.

The district court, applying the two-part *Pfaff*[11] test, held that although the claimed invention was "ready for patenting," it was not "the subject of a commercial offer for sale" because (1) BVL only sold manufacturing services, not pharmaceutical batches; and (2) the batches fall under the experimental use exception. *Id.* at 1368. On review, a panel of the Federal Circuit agreed that "title to the pharmaceutical batches did not change hands," but nonetheless concluded that the "on-sale" bar applied because TMC "commercially exploited" the invention. *Id.* at 1369.

The *en banc* court vacated the panel's decision and requested briefing on the following questions:

1. Do the circumstances presented here constitute a commercial sale under the on-sale bar of 35 U.S.C. § 102(b)?
    a. Was there a sale for the purposes of § 102(b) despite the absence of a transfer of title?
    b. Was the sale commercial in nature for the purposes of § 102(b) or an experimental use?
2. Should this court overrule or revise the principle in Special Devices, Inc. v. OEA, Inc., 270 F.3d 1353 (Fed. Cir. 2001), that there is no "supplier exception" to the on-sale bar of 35 U.S.C. § 102(b)?

11 *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67-68 (1998)

The *en banc* court summarized the history of the "on-sale" bar, and noted that *Pfaff*'s two part test replaced the prior "totality of the circumstances" test because it was "unnecessarily vague." *Id.* at 1372. The cases following *Pfaff* largely focused on the "ready for patenting" prong, but in those cases, the court has looked to the Uniform Commercial Code to determine whether a commercial offer for sale occurred. Specifically, the court explained that "[t]he transaction at issue must be a 'sale' in a commercial law sense," and that "[a] sale is a contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold." *Id.* at 1373 (citation omitted).

The court held that there was no commercial sale between TMC and BVL. First, the court found that BVL "sold contract manufacturing services – not the patented invention – to [TMC]." *Id.* at 1375. For example, BVL's invoices were for manufacturing bivalirudin, and TMC paid BVL "only about 1% of the ultimate market value" of the manufactured product. *Id.* Second, "[t]he absence of title transfer further underscores that the sale was only of [BVL's] manufacturing services." *Id.* The court explained that "[t]he passage of title is a helpful indicator of whether a product is 'on sale,'" since it suggests that "the inventor gives up its interested and control of the product." *Id.* However, while the UCC describes a "sale" as "the passing of title from the seller to the buyer for a price," the court "decline[d] to draw to draw a bright line rule making the passage of title dispositive." *Id.* at 1376. Rather, the court found "the absence of title transfer significant because, in most instances, that fact indicates an absence of commercial marketing of the product by the inventor." *Id.* Third, "the confidential nature of the transactions is a factor which weighs against the conclusion that the transactions were commercial in nature." *Id.* The court found that "the scope and nature of the confidentiality imposed on BVL supports the view that the sale was not for commercial marketing purposes." *Id.*

The court then considered whether "stockpiling" constitutes a commercial offer for sale. As an initial matter, the court explained that "commercial benefit generally is not what triggers § 102(b); there must be a commercial sale or offer for sale." *Id.* at 1377. Indeed, "[t]he statute itself says the invention must be 'on sale,' or that there must be an offer for sale of the invention," and thus "the mere stockpiling of a patented invention by the purchaser of manufacturing services does not constitute a 'commercial sale' under § 102(b)." *Id.* The court concluded that stockpiling (or building inventory) "is, when not accompanied by an actual sale or offer for sale of the invention, mere precommercial activity in preparation for future sale." *Id.*

As a final matter, the court declined to recognize a blanket "supplier exception" to 35 U.S.C § 102(b). The court explained that "[w]hile the fact that a transaction is between a supplier and inventor is an important indicator that the transaction is not a commercial sale, understood as such in the commercial marketplace, it is not alone determinative." *Id.* at 1380. For example, the court hypothesized:

> Where the supplier has title to the patented product or process, the supplier receives blanket authority to market the product or disclose the process for manufacturing the product to others, or the transaction is a sale of product at full market value, even a transfer of product to the inventor may constitute a commercial sale under § 102(b).

Id.

One interesting takeaway is that the court appears to view the first *Pfaff* prong similar to a "totality of the circumstances" test. For example, the court declined to draw to draw a bright line rule regarding the passage of title, but instead referred to various "factors" or "indicators" for determining whether a transaction is a commercial sale. While such "factors" are helpful, and clearly articulated in the context of a supplier of manufacturing services, the court will have to be mindful that its new test does not morph into a test the Supreme Court finds "unnecessarily vague."

An unqualified and specific offer to sell product to a specific buyer (understood at the time as an offer by both parties), sent in response to a purchase request by that buyer, creates an on-sale bar even if no binding contract established or final sale consummated.

In *Merck & Cie v. Watson Laboratories, Inc.*, 822 F.3d 1347 (Fed. Cir. 2016), Watson appealed the district court's holding that Merck's claim is not invalid under the on-sale bar of 35 U.S.C. § 102(b). The claim at issue recites a crystalline calcium salt of 5-methyl-(6S)-tetrahydrofolic acid ("MTHF") having a water of crystallization of at least one equivalent per equivalent of MTHF. As Merck conceded that MTHF was "ready for patenting" as of the critical date, the only issue on appeal was whether there was an invalidating commercial offer to sell the product prior to the critical date.

Merck and Weider had originally contemplated entering into a partnership and had executed a Confidentiality Agreement in the process. After deciding not to partner together, Weider nonetheless reached out to Merck to purchase 2 kg of MTHF, to which Merck responded by directing Weider to send Merck a purchase order to its manager who would "arrange everything." *Id.* at 1351. The commercial offer for sale question focused on a particular facsimile "Communication" between Merck's manager and Weider quoting a price of $25,000/kg, payment and delivery terms and an assurance that if Weider needed more than 2 kg of MTHF, Merck could deliver the additional quantities. The district court concluded that Merck's Communication did not qualify as an invalidating commercial offer because MTHF was "a potentially dangerous new drug," and

"important safety and liability terms, which … were standard in the industry, were missing" from the Communication. *Id.* at 1352.

The Federal Circuit reversed. The court explained that Merck's Communication was "not an unsolicited price quote sent to numerous potential customers," but rather an unqualified offer that "was sent in direct response to Weider's request to purchase two kilograms of MTHF" which provided "essential price, delivery, and payment terms" which "contained all the required elements to qualify as a commercial offer for sale." *Id.* at 1351. The court found that "both Merck and Weider proceeded on the understanding that Merck had made an unequivocal offer to sell MTHF," citing Weider's email confirming its order, its request for MTHF safety data sheets (which Merck provided, a "certificate of analysis," and an insurance certificate naming Weider (which Merck promised upon sending the product). *Id.* at 1352. After this, Merck sent Weider a letter confirming Weider's "first order" for two kilograms of MTHF. The court concluded that "[r]egardless of whether the communications between Merck and Weider … were sufficient to establish a binding contract for the sale of MTHF, they confirm that, at a minimum, both parties understood [Merck's Communication] was an offer to sell the product." *Id.* Further, "[a]lthough Merck ultimately failed to deliver any MTHF to Weider … this is not dispositive" because "[a]n offer to sell is sufficient to raise the on-sale bar, regardless of whether that sale is ever consummated." *Id.*

Lack of safety information in an offer to sell MTHF does not negate on-sale bar because (i) MTHF is simply a crystalline form of human folate and not a "dangerous new drug"; (ii) Merck failed to show inclusion of safety information in an offer to sell to be an industry standard; and (iii) Merck was willing to supply MTHF "immediately."

The court also rejected the district court's holding that Merck's Communication did not qualify as an invalidating commercial offer because it lacked the safety information for MTHF that was standard in the industry. First, the court found that MTHF "is simply a crystalline form of the natural isomer of folate produced by the human body," "sold as a folate supplement, similar to folic acid in most people's common understanding," and not a "dangerous new drug." *Id.* at 1352-53. Second, the court found that Merck failed "to demonstrate that it was standard practice in the industry to include such provisions in an offer to sell a particular product on a stand¬alone basis." *Id.* at 1353. Finally, the court found Merck's expert testimony that Merck would not have sold MTHF to Weider without first resolving safety and liability issues to be squarely contradicted by the Communication in which Merck's manager agreed to "arrange everything" and "immediately" supply Weider with 2 kg or more of MTHF. *Id.*

Anticipation/ Obviousness

Claim to a dosage form reciting less than 25 ppm of a 14-hydroxy impurity derived from "8α" compound formed during manufacturing process is a product by process limitation that imparts no structural or functional distinctions over the prior art.

In *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345 (Fed. Cir. 2016), the court reviewed the validity of Purdue's claims directed to an oxycodone hydrochloride formulation with low levels of 14-hydroxycodeinone ("14-hydroxy") impurity, which is an α, β unsaturated ketone ("ABUK").

The prior art process was as follows:

1. Thebaine —**oxidation**→ 14-hydroxy

2. 14-hydroxy —**hydrogenation**→ oxycodone free base

3. oxycodone free base —**HCl**→ oxycodone HCl

However, the end product contained high levels of 14-hydroxy, on the order of 1500 parts per million. Purdue's initial belief that it only need to carry out the hydrogenation step 2 more completely proved wrong. After further research, Purdue discovered that in addition to the known side product, 8,14–dihydroxy–7,8–dihydrocodeinone ("8β"), an unknown side product (8α) formed during the first step of the process as follows:

Thebaine —**oxidation**→ 14–hydroxy + 8α, 14–dihydroxy–7, 8–dihydrocodeinone ("8α")

It turned out that the 8αproduced in step 1 converted to 14-hydroxy during the acid catalyzed dehydration step 3.

8αα —**HCl**→ 14–hydroxy

Purdue removed the 14-hydroxy by performing an additional hydrogenation step after step 3. The relevant claim at issue recited an "oral dosage form … having less than 25 ppm 14-hydroxy …wherein at least a portion of the [14-hydroxy] is derived from [8α] during conversion of oxycodone free base to oxycodone hydrochloride...".

The district court concluded that the claim recitation that the 14-hydroxy is at least in part "derived from 8α" is a process limitation and thus immaterial in the obviousness determination of a product-by-process claim. The Federal Circuit agreed: "[T]he fact that the 14-hydroxy is derived from 8α imparts no structural or functional differences in the low-ABUK hydrocodone API as

compared to the prior art products," and "[t]hus, the [district] court did not err in disregarding the process limitation in its obviousness determination." *Id.* at 1354.

Even though it was not known that the 8α compound was the source of 14-hydroxy impurity, such knowledge was not necessary to arrive at the claimed dosage form because other sources of 14-hydroxy and the use of hydrogenation to remove 14-hydroxy were known.

Purdue argued that the district court failed to credit the discovery of 8α as the core of the claimed inventions. But the Federal Circuit found that "even if determining the source of 14-hydroxy in the end product was not obvious, that problem did not need to be solved to arrive at the claimed invention." *Id.* at 1352. "[H]ere, Purdue did not claim the remedy of the problem of remaining 14-hydroxy in the oxycodone API—performing a second hydrogenation step," but rather "the end product– an oxycodone API with low ABUK levels." *Id.* Moreover, since "[o]ne molecule of 14-hydroxy is the same as the next, whether derived from 8α or 8β," knowledge of 8α "did not make hydrogenation more or less effective as a technique for converting 14-hydroxy to oxycodone." *Id.* Accordingly, the court concluded that the issue turned on "whether it would be obvious to a person having ordinary skill in the art to use hydrogenation to remove the excess 14-hydroxy in the oxycodone API," and that "[o]ne need not know that the 14-hydroxy was derived from 8α…to answer that question." *Id.* at 1353.

Prior art disclosure of "analgesics such as aspirin, acetaminophen, d[i]flunisal and the like" covers a broader group of analgesics than just those listed in view of the phrases "such as" and "and the like" and properly anticipates opioids which are a major class of analgesics.

The court also reviewed the validity of Grunenthal's claim directed to a thermoformed dosage form comprising opiates and opioids in a controlled release matrix of at least 60% by weight of polyalkylene oxide ("PEO") having a molecular weight of 1– 15 million, wherein said dosage form has a breaking strength of at least 500 N. The district court found the claim anticipated by prior art disclosing a hot-melt extrusion of high molecular weight PEO to create a controlled-release dosage form for pharmaceuticals, including opioid formulations, which inherently possess a breaking strength in excess of 500 N.

Grunenthal argued that the prior art's disclosure of active agents including "analgesics such as aspirin, acetaminophen, d[i]flunisal and the like" was insufficient for anticipation of its claimed opioids because the prior art does not describe oxycodone or other opioid-containing formulations, but rather only non-opioids. *Id.* at 1356. Grunenthal argued that the terms "such as" and "and the like" should be understood as also referring to other non-opioids. The Federal Circuit disagreed, finding that the prior art "cannot be read so narrowly" because it "explicitly notes the use of its process with analgesics to treat pain, and the words 'such as' and the residual clause 'and the like' demonstrate that the application discloses a broader group of analgesics than just those listed." *Id.* Further, "opioids are a major class of analgesics" and "oxycodone was one of the most widely prescribed analgesics at the time." *Id.* Finally, the prior art "is directed to sustained-release dosage forms" and "the only analgesics on the market in a sustained-release form at the time were opioids." *Id.*

Where the list of therapeutic agents including analgesics in one portion of a reference is "directly related" to the list of carriers including a particular PEO in another portion of the reference, the claimed analgesic/PEO combination is anticipated and not the result of an improper picking and choosing.

Grunenthal also argued that the district court erred by using distinct sections of the prior art and reassembling them into an embodiment to find that all of the limitations were present, contrary to *In re Arkley*,[12] which held that an anticipating reference "must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." *Id.* at 1358. For example, the district court selected only "analgesics" from the long list of pharmaceutical categories that could be used as the active ingredient, and then further picked oxycodone, which was not even disclosed, to find anticipation. Moreover, rather than teaching at least 60% PEO as required by the claims, the prior art teaches that the amount of PEO will vary depending on various factors such that it was improper for the district court to choose only those examples that included the claimed amount of PEO to find anticipation.

The Federal Circuit found the arguments to be "without merit" because "[t]he disclosures pointed to by the district court are all 'directly related' and thus there is no impermissible picking and choosing." *Id.* at 1358-1359. For example, the court provided a single disclosure describing a controlled-release formulation using with over 60% PEO and, although not specifically identifying the therapeutic compound used, the reference did provide a list of contemplated therapeutic compounds which, "although in a distinct section of the reference, is directly related to the disclosure." *Id.* at 1359. Therefore, the court held "the district court did not impermissibly combine distinct disclosures [of the prior art] to arrive at the claimed invention." *Id.*

This case is another one in a trend where the court has exercised a somewhat relaxed standard to find anticipation. In particular, this is not simply a case where the court mixed and matched by choosing a component (analgesics) from among the therapeutic

12 *Application of Arkley*, 59 C.C.P.A. 804 (1972)

agents listed in column A for combination with the 60% PEO carrier from among the carriers from column B. A finding of anticipation under such circumstance would have been a close call. But here the court had to go even a step further than that, construing "analgesics such as aspirin, acetaminophen, d[i]flunisal and the like" as disclosing opiates. While we've seen cases where the court has mixed and matched specifically disclosed components from among two lists (*Wrigley*[13]) and cases where the court has construed a broad genus to anticipate a claimed species (*Ineos*[14]), it would seem to be more of a departure from a precedent to find anticipation involving both mixing and matching and reading a broad genus as disclosing a particular species. As for the court's statement that one can carry out such mixing and matching so long as the disparate disclosures are "directly related," it would be interesting to see whether there are any circumstances where the court would not construe portions of a single reference as not being "directly related" to each other. As a final matter, the court's reliance on the fact that "oxycodone was one of the most widely prescribed analgesics at the time" raises a question regarding whether the court will continue look outside a prior art reference to determine whether that reference anticipates.

Claim directed to method of enzymatic hydrolysis for 60–120 minutes resulting in 0.5 to 5% hydrolyzed soy fibers having 10–35% reduced water holding capacity obvious in view of prior art combination hydrolyzing fibers for 5 to 72 hours or 100 to 240 minutes where art shows correlation between fiber hydrolysis and reduced water holding capacity.

In *In re Urbanski*, 809 F.3d 1237 (Fed. Cir. 2016), the court reviewed the Board's finding of obviousness regarding Urbanski's claim directed to a method of enzymatic hydrolysis of soy fiber to reduce the water holding capacity of the fiber for use in food additives. The method includes the steps of (i) contacting unhydrolyzed soy fiber swelled with water with an endoglucanase enzyme; and (ii) mixing for about 60-120 minutes to hydrolyze between about 0.5% and about 5% of the fiber's glycosidic bonds to produce a soy fiber with 10-35% reduced water holding capacity compared to the unhydrozyzed fiber and a free simple sugar content of <1%.

The examiner and the Board relied on two references teaching methods of enzymatic hydrolysis of dietary fibers. The first, Gross, teaches conversion of dietary fibers into "stable, homogeneous colloidal dispersions or gels," using a longer hydrolysis time (5 to 72 hours) to produce hydrolyzed fibers that absorb less water than unhydrolyzed fibers. The second, Wong, uses a shorter hydrolysis time (100 to 240 minutes) to produce a soy fiber product of improved sensory properties, including smoothness and mouthfeel, without substantially reducing the fiber content. Finding that "both Gross and Wong recognize reaction time and degree of hydrolysis as result-effective variables that can be varied in order to adjust the properties of the hydrolyzed fiber in a predictable manner," the Board held "that the claimed water holding capacity and free simple sugar content would have been obvious in view of the combined teachings" of the references. *Id.* at 1241.

The Federal Circuit agreed with the Board, finding that "Wong suggests that a shorter reaction time and a lower degree of hydrolysis improves soy fiber's sensory properties without substantially reducing the fiber content; whereas Gross suggests that a longer reaction time and a higher degree of hydrolysis results in fibers capable of forming a stable dispersion." *Id.* at 1242. The court concluded that substantial evidence supported the Board's finding "that a person of ordinary skill would have expected that, by adjusting the reaction time, the degree of hydrolysis and the properties of the fiber would be altered." *Id.* The court further concluded that "[o]ne of ordinary skill thus would have expected that modifying the Gross process by shortening the reaction time would have resulted in a lesser change in water holding capacity," and that, "shortening the reaction time and lowering the degree of hydrolysis would result in a lower free simple sugar content." *Id.*

Even though a combination of references renders the primary reference unsuitable for its intended purpose of forming a colloidal fiber dispersion, there is no teaching away where other desirable properties would be expected from the combination.

The court also rejected Urbanski's argument that modifying the Gross process by shortening the reaction time, taught by Wong, would render the Gross process unsatisfactory for its intended purpose (a stable homogenous colloidal dispersion or gel), thus evincing a teaching away from the modification. Although acknowledging its precedent that a combination of references that produces a seemingly inoperative device teaches away from the combination, the court explained that "Gross and Wong are combinable, as both references concern the enzymatic hydrolysis of dietary fibers and recognize that reaction time and degree of hydrolysis can be varied in order to adjust the fiber's properties." *Id.* at 1243. Here, "one of ordinary skill would have been motivated to pursue the desirable properties taught by Wong, even at the expense of foregoing the benefit taught by Gross" because "[n]othing in the prior art teaches that the proposed modification would have resulted in an 'inoperable' process or a dietary fiber product with undesirable properties." *Id.* at 1244. The court thus concluded that "[a]lthough Gross generally discloses a relatively longer reaction time that results in fiber capable of forming stable dispersions, Gross does not criticize or discredit the use of a shorter reaction time." *Id.*

13 *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356 (Fed. Cir. 2012).

14 *Ineos USA LLC v. Berry Plastics Corp.*, 783 F. 3d 865 (Fed. Cir. 2015).

One question that arises is why the Patent Office did not simply rely on Wong alone in rejecting Urbanski's claims since Wong enzymatically treats dietary fibers for a period of time (100-240 minutes, with 120 minutes preferred)—substantially overlapping with the claimed treatment time (60-120 minutes). The reason given by the PTO and the court for the citation of Gross is its teaching that the more a fiber is hydrolyzed, the less water it absorbs, i.e., that hydrolysis is a result effective variable affecting water absorbability. But since Wong already enzymatically treats the fibers for an amount of time substantially overlapping with that claimed, why wouldn't Wong's product inherently possess the same degree of hydrolysis and water absorbability as the claimed product, reciting "an average degree of hydrolysis of between about 0.5% and about 5%; a water holding capacity which is reduced by about 10% to about 35% as compared to the water holding capacity of the unhydrolyzed soy fiber?"[15]

The other interesting takeaway is the court's handling of Urbanski's teaching away argument. One of the arrows in every patent attorney's quiver is the argument that it would not be obvious to combine the teachings of a secondary reference into a primary reference if such combination would render the primary reference inoperable for its "intended" purpose. Yet this is precisely what happened here. Gross sought to prepare a colloidal dispersion and, to this end, required a 5 to 72 hour enzymatic treatment of the fibers to achieve this objective. There was no dispute that the far shorter treatment times claimed, and taught by Wong, would undermine the intended purpose of colloidal dispersion formation. What both the Board and the court did here was to read out the word "intended," concluding that "[n]othing in the prior art teaches that the proposed modification would have resulted in an 'inoperable' process or a dietary fiber product with undesirable properties." *Id.* at 1244. The problem with this approach is that combinations of reference will never been inoperable under such a test for the very reason that the combination results in the invention which presumably is operable.

This may be a case where the court and the Board reached the correct result but unnecessarily muddied the legal waters in getting there.

A "reasonable expectation of success" in combining references is defined with reference to the claim and not the prior art, such that a protecting group incapable of quantitative removal can be substituted for one capable of quantitative removal in another reference where the claim does not recite such removal.

15 *Galderma* is instructive in this regard. *See Galderma Laboratories, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (2013) ("where there is a range disclosed in the prior art, and the claimed invention falls within that range, the burden of production falls upon the patentee to come forward with evidence that (1) the prior art taught away from the claimed invention; (2) there were new and unexpected results relative to the prior art; or (3) there are other pertinent secondary considerations.").

In *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.,* 821 F.3d 1359 (Fed. Cir. 2016), the court reviewed the Board's holding that Intelligent Bio-Systems ("IBS") failed to establish the obviousness of Illumina's claims during an *inter partes* review ("IPR") proceeding at the PTO. The claim at issue recites a method of labeling a nucleic acid molecule with (i) a detectable label attached at its base; and (ii) a removable azido protecting group attached via the 2′ or 3′ oxygen atom of its sugar moiety. The removal of the azido protecting group exposes a 3′ OH group, thereby permitting a sequencing by synthesis ("SBS") method to be carried out. The prior art (Ju and Tsien) disclosed the SBS method but with a different protecting group. The secondary reference Zavgorodny discloses an azido protecting group for the same 3′ OH position of nucleosides as in Ju's or Tsien's process, which is cleavable under mild conditions.

At the Board, IBS argued that one of ordinary skill in the art would have been motivated to improve the efficiency the sequencing method taught in Tsien by using "other protecting groups that meet the criteria of Tsien, such as the azidomethyl group taught by Zavgorodny" with a "reasonable expectation of success," based on the recognition "that Zavgorodny's azidomethyl group met Tsien's criteria for a suitable 3′ OH protecting group." *Id.* at 1364. Illumina countered that the prior art of record "demonstrates that an ordinary artisan would have expected Zavgorodny's azidomethyl group to be removed at a much lower efficiency than required by Tsien's methods." *Id.* The Board agreed, finding that Zavgorodny would not be "obvious to use" with Tsien or Ju because its azidomethyl group would not be removed quantitatively (at or near 100%). *Id.* at 1367.

On appeal, IBS argued that the claims do not require quantitative cleavage, and thus the Board erred by imposing such a requirement through its reasonable expectation of success analysis. The Federal Circuit agreed, noting that "[t]he reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the limitations of the claimed invention." *Id.* Here, the "claimed invention" does not require removal of the protecting group to allow subsequent nucleotide incorporation, let alone quantitative removal. The Board's error was its belief that the "'reasonable expectation of success' inquiry looked to whether one would reasonably expect the prior art references ***to operate as those references intended once*** combined." *Id.* (emphasis added). However, "[t]hat is not the correct inquiry—one must have a motivation to combine accompanied by a reasonable expectation of achieving ***what is claimed*** in the patent-at-issue. *Id.* (emphasis added).

Although the failure to recite "quantitative deblocking" in the claim makes such property irrelevant to the "reasonable expectation of success" inquiry, such property is relevant to regarding "motivation to combine" where petitioner bases its motivation argument on possession of such property by both references.

Although "the Board conflated two different legal concepts–reasonable expectation of success and motivation to combine," the court found that the Board "nevertheless made sufficient factual findings to support its judgment that the claims at issue are not invalid" because IBS failed to demonstrate motivation to combine the references. *Id.* IBS argued motivation to combine based on "a shared purpose," namely that in order to improve the efficiency, reliability, and robustness of the SBS method taught in Tsien, one of ordinary skill would have been motivated to use other protecting groups that meet the criteria of Tsien (including quantitative deblocking), such as the azidomethyl group taught by Zavgorodny. *Id.* at 1368. However, IBS's "Petition did not provide a specific or credible explanation why an ordinary artisan would have expected Zavgorodny's azidomethyl protecting group to meet Tsien's quantitative deblocking requirement under conditions suitable for use in Tsien's sequencing methods." *Id.* "While this shortcoming is irrelevant to a finding that there was no reasonable expectation of success" for claims not requiring quantitative deblocking, "it is central to a finding of no motivation to combine … because the petitioner's sole argument for [combining] Zavgorodny's azidomethyl group with Tsien's SBS method was because it would meet Tsien's quantitative deblocking requirement." *Id.*

Motivation to combine based on achieving improved efficiency rebutted by evidence showing that protecting group of secondary reference would have been expected to perform inefficiently if substituted for the protecting group of the primary reference.

Finally, the court found "substantial evidence to support a finding that a person of ordinary skill would not have had reason to combine Tsien or Ju with Zavgorodny to achieve the claimed invention." *Id.* Specifically, Illumina cited prior art teaching that azidomethyl methyl groups are removed from phenols with modest efficiency (60-80% yield), and that removal of an azidomethyl methyl group from the 3αhydroxyl position of a deoxyribonucleotide moiety is likely to proceed with even lower efficiency. The court found "that these references support a conclusion that the claimed efficiency that allegedly motivated the combination would not be achieved," and that the skilled person would not have been motivated to use the Zavgorodny's azidomethyl group to expose a 3αOH of a nucleic acid molecule since it "would have been expected to perform inefficiently in that role." *Id.* at 1368-1369.

Petitioner impermissibly waited until Reply Brief Stage of IPR to present evidence of a motivation to combine based on an argument different than its original argument of increasing efficiency and therefore such new argument is belated.

On a procedural note, IBS argued that "the Board must additionally consider whether it is within the skill of the ordinary artisan to modify the cleavage conditions to satisfy the alleged cleavage requirements." *Id.* at 1369. The Board did not consider this argument since it was raised for the first time in IBS's reply brief and expert declaration. Citing the Board's rules, the court noted that it is of "the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify 'with particularity' the 'evidence that supports the grounds for the challenge to each claim.'" *Id.* Therefore, the court found no error in the Board's refusal to consider IBS's reply brief as improper under 37 C.F.R. § 42.23(b) because IBS relied on an entirely new motivation to combine rationale. *Id.* at 1370.

Urbanski and IBS highlight the importance of motivation to combine arguments. In both cases, a less than an ideal outcome occurred by combining references–the colloidal dispersion of the primary reference was destroyed by the *Urbanski* combination, and the efficiency of the quantitative deblocking of the primary reference was reduced by the *IBS* combination. Yet the court found motivation to destroy the colloidal dispersion in the former, but did not find motivation to reduce the efficiency of the protecting agent in the latter. The difference? It was a matter of how the arguments were framed regarding the motivation to combine. In *Urbanski*, the court found it acceptable to argue a motivation to combine even if there is a less than ideal result from the combination, whereas, in *IBS*, the Petitioner based its motivation to combine argument on the fact that efficiency was increased.

Because the Board's final IPR decision relied on the same grounds of unpatentability as in the institution decision, it was proper for the Board to rely on other references raised by petitioner at the IPR's reply stage where patent owner had both notice of the other references and an opportunity to address them.

In *Genzyme Therapeutic Products Ltd. Partnership v. Biomarin Pharmaceutical Inc.* 825 (Fed. Cir. 2016), the court reviewed the Board's final IPR decision holding the claims of Genzyme's patents obvious. The claims recite a method of treating a human patient with Pompe's disease, comprising intravenously administering biweekly to the patient a therapeutically effective amount of human acid α-glucosidase ("GAA"), whereby the concentration of accumulated glycogen in the patient is reduced and/or further accumulation of glycogen is arrested.

On appeal, Genzyme argued that the Board improperly relied on "facts and legal arguments" not set forth in the institution decisions, and thus changed patentability theories midstream without giving Genzyme reasonable notice of the change or an opportunity to respond. Specifically, Genzyme alleged the Board erred by relying on two references, relating to the "state of the art," that were not included in the prior art combinations cited in the IPR institution decision. The court disagreed, holding that "[t]he Board's final written decisions were based on the same combinations of references that were set forth in its institution

decisions," and "Genzyme therefore cannot argue that it lacked notice of the specific combinations of references that the Board relied on in finding the claims invalid." *Id.* at 1366. With regard to the two additional references, the court found that "the introduction of new evidence in the course of the trial is to be expected" in an IPR and that such new evidence is properly raised "as long as the opposing party is given notice of the evidence and an opportunity to respond to it." *Id.* The court found that there was adequate notice because Genzyme, in its Patent Owner's Response, and Biomarin, in its Reply, discussed the two references to show "the state of the art." The court further noted that "the regulations governing inter partes review proceedings provide patent owners with procedural mechanisms either to respond to evidence raised in the petitioner's reply or to move to exclude it." *Id.* at 1368.

The Board may properly cite a reference even if not forming part of the grounds in the original institution decision where such reference being relied on to show the state of the art.

The court found that "[a]lthough Genzyme characterizes this case as being about the sufficiency of notice and an opportunity to be heard, the substance of Genzyme's argument is to challenge the propriety of the Board's use, for any purpose, of a reference that was not part of the combinations set forth in the institution decisions." *Id.* at 1368-69. However, "those brief references by the Board merely served to describe the state of the art," and "were not among the prior art references that the Board relied upon to establish any claim limitations." *Id.* at 1369. This court reiterated "that the Board may consider a prior art reference to show the state of the art at the time of the invention, regardless of whether that reference was cited in the Board's institution decision." *Id.*

Lack of an explicit finding by Board as to the level of skill of one of ordinary skill in the art in its obviousness analysis is not a reversible error where the prior art itself reflects this level or where the parties' definitions are so close that any difference does not affect the result of an obviousness analysis.

Genzyme also alleged Board error in "not making an explicit finding as to the level of skill of a person of ordinary skill as part of its obviousness analysis." *Id.* at 1371. However, the court explained that "the failure to make explicit findings regarding the level of skill in the art does not constitute reversible error when 'the prior art itself reflects an appropriate level and a need for testimony is not shown.'" Here, the court found that the Board's failure to make an explicit finding as to the level of skill is not reversible error because both parties proposed nearly identical language to describe a person of ordinary skill, and Genzyme did not show that the outcome would have been different based on which definition was used.

It is interesting to contrast this case with the previous *IBS* case in terms reliance on additional prior art. In *IBS*, the Board did not permit the petitioner to rely on a new motivation to combine rationale, even though based on the same references, because it is "of the utmost importance" that petitioners identify "with particularity" the "evidence that supports the grounds for the challenge to each claim." In *Genzyme,* however, the Board was able to rely on new "state of the art" evidence because the combination establishing the claim limitations remained the same. Why presenting new evidence based on the same combination was impermissible in the former case but not in the latter is difficult to decipher. One explanation may be that under "substantial evidence," neither approach by the Board can be reversed by the court. Therefore, the best advice, regardless of whether you represent the patent owner or petitioner, is to prevail on this issue at the Board.

Motivation to combine the excipients of a secondary reference with the active ingredient of the primary reference, based on "cursory" testimony that a skilled artisan "could have" put the information together, is insufficient.

In *Intendis GMBH v. Glenmark Pharmaceuticals Inc. USA,* 822 (Fed. Cir. 2016), the court reviewed the district court's holding of non-obviousness regarding Intendis' claims directed to a composition in the form of a hydrogel comprising 5 to 20% azelaic acid as a therapeutically active ingredient, 0.5 to 5% triglycerides, propylene glycol, a polysorbate aqueous phase that further comprises water and salts, at least one polyacrylic acid, and lecithin. The claim covers the commercial product Finacea® Gel, which is indicated for the topical treatment of inflammatory papules and pustules of mild to moderate rosacea.

The district court determined that the asserted claims would not have been obvious over the previously-marketed Skinoren® cream (containing 20% azelaic acid and marketed for skin conditions) in view of prior art disclosing either formulations containing the claimed excipients or formulations containing azelaic acid. The district court found motivation to both (i) develop an alternative to Skinoren® in a different dosage form (given Skinoren's® known deficiencies); and (ii) pursue azelaic as a hydrogel formulation based on prior art disclosing a azelaic acid hydrogel formulation. However, the district court found no motivation to use the claimed excipients (triglyceride and lecithin) of the secondary references in combination with azelaic acid. Glenmark's expert offered only "cursory" testimony that a skilled artisan "could have put ... information together from another two publications" to render the claim obvious, which was "insufficient to meet Glenmark's burden" to show a motivation to combine. *Id.* at 1366.

Even if there were a motivation to combine, the district court found that "Glenmark failed to carry its burden to demonstrate a reasonable expectation of success in making the combination" based on fact and expert testimony that "swapping ingredients in complex chemical formulations is anything but 'routine'" without providing "other evidence regarding an expectation of success." *Id.*

On review, the Federal Circuit found "no clear error in the district court's finding that a skilled artisan would not have been motivated to combine the prior art or in finding no reasonable expectation of success based on the evidence of record." *Id.* at 1366-1367.

A claim properly construed to require no altering of properties of collagen fibers compared to normal hydrated tissue is not anticipated by prior art that altered such properties.

In *LifeNet Health v. LifeCell Corp.*, 837 (Fed. Cir. 2016), the court reviewed LifeNet's claims directed to a ***plasticized soft tissue graft*** suitable for transplantation into a human for both anticipation and obviousness. The claims recited both (i) a ***cleaned*** soft tissue graft having an internal matrix; and (ii) one or more plasticizers contained in said internal matrix. The claim further required that the one or more plasticizers are not removed from said internal matrix of said plasticized soft tissue graft prior to transplantation into a human.

The asserted prior art discloses a process for treating a soft tissue with hydrogen peroxide and other steps to increase biological stability. LifeNet argued that the art failed to meet (1) the "cleaned" and (2) the "plasticized soft tissue graft" limitations. The district court construed "plasticized soft tissue graft" to specifically require that plasticization occur "without altering the orientation of the collagen fibers, such that the mechanical properties, including the material, physical and use properties, of the tissue product are similar to those of normal hydrated tissue." *Id.* at 1328. The Federal Circuit found substantial evidence to support a jury finding that the prior art does not disclose a plasticized soft tissue graft under the district court's construction based on LifeNet's expert testimony that, unlike the claimed invention, the prior art process significantly alters the mechanical properties from native tissue by increasing tensile strength by a factor of 1.7 to 7.0. Although there was some challenge regarding the statistical significance of these numbers, the court took this testimony and what it perceived as some ambiguity in the testimony of LifeCell's expert regarding the tensile strength differences to conclude that "[t]he ultimate issue on this record was a classic factual dispute that the jury was free to resolve in LifeNet's favor." *Id.* at 1328-1329.

Based on the court's claim construction, the holding of non-anticipation is hardly surprising or particularly remarkable. However, the story does not end here because buried in this decision, under the guise of claim construction, is a rather surprising holding affecting the law of anticipation. In particular, during prosecution, the examiner cited a reference meeting the structural limitations of the claim (a cleaned soft tissue graft having an internal matrix and one or more plasticizers contained in said internal matrix). LifeNet argued, however, that the reference required removal of the plasticizer before use and was able to distinguish the reference by adding the recitation "that the one or more plasticizers are not removed from said internal matrix of said plasticized soft tissue graft prior to transplantation into a human." *Id.* at 1320.

This is remarkably similar to what happened in *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.,* 471 F.3d 1363 (Fed. Cir. 2006). Abbott claimed the drug sevuflorane saturated with water based on its discovery that water-saturation imparted the property of resisting Lewis acid degradation reaction of the drug. Specifically, the claim recited that the water was present "in an amount effective to prevent degradation by a Lewis acid of said quantity of sevoflurane." *Id.* at 1365. Similar to the present case, the prior art disclosed sevoflorane saturated with water, disclosed that it was necessary to remove the water before use, and was distinguished by specifically reciting such saturation. However, unlike the present case, the court in *Abbott* found that since the prior art "discloses sevoflurane saturated with water – i.e., unable to absorb any additional water to further protect it from the degradation reaction – it anticipates the claims of [Abbott's] patent" even though the art did not recognize the benefits derived from inclusion of the water. *Id.* at 1368. In *LifeNet*, the court could have similarly held that since the prior art discloses a cleaned soft tissue graft having an internal matrix and one or more plasticizers contained in said internal matrix–i.e., a plasticized soft tissue graft suitable for transplantation into a human – it anticipates the claims of LifeNet's patent even though the art did not recognize the benefits derived from inclusion of the plasticizer in the graft.

Disclosure by prior art of administration of drug by "inhalation," includes "oral" inhalation as claimed because inhalation can only be carried out via the nose or the mouth and the reference does not limit its disclosure to nasal inhalation.

In *In re Efthymiopoulos*, 839 F.3d 1375 (Fed. Cir. 2016), the court reviewed the Board's holding of obviousness regarding applicant's claims directed to methods of treating or preventing influenza by administering the drug zanamivir by oral inhalation.

The PTO cited (i) a first reference disclosing administration of zanamivir to treat and prevent infections by the influenza virus, but only by nasal, and not oral inhalation; and (ii) a second reference disclosing the administration of an adjacent homologue of zanamivir, for the treatment and prevention of influenza by a large list of methods, such as "inhalation" (without specifying whether nasal or oral). The Board found that the second reference's disclosure of generic "inhalation" for treating influenza with its compounds "is reasonably understood to disclose inhalation by either the nose alone, mouth alone, or both" and thus concluded that the combination of references rendered the claims obvious. *Id.* at 1377.

The Federal Circuit affirmed, concluding that Board's findings are supported by substantial evidence. The court found further support in both references' disclosure of administration of a dry powder through an inhaler–a form often used for oral inhalation.

Although the prior art teaches that oral inhalation targets the lower respiratory tract and not the upper respiratory tract where the flu viruses reside, there was a reasonable expectation of success that oral inhalation would be effective because certain flu strains reside in the lower tract and oral inhalation delivers more drug than nasal inhalation.

Applicant argued that a person of ordinary skill would not have expected the administration of zanamivir solely by oral inhalation would have been effective because oral inhalation delivers more drugs to the lower respiratory tract, and it was thought that delivery of anti-influenza drugs to the upper respiratory tract was required to be effective. The court disagreed, concluding that substantial evidence supported (1) "that certain strains of the virus also attack the lower respiratory tract and … young children in particular were more susceptible to lower respiratory tract infections from the virus; and (2) oral inhalation delivers more drugs to the lungs as compared to nasal inhalation." *Id.* at 1378.

Because applicant (i) failed to directly compare the claimed oral versus the prior art nasal administration of anti-flu drug; (ii) presented statistically insignificant findings; and (iii) only showed results for flu prevention whereas claims recited both prevention and treatment, substantial evidence supported the Board's finding of no unexpected results.

Applicant also argued that the Board disregarded its evidence of unexpected results set forth in its expert Declaration. The court disagreed, concluding that substantial evidence supported the Board's finding that the evidence "did not show unexpectedly superior results between oral and intranasal inhalation." *Id.* Instead, the expert conceded that "'adding intranasal administration of zanamivir did not obviously improve' the results of using oral administration alone for the treatment of influenza," which showed that "the claimed method would not necessarily yield an unexpectedly superior result." *Id.* The court also affirmed the Board's rejection of evidence related to a study involving preventing influenza because "its findings were admittedly not statistically significant, and it dealt only with prevention of influenza, while the claims are directed to the treatment of influenza." *Id.* at 1378-1379.

In her dissent, Judge Newman pointed out that despite the failure of the prior art to teach or suggest treatment of influenza by oral inhalation of zanamivir or any related compound, "[m]y colleagues nonetheless deem this treatment of influenza obvious on the ground that inhalation occurs only through the nose or the mouth." *Id.* at 1379. Interestingly, both Judge Newman and the majority are arguably right, depending on how one defines the group from which oral inhalation is selected. If selected from "inhalation," then indeed there are only two possibilities—oral and nasal inhalation—which would seem to be the epitome of the "finite number of identified, predictable solutions." *KSR V. Teleflex,* 550 U.S. 398, 416 (2007). However, if selected from all forms of oral, parenteral, topical, rectal, vaginal, and intranasal administration disclosed by the prior art, with no mention of oral inhalation, then perhaps this is not a "finite number of identified, predictable solutions." The majority and dissent also had different takes on the unexpected results. The majority saw a lack of a direct comparison between the prior art nasal and the claimed oral inhalation to show an unexpected result. The dissent viewed the fact that oral inhalation even worked in the first place to be an unexpected result. At bottom, this is a case where either an affirmance or reversal would not have been unreasonable, and had the Board found non-obviousness, it is quite possible that the court would have likewise affirmed under the substantial evidence standard.

The applicant may have been able to do more to help his case. For example, applicant argued that oral inhalation was not obvious because it targeted the lower respiratory tract, whereas the flu virus resides in the upper respiratory tract—the target of nasal inhalation. The court rejected this argument at least partly because certain flu strains were known to reside in the lower respiratory (especially in children). Had applicant specifically claimed methods of treating flu limited to viruses that predominate in the upper tract, such as claiming administration solely to an adult population, perhaps applicant could have overcome the obviousness rejection. Further, even the panel majority did not seem to believe that one would have expected oral inhalation to work as well as nasal inhalation at the time of the invention. Therefore, applicant may have been successful by trying to claim a specific degree of therapeutic efficacy.

Prior art disclosing peak area percentages of even-carbon-number paraffins explicitly anticipates, and does not inherently anticipate, claims drafted in terms of weight percentages of the paraffins because a skilled artisan could readily convert one to the other.

In *REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F.3d 954 (Fed. Cir. 2016), the court reviewed the Board's holding of anticipation for REG's claim directed to a phase change material composition comprising at least 75 wt% even carbon number paraffins produced by hydrogenation/hydrogenolysis of naturally occurring fatty acids and esters. The court's anticipation analysis focused on the "at least 75 wt% even carbon number paraffins" limitation.

The complication in this case is that the prior art disclosed peak area percentages rather than weight percentages as claimed, with no information regarding how to carry out an accurate conversion. Citing the Board's finding that it was ***unlikely*** that the prior art did not disclose the claimed weight percentage limitations, REG argued that the Board used an erroneous inherency standard in finding the invention anticipated. Citing the fact that the prior art expressly discloses the concentration of even-carbon-number paraffins in area percentages, which one of ordinary skill could readily convert to weight percentages, Neste countered that the

Board did not rely on inherency but rather an on express disclosure of the concentration of even-carbon-number paraffins. The court agreed with Neste based on expert testimony showing how the conversion could be carried out, and concluded that "[t]his is not an inherency issue because the challenged limitation is not missing from the [prior art]." *Id.* at 961. Rather, the prior art "expressly discloses this concentration in area percentage," which Neste's expert simply converted to weight percent. *Id.* Thus, the court held that substantial evidence supports the Board's factual finding that the area percent disclosed in the prior art could be reliably translated to the weight percent recited in the claim.

The interplay between explicit and inherent anticipation is interesting. It is black letter law that inherent anticipation cannot be established by possibilities or probabilities, but rather requires that the invention be the necessary and natural result from following the prior art teachings. Seizing on the Board's language that it was ***unlikely*** that the prior art's disclosure of peak area percentages did not disclose the claimed weight percentage limitations, REG tried to convince the court that the certainty required for inherent anticipation was lacking. The problem for REG was that the question here did not relate to whether the prior art actually produced its composition—it did. Rather, the question was whether the methodology used by Neste's expert to convert the prior art composition's peak area percentages to weight percentages was sound—the Board found it was. Thus, while it is fair to challenge measurement methodology used in interpreting a reference, it is not the province of the doctrine of inherency to challenge a composition that is explicitly disclosed, albeit using different terminology.

Therefore, there seems to be a distinction between (i) not disclosing a limitation at all versus (ii) disclosing a limitation but in different terms. For example, had there not even been a peak area percentage disclosed, Neste probably would have had to rely on inherency to establish anticipation.

Although both claimed and prior art ethanol manufacturing processes add phytase, finding of inherent anticipation by summary judgment was in error in view of conflicting evidence whether the prior art processes necessarily reduce insoluble deposits as recited by the claims.

In *U.S. Water Services, Inc. v. Novozymes A/S*, 843 F.3d 1345 (Fed. Cir. 2016), the court reviewed the district court's grant of summary judgment, in favor of the defendant Novozymes, that the prior art inherently anticipated patentee's claims directed to an ethanol-manufacturing method. The district court found that the critical facts "are not in dispute," namely that (i) the claims at issue recite a method for making ethanol using phytase at particular dosage ranges, temperatures, and pHs with the goal of reducing the formation of insoluble deposits; and (ii) the prior art discloses "the same method, using overlapping and often narrower ranges." *Id.* at 1351. The district court held that although the prior art does not "expressly identify the benefit" of deposit reduction, such benefit was the "natural result of following the prior art," and therefore inherent. *Id.*

On review, the court agreed with the district court that the case ultimately turns on the issue of whether the prior art "inherently disclose using phytase to reduce deposits in ethanol production machinery." *Id.* However, the court found that by "deeming irrelevant" patentee's evidence (including expert testimony) that practicing the prior art "will not always result in deposit reduction," the district court erred in finding no genuine dispute of material fact as to inherent anticipation. *Id.* The court found that patentee's experts' testimony "demonstrates that there is a dispute as to whether adding phytase in the manner disclosed in [the prior art] will necessarily lead to a reduction of insoluble organometallic salt deposits as claimed." *Id.* at 1352.

It will be interesting to follow this case on remand. Even if the patentee is able to survive invalidity based on inherent anticipation, the issue of obviousness may still arise. In particular, the court has made it clear that an otherwise obvious process is not rendered patentable merely because applicant discovers a new result of the process. Accordingly, Novozymes may be able to show that there are particular dosage ranges, temperatures and pH's that (i) are obvious in view of the prior art; and (ii) would, under those conditions, result in reduction in deposits.

Written Description

An application need not disclose a protein's complete N-terminus sequence in order to provide an adequate written description; rather the protocol to isolate the protein, its molecular weight, biological activity and degradation characteristics are sufficient to show inherent possession of protein.

In *Yeda Research & Development Co., Ltd. v. Abbott GMBH & Co. KG*, 837 F.3d 1341 (Fed. Cir. 2016), the court reviewed whether Abbott's claim reciting TBP-II, a TNFαbinding protein which has a molecular weight of about 42,000 Da and has a specifically recited N-terminus amino acid sequence found written description support in its priority applications.[16] Neither of the priority applications discloses the full N-terminus sequence claimed. Instead, they disclose a partial N-terminus sequence, a protocol for obtaining the protein from its biological source, and additional properties of the protein, such as molecular weight, biological activity, and degradation characteristics. The parties agreed that the only protein containing the N-terminus sequence set forth in the priority applications is TBP-II—i.e., the same protein claimed in the patent.

16 The issue of eligibility under Section 101 was not before the court.

Yeda argued that unless a person of ordinary skill in the art would have understood that the partial N-terminus sequence in the priority application included the additional amino acids identified in the patent claims at issue, there was no support. Abbott responded that the priority application need only describe and enable the TBP-II protein, which Abbott did by describing both a partial amino acid sequence and other biological characteristics.

On review, the court noted that "[u]nder the doctrine of inherent disclosure, when a specification describes an invention that has certain undisclosed yet inherent properties, that specification serves as adequate written description to support a subsequent patent application that explicitly recites the invention's inherent properties." *Id.* at 1345. Here, "it is undisputed that TBP-II is the only protein with the same partial N-terminus sequence and additional traits disclosed in the [priority] application." *Id.* As such, the priority application "inherently discloses the remaining amino acids in the N-terminus sequence of TBP-II and serves as adequate written description support" for a claim to TBP-II. *Id.* Accordingly, the court found that it "is not necessary for an application to disclose a protein's complete N-terminus sequence in order to provide an adequate written description of that protein." *Id.*

Patentee did not improperly rely on a limitation material for patentability to support its inherent disclosure of the TBP-II protein in its priority application, as some of the amino acids distinguishing the prior art were disclosed in the priority application.

Yeda also argued that the prosecution history belies Abbott's reliance on inherent disclosure because in "the context of priority determinations, the allegedly inherent limitation cannot be material to the patentability of the invention." *Id.* Yeda asserted that the amino acids missing from the priority application are material because during prosecution Abbott relied upon their absence to distinguish its claimed TBP-II from the TBP-I disclosed in the prior art. The court disagreed, finding that Abbott's response "did not solely rely on amino acids missing from the priority applications; three of the five amino acids disclosed in [the reference] were disclosed in the [priority] application and were themselves sufficient to distinguish TBP-I from TBP-II." *Id.*

Patentees facing priority challenges (e.g., in an *inter parties* review) should consider the applicability of this case to support a claim to priority. The cases most applicable will be those "where it is undisputed that the invention described in an earlier application was the exact invention claimed by the later patent." *Id.* at 1345.

Indefiniteness

Claim failing to recite viscosity measurement temperature not indefinite because, although extrinsic evidence conflicting, court properly weighed extrinsic evidence and specification to conclude that one of skill in the art would measure viscosity at room temperature.

In *Akzo Nobel Coatings, Inc. v. Dow Chemical Co.*, 811 F.3d 1334 (Fed. Cir. 2016), Dow argued that Akzo's claims reciting the step of lowering the temperature of a dispersion to a "viscosity below 10 Pa.s" renders the claims indefinite because it fails to recite the temperature at which the viscosity measurement is to be taken. Citing extrinsic evidence, the district court found that one of skill in the art would measure viscosity at room temperature in the absence of a specified temperature.

The Federal Circuit acknowledged that the extrinsic evidence considered by the district court was conflicting between (i) patentee's expert's testimony that where the temperature is not specified for a given measurement, room temperature is implied; and (ii) the "ASTM protocol" cited by Dow disclosing a temperature of up to 175° C for determining the viscosity of hot melt adhesives. The court found the ASTM protocol discussing "hot melt adhesives" to be "inapposite to the claimed product that has been cooled to below 100° C." *Id.* at 1344. The court also found the room temperature construction supported by the intrinsic evidence, noting that although "neither the claim language nor the specification indicates a temperature for the final viscosity measurement," "room temperature is the only temperature mentioned at all in the … patent in connection with a viscosity measurement." *Id.*

Claim not indefinite for failing to specify which steps of the process occur at elevated temperatures because the specification makes it clear that it is during the dispersing step, before exiting the extruder, when the temperature necessarily exceeds the melting point of the polymer.

Dow also argued that the phrase "carried out at a temperature of from 5 to 150° C above the melting point of the polymer," recited in claim 2, was indefinite because it fails to specify which steps in the claimed process occur at those elevated temperatures. The district court found that the specification supports the construction that the phrase refers to the elevated temperature phases and not to the stages that follow. The Federal Circuit agreed. The court noted that claim 1, from which claim 2 depends, recites a process "for producing a dispersion in an aqueous medium in which the polymer is dispersed in an aqueous medium in an extruder at a temperature above 100° C." Citing the specification's teaching that the dispersing step necessarily takes place before the dispersion exits the extruder, the court found that it is during that dispersing step when the temperature necessarily exceeds the melting point of the polymer. In so holding, the court rejected Dow's suggestion that the court was improperly redrafting claims to sustain their validity, noting that "we are not redrafting the claims, but rather construing the claims to require the heightened temperature range to apply to the elevated temperature phases in accordance with the specification." *Id.* at 1345.

Although Akzo ultimately prevailed against the indefiniteness attack, it is preferable, when dealing with a temperature-dependent variable such as viscosity, to set forth the measurement temperature. The reader will recall that Teva's claim was held invalid when it failed to specify the manner in which it measured its claimed molecular weights. *Teva Pharms USA, Inc. v. Sandoz, Inc.*, 789 (Fed. Cir. 2015).

A process limitation in a product claim is not indefinite where it defines a property of an element of the claim such that an infringer need not carry out a process step to infringe.

In *LifeNet Health v. LifeCell Corp.*, 837 F.3d 1316 (Fed. Cir. 2016), the court addressed whether LifeNet's use of a process limitation in its apparatus claims rendered those claims indefinite. Although directed to an apparatus, the claims recited the limitation that "one or more plasticizers are not removed from [an] internal matrix of [the] plasticized soft tissue graft prior to transplantation into a human."

LifeCell argued that because the non-removal limitation describes a method of use, while the remainder of the claims describes an apparatus, those claims are indefinite for covering both an apparatus and a method of using that apparatus. LifeCell relied on *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377 (2005), where the court held a claim invalid for indefiniteness when "as a result of the combination of two separate statutory classes of invention, a manufacturer or seller of the claimed apparatus would not know from the claim whether it might also be liable for contributory infringement because a buyer or user of the apparatus later performs the claimed method of using the apparatus." *Id.* at 1384. Here, however, the court found that "the non-removal limitation defines a property of the recited plasticizer in that the plasticizer is biocompatible and does not need to be removed from the internal matrix before transplantation in the context of [the apparatus claims], so no later action by a user of the tissue graft is necessary." *Lifenet Health*, 837 F.3d at 1327. Therefore, the claims are not indefinite because they do not improperly mix an apparatus with a method of using that apparatus.

District court properly relied on non-technical dictionaries from the present day to discern the ordinary meaning of the claim term "three-dimensional" because the defendant failed to show how a dictionary from the time of patent filing would define the term differently.

In *MIT v. Shire Pharmaceuticals, Inc.,* 839 (Fed. Cir. 2016), Shire asserted that the term "three-dimensional scaffold" in MIT's claims is indefinite because the intrinsic record provides "no guidance" as to the meaning of "three-dimensional." The district court construed the term "three dimensional" according to its accepted, ordinary meaning, as confirmed by dictionary definitions.

On appeal, Shire argued that the dictionaries cited by the district court are from the present day and are not technical in nature. The court rejected Shire's argument, concluding that "Shire does not explain how technical dictionaries or dictionaries contemporaneous to the patents' filing date would define the term any differently." *Id.* at 1124. The court further found that "the district court's construction is consistent with Shire's own expert's opinion regarding the term's ordinary meaning at the time of the invention." *Id.* Accordingly, "[g]iven the ordinary meaning of 'three-dimensional' and Shire's own expert's description of 'three-dimensional scaffold,'" the court agreed that the claim language is sufficiently definite under *Nautilus*.[17]

Claim Construction/ Infringement

Term "fractionating" properly limited to distillation, so as to exclude accused extraction, because the specification uses the term to refer specifically to distillation and because patentee specifically disclaimed conventional extraction processes

In *David Netzer Consulting Engineer LLC v. Shell Oil Co.,* 824 F.3d 989 (Fed. Cir. 2016), the court construed Netzer's claims directed to a process for the coproduction of ethylene and purified benzene and, specifically, the final step of "fractionating the pyrolysis gasoline to form a purified benzene product comprising at least about 80 wt % of benzene." Netzer argued that "fractionating" should be construed broadly to mean "separating a chemical mixture into fractions, no matter the process units used," including distillation (for separating chemicals based on differences in boiling points), extractors (for separating chemicals based on solubility differences), and hydrotreaters (for hydrogenating unsaturated hydrocarbons, such as olefins). Shell argued, citing specification and prosecution history disclaimers, and the district court agreed, that "fractionating" means "conventional distillation," thereby excluding Shell's accused process that performs separation by extraction.

On review, the Federal Circuit affirmed that the term "fractionating" means separating compounds based on differences in boiling points, i.e., distillation, which excludes extraction, such as Shell's accused "Sulfolane" process–a process developed in the 1960s. The court found that "[t]he specification repeatedly and consistently uses 'fractionating' or 'fractionation' to describe separating petrochemicals based on boiling point differentials." *Id.* at 994. In addition, the court found that patentee disclaimed conventional extraction methods producing 99.9% pure benzene from conventional fractionation, arguing "[u]nlike conventional

17 *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014).

fractionation, conventional extraction—which includes the Sulfolane process—can successfully remove non-aromatic hydrocarbon azeotropes to produce highly pure benzene." *Id.* at 995. Furthermore, the specification "clearly disclaimed conventional extraction … distinguishing it from the 'present invention'," and patentee "twice stated during prosecution that the claimed process is 'particularly useful' 'to produce a benzene product that need not have a purity over 99 wt%, much less over 99.9 wt%, as previously required.'" *Id.* at 995-996. Accordingly, the court found Shell's accused Sulfolane process to be a conventional extraction excluded from the "conventional fractionation" claimed.

Even though an open-ended "comprising" claim generally covers an accused teaching with additional steps, each claimed step must still be performed as written.

Netzer contended that Shell literally infringes under its own proposed construction because it directs pyrolysis gasoline through a series of process units, some of which are distillation columns, and forms 99.9% pure benzene in the end. According to Netzer, "[i]t is irrelevant that the mixture also passes through an extractor as part of that process … because adding an extra step to an otherwise infringing process does not defeat a finding of infringement." *Id.* at 997. The court disagreed, holding that while "[i]t is true that a method claim with the word 'comprising' appearing at the beginning generally allows for additional, unclaimed steps in the accused process, … each claimed step must nevertheless be performed as written." *Id.* at 998. Here, "Netzer's infringement theory requires rewriting the claimed step to read 'fractionating the pyrolysis gasoline [and] form[ing] a purified benzene product' rather than 'fractionating the pyrolysis gasoline *to* form a purified benzene product,' as the claim is written." *Id.* (emphasis in original). Further, "the patentee disclaimed conventional extraction, including the Sulfolane process," and thus "Netzer cannot now assert that the claimed fractionating step is literally infringed by the Sulfolane process." *Id.*

Accused extraction process not the "equivalent" of the claimed 'fractionation" process (construed as limited to distillation) in view of patentee's disclaimer of extraction and fact that extraction does not separate components is substantially the same way as distillation.

The court also found that Netzer cannot show infringement under the doctrine of equivalents because "[t]he disclaimer of the Sulfolane process for literal infringement applies equally to infringement under the doctrine of equivalents." *Id.* Furthermore, no reasonable jury would find that the accused process satisfies the function-way-result test because "almost all of the purification in the Sulfolane process is done through extraction, i.e., separating compounds based on solubility differences, which is substantially different from the claimed process of separating compounds based on differences in boiling points." *Id.*

This case seems to reaffirm the longstanding doctrine that an accused infringer practicing in accordance with the prior art cannot infringe a claim. This is also another case where the court found a disclaimer based on distinguishing the prior art from "the present invention."

A patent need not spell out a claim element's function, way, and result in order for the doctrine of equivalents to apply as to that element; therefore reference to the element's function to the FDA in an ANDA filing was sufficient to establish that function.

In *Intendis GMBH v. Glenmark Pharmaceuticals Inc., USA*, 822 F.3d 1355 (Fed. Cir. 2016), the court reviewed whether the isopropyl myristate in Glenmark's generic product met the triglyceride and lecithin elements in Intendis' claims directed to a hydrogel composition under the doctrine of equivalents. The district court found that it did, relying on the function-way-result test.

On appeal, Glenmark argued that its isopropyl myristate did not perform substantially the same function as the claimed triglyceride and lecithin. The court framed the issue not as "the substantiality of the differences between the chemical structures of isopropyl myristate, triglyceride, and lecithin," but whether "triglyceride and lecithin function as penetration enhancers in the claimed compounds." *Id.* at 1361. Glenmark argued that the "absence of support in the patent itself for the notion that the claimed excipients function as penetration enhancers is fatal to Appellees' infringement case." *Id.* at 1362. The Federal Circuit disagreed, holding that even though "a patent's disclosure is relevant and can at times be dispositive of the function," "[w]e have never held that a patent must spell out a claim element's function, way, and result in order for the doctrine of equivalents to apply as to that element." *Id.* Rather, "[t]he relevant inquiry is what the claim element's function in the claimed composition is to one of skill in the art, and a fact finder may rely on extrinsic evidence in making this factual determination." *Id.*

Glenmark cited Appellees' FDA filings as extrinsic evidence identifying the claimed lecithin and triglyceride as an emulsifier and an emollient, respectively, and not as a penetration enhancer. However, "[f]atal to Glenmark's argument is its own ANDA submission to the FDA repeatedly referring to the claimed excipients (triglyceride and lecithin) as penetration enhancers." *Id.* The court saw "no reason why a district court acting as a fact finder should ignore a party's representation to a federal regulatory body that is directly on point." *Id.*

Court properly limited "hypothetical claim" to the claimed triglyceride/lecithin "penetration enhancer" and the accused isopropyl myristate penetration enhancer, as opposed to all penetration enhancers, and, as such, claim did not ensnare the prior art, equivalents found.

Glenmark also argued that infringement under the doctrine of equivalents would encompass or ensare the prior art. Using a "hypothetical claim" analysis,[18] the district court held that a claim reciting both the accused isopropyl myristate and the glyceride/lecithin combination literally recited in the claim would not ensnare the prior art, thereby making Glenmark's isopropyl myristate an equivalent. On appeal, Glenmark argued that the court's hypothetical claim was "inexplicably narrower" than Appellees' range of equivalents because "a proper hypothetical claim should have matched Appellees' theory of infringement and thus included any penetration enhancer," not just Glenmark's isopropyl myristate. *Id.* at 1364. According to Glenmark, such a hypothetical claim would have been invalid over the prior art and thus the doctrine of equivalents should be precluded.

The Federal Circuit disagreed, finding that "[t]he district court adopted a proper hypothetical claim, one that includes triglycerides and lecithin or alternatively isopropyl myristate," and "correctly rejected as too broad Glenmark's proposed hypothetical claim which would cover all penetration enhancers." *Id.* Glenmark did not challenge the district court's determination that the hypothetical claim as constructed would have been patentable, and thus the court saw no reversible error in the district court's conclusion that Glenmark's product infringes the asserted claims under the doctrine of equivalents.

Amending a dependent claim to require a quantity of lecithin is not a "narrowing amendment" but a "clarifying amendment" because the independent claim always required lecithin; thus no amendment-based estoppel as to accused lecithin-free composition.

The district court also rejected Glenmark's argument that patentee surrendered a lecithin-free composition (e.g., Glenmark's proposed generic product) as an equivalent during prosecution. In response to an examiner's position during prosecution that dependent claims reciting lecithin concentrations of "up to 1%" and "up to 3%" could include zero lecithin, patentee amended the dependent claims to recite a lecithin concentration of "from more than 0 to 1%" or "from more than 0 to 3%" to expressly state what has already been made clear on the record. The district court found that the amendments were merely for clarification purposes and not to disclaim formulations with zero lecithin, noting that Glenmark itself did not dispute that because the independent claim always required lecithin, both dependent claims also always required lecithin. On appeal, Glenmark argued that patentee expressly disavowed and disclaimed formulations without lecithin." The Federal Circuit disagreed, finding that "[t]he district court correctly determined that prosecution history estoppel did not preclude the capture of Glenmark's lecithin-free composition as an equivalent." *Id.* at 1365. For example, "[a]mendment-based estoppel does not apply because the amendment was not a narrowing amendment made to obtain the patent," but rather "a clarifying amendment" because "[a]s dependent claims can never be broader than the independent claim from which they depend, the dependent claims as originally written could not have included 0% lecithin." *Id.* As a "clarifying amendment," "it does not give rise to prosecution history estoppel." *Id.* at 1365-1366.

This is one of the few cases in recent memory that takes an expansive view of the doctrine of equivalents. First, the case holds that for purposes of satisfying the function prong of the function/way/result equivalents test, it is not necessary that the specification explicitly set forth the function achieved by the allegedly equivalent element, so long as such functionality can be established by extrinsic evidence. Second, this case makes clear that in proposing a "hypothetical claim" that covers both the original claimed subject matter and the infringing teaching, it is not necessary for the patent to provide written description support for the language added to cover the infringing teaching. Here, for example, the specification does not provide written description support for isopropyl myristate, yet Intendis was able to propose a hypothetical claim reciting the originally claimed lecithin/triglyceride combination and the isopropyl myristate of the accused teaching, which was narrow enough to avoid the prior art showing generic penetrating agents. In a way, this result makes sense because a rule requiring that a hypothetical claim find literal support in the specification would likely run afoul of the disclosure-dedication rule, which does not permit a patentee to cover, by equivalents, that which is expressly disclosed in the specification but not claimed.

"Whereby" clause reciting reduction of accumulated glycogen is properly construed broadly to include reductions anywhere in the patient's body, not solely in skeletal muscles, because claim language is broadly written and supported by specification and prosecution history.

In *Genzyme Therapeutic Products Ltd. Partnership v. Biomarin Pharmaceutical Inc.*, 825 F.3d 1360 (Fed. Cir. 2016), Genzyme appealed the Board's IPR claim construction of a "whereby" clause in its claims reciting a method of treating a human patient with Pompe's disease. The claims recited intravenously administering biweekly to the patient a therapeutically effective amount of human acid αglucosidase ("GAA"), "whereby the concentration of accumulated glycogen in the patient is reduced and/or further accumulation of glycogen is arrested." The Board construed the "whereby" clause not as a separate step, but rather as describing the result achieved when a patient is given a therapeutically effective dose of GAA. The Board also did not limit the "whereby" clause as requiring a reduction of glycogen in the patient's skeletal tissues.

18 "Hypothetical claim analysis is a two-step process. The first step is "to construct a hypothetical claim that literally covers the accused device.' Next, prior art introduced by the accused infringer is assessed to 'determine whether the patentee has carried its burden of persuading the court that the hypothetical claim is patentable over the prior art.' In short, we ask if a hypothetical claim can be crafted, which contains both the literal claim scope and the accused device, without ensnaring the prior art." *Id.* at 1363 (citing *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1324 (Fed. Cir. 2009)).

On appeal, Genzyme argued that the "whereby" clause should be construed to require that the reduction of glycogen occur specifically in the patient's skeletal muscles, rather than occurring anywhere in the patient's body, including the heart, skeletal muscles, or liver as found by the Board. The court disagreed, holding that "[b]ecause the claim language does not expressly or implicitly require that the administration of GAA reduce glycogen in any particular organ of the body, the Board was correct to reject Genzyme's narrower construction." *Id.* at 1370. Genzyme's citation to passages in the specification describing the reduction of glycogen buildup specifically in the skeletal muscle was to no avail because other portions of the specification describe how GAA is taken up by the heart, liver, and skeletal muscles, thereby supporting the broader interpretation. Nor was Genzyme's cause helped by the prosecution history because the addition of the "whereby" clause to the claim cited specification passages that failed to suggest the requirement of a decrease in skeletal muscle glycogen. Thus, "[a]lthough it was understood at the time of the invention that the claimed therapeutic effect of the patented methods would typically result in a reduction in the glycogen level in either the heart or the skeletal muscles, the evidence before the Board suggests that the patentees chose not to restrict the whereby clause in that fashion, but instead elected to describe the effects of the therapy in a more general manner, claiming any effective GAA therapy." *Id.* at 1371. The court also rejected Genzyme's argument that the Board's construction cannot be correct because "reduction of glycogen in liver alone does not treat Pompe Disease, as everyone at the time of the invention fully understood." *Id.* The court found that the claims required the administration of "a therapeutically effective amount" of GAA, and thus the "Board's construction is therefore consistent with the patentees' apparent choice to draft their claims broadly to reach any method of GAA administration that had therapeutic effects and reduced glycogen concentrations somewhere in the body." *Id.*

This case is somewhat hard to understand because the court acknowledges that the claims require therapeutic efficacy and the reduction of glycogen in the liver alone would not be therapeutically effective. However, it appears to affirm a claim construction that would include reduction of glycogen solely in the liver, which would not be therapeutically effective. Nonetheless, the patent owner could have helped its own cause if it had specifically claimed a reduction of glycogen in the patient's skeletal muscles.

Phrase "pressurized collection vessel" properly construed to require accumulation of material in the vessel, as opposed to mere passage of material through a pipe, as such construction consistent with the specification and prevents rendering the word "collection" entirely superfluous.

In *Akzo Nobel Coatings, Inc. v. Dow Chemical Co.*, 811 F.3d 1334 (Fed. Cir. 2016), the court reviewed Akzo's claims directed to an extrusion process that generates low viscosity aqueous polymer dispersions. To prevent boiling of the aqueous carrier liquid during extrusion, the claimed process requires a pressure "above atmospheric for the extruder at the outlet with a *pressurized collection vessel*." Because the claimed process requires a "pressurized collection vessel" whereas "Dow's accused process uses a valve and allows the polymer dispersion to flow continuously," without accumulation in a collection vessel, the district court found no literal infringement. *Id.* at 1338.

On review, the Federal Circuit agreed with Dow and affirmed the district court's construction of "pressurized collection vessel" as "tubing, piping, or other container where a desired material accumulates, which is maintained above atmospheric pressure." *Id.* at 1339. The court found that Akzo's proffered construction of "gather or receive" would render the term "collection" in the claim "entirely superfluous and allow any pressurized vessel to constitute a 'pressurized collection vessel'; such a result is disfavored." *Id.* at 1340. By contrast, the district court's construction of "accumulation," gives the term "collection" proper meaning in context. The court also found such construction to be consistent with the specification's use of the terms "collection" and/or "collected" in the examples, all of which "clearly contemplate a buildup or accumulation of dispersion in the collection vessel before the eventual 'periodic removal.'" *Id.*

Claims requiring "accumulation" of dispersion in a collection vessel not infringed by passage of material through a pipe, because even though the material is resident for a period of time in a pipe, it does not involve the accumulation envisioned by the claims.

Akzo argued that even under a claim construction requiring accumulation of the dispersion, Dow's process infringes because the dispersion "accumulates" in Dow's heat exchange equipment. Akzo relied on expert testimony stating that the piping "represents a defined volume of space in which the dispersion collects and is resident for a period of time such that a backpressure is created" on the extruder. *Id.* at 1341. Akzo argued that this unrebutted evidence established a genuine issue of material fact as to whether Dow's pipes and heat exchangers "accumulate" dispersion, as required by the claims. The court disagreed, holding that the expert testimony "is ambiguous at best as to whether accumulation occurs in Dow's accused process." *Id.* The fact that the dispersion is "resident for a period of time" in the piping "does not invoke the 'accumulation' envisioned by the claims," as "liquid passing through pipes is always 'resident for a period of time.'" *Id.*

"Vitiation" is akin to a finding of no equivalents under the function-way-result test; here the patentee failed to articulate how the difference in the way the claimed collection vessel worked versus the way the accused valve and pipes worked was insubstantial.

Akzo contended that the district court erroneously applied the concept of vitiation in finding no infringement under the doctrine of equivalents. The court noted that "saying that a claim element would be vitiated is akin to saying that there is no equivalent to the claim element in the accused device based on the well-established 'function-way-result' or 'insubstantial differences' tests." *Id.* at 1342 (citations omitted). Here, "Akzo failed to establish a genuine issue of material fact as to whether Dow's process operates in substantially the same way." *Id.* In particular, whereas "[t]he claimed process operates by using a pressurized collection vessel wherein dispersion accumulates to maintain backpressure in the extruder," "Dow's accused process … uses a valve and does not allow for accumulation in the downstream pipes." *Id.* According to the court, Akzo's expert failed "to articulate which construction of 'collecting' he invokes, much less articulate how the differences between the two processes are insubstantial." *Id.* at 1342-1343.

It is not clear whether the "collection," i.e., accumulation of the dispersion in some form or other of container was particularly critical to the process for generating low viscosity polymer dispersions. If not, then there is a valuable lesson to be drawn here regarding the importance of not limiting claims to non-critical aspects of an invention.

A second noteworthy aspect of this case relates to how the court is addressed the issue of vitiation. There was a time was when vitiation was a useful defense to infringement under the doctrine of equivalents. This case, as well as *Cadence Pharmaceuticals Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364 (2015), represent a newer viewpoint that "vitiation" is a nothing more than a conclusion of non-equivalents one reaches based on the function/way/result test or the insubstantial differences test. It is not a means to find no equivalents in its own right.

A Markush claim reciting that each layer in a multlayered wrap is "selected from the group consisting of" the polymer resins LLDPE, VLDPE, ULDPE and mLLDPE closes the claim to inclusion of other resins in each layer.

In *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.* 831 F.3d 1350 (Fed. Cir. 2016), the court reviewed the construction of Multilayer's claims directed to multilayered plastic cling wrap films including both inner and outer layers. At issue was the element (b) of the claim reciting "five [identifiable] inner layers, with each layer being selected from the group consisting of linear low density polyethylene [('LLDPE')], very low density polyethylene [('VLDPE')], ultra low density polyethylene [('ULDPE')], and metallocene-catalyzed linear low density polyethylene [('mLLDPE')] resins." The parties agreed that the claim was written in "Markush" claim format. On appeal, the court addressed two claim construction issues: first, whether the Markush group is closed to resins other than the four listed, and, second, whether the Markush group is closed to blends of the four listed resins.

On review, the Federal Circuit agreed with the district court's construction of the claim as closed to unrecited resins–i.e., types of resin other than LLDPE, VLDPE, ULDPE, and mLLDPE, holding that:

> [T]he Markush group of element (b) must be construed as closed to resins other than LLDPE, VLDPE, ULDPE, and mLLDPE. To construe the inner layers of element (b) as open not only to the four recited resins but also to any other polyolefin resin … would be to construe the claims to cover any plastic film with five compositionally different inner layers, each of which contains any amount of one of the four recited resins. Construing element (b) in this manner would render the …. patent's Markush language–"each layer being selected from the group consisting of"– equivalent to the phrase "each layer comprising one or more of."

Id. at 1358.

The "very strong presumption" that the phrase "consisting of" in a Markush claim reciting four alternative polymers is closed to other polymers, is not overcome by the fact that the specification discloses the recited polymers in combination with the other polymers.

The court noted that the transitional phrase "consisting of," is a term of art that "creates a very strong presumption that that claim element is 'closed,'" and therefore "excludes any elements, steps, or ingredients not specified in the claim. *Id.* (citation omitted). While there "may be a scenario where a patent's specification or prosecution history give 'consisting of' the meaning of 'comprising,'" such as where "the specification and prosecution history [] unmistakably manifest an alternative meaning," "[t] hey do not here." *Id.* at 1359. Multilayer cited the specification's description of LDPE as a resin suitable for use in both inner and outer layers as showing that the patent manifests a clear intent to open the Markush group of element (b) to LDPE. The court disagreed, noting that the specification also describes several other types of resin as suitable for incorporation into the inner layers–polypropylene, medium density polyethylene, and high density polyethylene–which, like LDPE, are not recited in the Markush group of element (b). The court concluded that such listing of these other resins in the specification was not sufficient to overcome the presumption created by the "consisting of" claim language.

Claim differentiation is inapplicable where the language of an independent claim is clear on its face.

The court also rejected Multilayer's claim differentiation argument that because dependent claims recite inclusion of LDPE in one of the five inner layers, it necessarily follows that the independent claim permits the use of LDPE in the inner layers. While

acknowledging that other claims of the patent in question can be "valuable sources of enlightenment as to the meaning of a claim term," the court held that "the language of a dependent claim cannot change the scope of an independent claim whose meaning is clear on its face." *Id.* (citation omitted). The court reiterated the oft-stated principle that claim differentiation is only an aid to interpretation, not a conclusive doctrine.

Dependent claim reciting an additional polymer that is excluded by a Markush group in an independent claim is invalid under §112(d) because such dependent claim contradicts, rather than narrows, the claim from which it depends.

As a result of its construction that element (b) of claim 1 is closed to unrecited resins, including LDPE, the court found no error in the district court's conclusion that dependent claim 10 (reciting LDPE) is invalid. "Independent claim 1 excludes LDPE from the inner layers, while dependent claim 10 includes it," and thus "claim 10 is inconsistent with claim 1 and, indeed, contradicts claim 1," rendering it invalid under 35 U.S.C. § 112(d). *Id.* at 1362.

Although there is a presumption that a Markush group is closed to mixtures of the listed elements, such presumption can be overcome by intrinsic evidence such as where there is overlap between two of the elements, LLDPE and mLLDPE.

The court next considered whether element (b) of the claim was also closed to layers including blends of the recited polymers, LLDPE, VLDPE, ULDPE, and mLLDPE, as the district court held. On review, the Federal Circuit held that the "Markush group of element (b) must be construed to permit blends of the four recited resins." *Id.* at 1362-1363. The court acknowledged its earlier holding in *Abbott*[19] "that there is a presumption that a Markush group is closed to mixtures of the listed elements." *Id.* at 1363. However, "[b]y itself, the use of the transitional phrase 'consisting of' does not necessarily suggest that a Markush group is closed to mixtures, combinations, or blends," since "a layer could still 'consist' of the listed resins even if the layer 'consists' of a mixture of those resins." *Id.* As such, even under *Abbott*, "the presumptions created by Markush claim language can be overcome by intrinsic evidence." *Id.* According to the court, the *Abbott* presumption that Markush claims are closed to blends is "not as strong as" the presumption that "unlisted resins are excluded, which flows from the transitional phrase 'consisting of'." *Id.*

Here, "the intrinsic evidence … is unequivocal that the inner layers described in element (b) … are open, not closed, to blends of the recited resins, LLDPE, VLDPE, ULDPE, and mLLDPE." *Id.* Thus, the Markush group polymers are not mutually exclusive but instead overlap to some extent. For example, LLDPE encompasses mLLDPE, which is merely an LLDPE prepared by a particular type of catalyst. The fact that the claims "contemplate the use of polyolefin resins that are classifiable both as an LLDPE and as an mLLDPE … supports reading element (b) as open to 'blending' LLDPE and mLLDPE within a single layer (and open to other blends of the listed resins)." *Id.* at 1364.

Claim differentiation, the disclosure of blends of the recited Markush polymers with other polymers, and the fact that there is nothing contradictory in the prosecution history further rebut the presumption that the Markush group excludes mixtures of the recited elements.

Here, the court found Multilayer's claim differentiation argument to be effective, holding that one of the dependent claims "suggests reading element (b) as open to blends, as it recites '[t]he multi-layer, thermoplastic stretch wrap film of claim 1, wherein at least one layer comprises a blend of at least two of said resins.'" *Id.* Moreover, the "specification similarly supports construing element (b) as open to blends, as it repeatedly and consistently references blends in describing any and all resins, including the four resins of element (b)." *Id.* The court also found that "there is nothing in the prosecution history … to suggest that blends are excluded and therefore nothing to contradict what is apparent from the specification." *Id.* Therefore, view of the "strong intrinsic evidence, the Markush group of element (b) must be read as open to blends of the four listed resins, LLDPE, VLDPE, ULDPE, and mLLDPE." *Id.*

This case waters down *Abbott* in holding that "[b]y itself, the use of the transitional phrase 'consisting of' ***does not necessarily suggest*** that a Markush group is closed to mixtures, combinations, or blends." *Id.* at 1363 (emphasis added). Nonetheless, if one were to write up a manual of best claim drafting practices based on this case and *Abbott*, the best advice would be to avoid the Markush terminology altogether and, instead, employ language, open claim language such as "comprising." To the extent that one still prefers to employ the classical Markush terminology, then, at the very least, include "and mixtures thereof" at the end of the listing.

Claim reciting a monoclonal antibody properly construed to not include chimeric or humanized antibodies, despite knowledge of such antibodies as of the priority date, because one skilled in the art would not have appreciated that the claimed "monoclonal antibodies" included chimeric or humanized antibodies as of that date.

In *UCB, Inc. v. Yeda Research & Development Co., Ltd.,* 837 F.3d 1256 (Fed. Cir. 2016), UCB sought a Declaratory Judgment of non-infringement of Yeda's claims directed to a monoclonal antibody that binds a defined human cytotoxin and is "obtainable from stimulated human monocytes." At issue was whether Yeda's claims include chimeric or humanized antibodies, when the

19 *Abbott Labs v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274 (2003)

patent specification describes only murine (mouse) monoclonal antibodies. Yeda argued that since chimeric monoclonal antibodies were known at the time its priority application was filed, the claims should be construed to cover such chimeric antibodies, as well as humanized antibodies. UCB responded, and the district court agreed, that the prosecution history prohibits coverage of chimeric and humanized antibodies. Instead, the court construed a monoclonal antibody as "a homogenous population of a single type of antibody produced via hybridoma and not including chimeric or humanized antibodies." *Id.* at 1259.

On appeal, Yeda pointed out that the claim does not mention any particular monoclonal antibody or species of chimera, and should not be limited to the examples in the specification. Yeda stated that every embodiment need not be specifically described and claimed to be within the scope of a generic term in a claim. The Federal Circuit agreed that "generic terms in claims are construed in light of that which is already known," and that chimeric monoclonal antibodies were known at the time Yeda filed its priority application. However, "[e]stablishing that chimeric antibodies existed [at Yeda's filing date], however, is different from establishing that a person of ordinary skill in the art would have understood chimeric antibodies to be monoclonal antibodies" as of that date. *Id.* at 1260. Thus, the court agreed with the district court's conclusion that "the extrinsic evidence relied upon by Yeda's experts does not support the conclusion that the understanding of 'monoclonal antibodies' [as of the priority date] included either chimeric or humanized antibodies." *Id.*

Patentee who presented claims directed to chimeric and humanized antibodies and then cancelled such claims in response to a new matter rejection to obtain issuance of the patent cannot obtain a claim construction that recovers the cancelled new matter.

The court also found the prosecution history inconsistent with Yeda's proffered construction of "monoclonal antibody." The court reiterated the district court's finding that "for the first ten years of prosecution, neither Yeda nor the examiner understood the term 'monoclonal antibodies' to include chimeric or humanized antibodies." *Id.* Furthermore, Yeda submitted claims to "rat, hamster and human antibodies and chimeras thereof," as well as claims specifically encompassing "chimeras of" mouse monoclonal antibodies and "nonmurine" monoclonal antibodies. *Id.* However, the Examiner rejected the claims as introducing new matter not supported in the specification and, in response, Yeda canceled the claims. The court agreed with the district court's conclusion that "Yeda cannot now obtain a claim construction that recovers claim scope that was yielded in order to obtain issuance of the patent," and agreed that the claims exclude chimeric and humanized antibodies. *Id.*

The estoppel rule that a patent applicant cannot later obtain scope that was requested during prosecution, rejected by the examiner, and then withdrawn by applicant may apply to other claims even if they were not amended.

Finally, Yeda argued that absent a narrowing amendment during prosecution to the claim now being enforced, there can be no prosecution estoppel to the scope of that claim merely because different claims were rejected by the examiner and canceled by applicant. The court disagreed, stating that "[a]lthough each claim in a patent warrants independent consideration … the general rule is that a patent applicant cannot later obtain scope that was requested during prosecution, rejected by the Examiner, and then withdrawn by the applicant." *Id.* at 1261. Accordingly, "[s]uch estoppel was reasonably applied" to the claim even though it had not been amended. *Id.*

At first glance, it is tempting to conclude that had Yeda not attempted to specifically claim the recombinant or humanized antibodies and then dropped such claims, it may have been able to garner a more favorable claim construction. Indeed, Yeda had been successful, through an expert declaration, in convincing the examiner that such claims were enabled. Nonetheless, for at least two reasons, even absent its unsuccessful amendment, Yeda would have still had a difficult road. First, the court was not convinced that one of ordinary skill would have considered recombinant or humanized antibodies to be "monoclonal" antibodies as of the filing date. Second, even if Yeda was successful in advancing such a construction, it would have likely prompted a written description defense, especially given Yeda's ten years of prosecution where both Yeda and the examiner did not treat the term as including recombinant or humanized antibodies.

A practitioner confronting a similar fact pattern might want to consider two things based on this case. First, if presenting claims that have some likelihood of prompting a new matter rejection, it is probably a best practice to vet those claims to an examiner during an interview. Of course, if the examiner indicates the claims may have a new matter issue, then you can simply opt not to file the claims and avoid estoppel. Second, although Yeda was successful in using declaration evidence to show that its new claims covering recombinant or humanized antibodies were enabled, the problem was not the knowledge of such antibodies as of the filing date, but rather whether one of ordinary skill would have considered such antibodies to be monoclonal antibodies as of the filing date. As such, one should consider presenting expert evidence explaining how that the term was understood at the time of filing.

Because the term "not removed" regarding plasticizers in a soft tissue graft is easily understood by a person skilled in the art to mean that no plasticizers are removed, construction of the term by the district court was not necessary.

In *LifeNet Health v. LifeCell Corp.,* 837 F.3d 1316 (Fed. Cir. 2016), the court addressed competing constructions as to LIfeNet's claims directed to a plasticized soft tissue graft suitable for transplantation into a human. The claims required that "one or more plasticizers are not removed from [an] internal matrix of [the] plasticized soft tissue graft prior to transplantation into a human." At issue was whether the recitation that the "plasticizers are not removed" required that no plasticizer be removed (LifeCell's position) or allowed for some, but not all, plasticizer to be removed (LifeNet's position). The district court found construction of the term was "unnecessary," because the phrase "'not removed' is easily understood by a person of ordinary skill in the art to have its plain meaning that ***no plasticizers*** are removed prior to transplantation," as argued by LifeCell. *Id.* at 1321 (emphasis added). And even though LifeCell's accused process removed as much as 50% of the plasticizer from the graft, the Federal Circuit found substantial evidence supported a finding that LifeCell infringed because it only removed plasticizer from the gaps and voids of the graft, and not from its ***internal matrix*** as claimed.

Because it is not necessary for a third party to take action for the "not removed" limitation of the claim to be met, the limitations of the claim are satisfied at the moment of manufacture and defendant manufacturer is liable for direct infringement.

LifeCell also argued that it cannot be liable for direct infringement because the non-removal limitation cannot be met until an independent third party, such as a surgeon, actually prepares and uses the accused products, and it is unknown when LifeCell sells a graft if and how that graft will be used for transplantation. However, the court agreed with LifeNet that the final product that leaves LifeCell's hands is complete and infringes in that condition without affirmative action by a third party. The court noted that functional limitations recited in the negative may describe a capability or structural element and found that the limitation is "satisfied by the graft from the moment it is manufactured unless and until the plasticizer is removed from the internal matrix before transplantation." *Id.* at 1326. The court distinguished cases such as *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293 (2005), because the surgical implants claimed there required that an interface be "operatively joined" to a segment of bone by a surgeon such that the manufacturer itself could not directly infringe. Therefore, unlike these cases, no action by a third party is required to meet all the elements of LifeNet's claim.

The specification's description of "the present invention" as providing a dehydrated or freeze-dried plasticized product did not limit the claim since there was no indication patentee intended such limitation.

LifeCell also argued that the phrase "plasticized soft tissue graft" should be construed as requiring that the tissue graft be "dehydrated," in the sense that the tissue can only have "low residual moisture." *Id.* at 1327. LifeCell argued that its products cannot infringe as a matter of law because they have at least 60% moisture. The court agreed with LifeNet that "dehydration," merely means that ***some*** of the water has been replaced with plasticizer. The court found that although the written description repeatedly uses the word "dehydrated," it does so broadly. Furthermore, although the specification states that "[t]he present invention provides a dehydrated or freeze-dried plasticized bone or soft tissue product, preferably containing less than 5% residual moisture," the court declined to confine the claims to such an embodiment. *Id.* To this end, the court concluded that there is no indication that the patentee intended for the claims and the embodiments in the specification to be strictly coextensive, and there was no support that the claimed soft tissue graft must be dehydrated to a certain degree.

There is no clear and unmistakable surrender to exclude skin cells from the ordinary meaning of the term "vascularized tissue" because applicant's prosecution statements and declaration distinguishing its claims from skin arose in the context of different claims not including the disputed term.

In *MIT v. Shire Pharmaceuticals, Inc.*, 839 F.3d 1111 (Fed. Cir. 2016), the court reviewed the district court's construction of MIT's claims directed to a cell-scaffold composition prepared *in vitro* for growing cells to produce functional vascularized organ tissue *in vivo.* Shire argued that the terms "vascularized organ tissue" and "cells derived from a vascularized tissue" should be construed to exclude skin as an organ, as used in Shire's accused Dermagraft®, based on various statements made by MIT during prosecution of the asserted patents. According to Shire, as properly construed, the claims cover only certain types of non-skin cells, namely parenchymal cells and bone forming cells.

On appeal, Shire acknowledged that the ordinary meaning and specification supported a construction of the disputed claim terms to include skin, but argued that MIT's prosecution statements amounted to a clear and unmistakable disclaimer of skin from the claim terms. Shire asserted that MIT's interview summary statement evinced such surrender by stating that the asserted prior art "was limited to extremely thin pieces of collagen matrix for use in preparing skin substitutes, which could not be used to create organ equivalents." *Id.* at 1120. The court disagreed, finding that "[t]hese statements … were made in the context of different claims that did not include the [disputed] terms," but rather recited "a matrix formed of a biocompatible material." *Id.* Moreover, the summary emphasized the structure of the invention's scaffold, not the type of organ it can be used to grow.

The court carried out the same analysis and reached the same conclusion regarding MIT's Declaration statement distinguishing the prior art's making of skin equivalents (not requiring the use

of thick layers of cells) from the invention directed to making functional organs in vivo (requiring use of a thick layer of cells). Once again, the claims under review at the time did not include the disputed claim terms, but instead related to maintaining the viability of the cells at the interior of a cell mass of greater than 200 microns by diffusion of nutrients and oxygen through the cell mass. Moreover, MIT's intent to surrender skin was also belied by Declarant's statements that the claimed polymer matrices can be used "with different cell types," and that while the research focused on growing artificial livers, "a great strength of our approach is the generic application of knowledge to other organ systems." *Id.* The court therefore concluded that "[a] skilled artisan would not read these statements in context as limiting the invention to any particular organ or as excluding skin." *Id.*

An applicant's unsuccessful attempt to add a "non-skin" limitation during prosecution, which was rejected on new matter grounds, followed by presentation of new claims without such limitation, does not create an inference of a clear and unmistakable surrender of scope.

The court also found that MIT's attempt to add the "non-skin" limitation during prosecution reinforced its conclusion that the claims include skin within their scope. In particular, when MIT tried to exclude skin organ cells from its claims, the examiner rejected the "non-skin" limitation under § 112 as new matter and MIT never again sought to limit the claims to exclude skin organ cells. The court found that "[h]ad the examiner actually agreed with MIT's arguments and allowed the proposed amendments, the claims could well have a different claim scope, "[b]ut the examiner did not, and MIT took a different approach." *Id.* at 1120-21. The court thus concluded that "[s]ince claims to 'vascularized organ tissue' were ultimately allowed over the prior art without the proposed 'non-skin' amendment, it is difficult to infer that a skilled artisan would interpret other isolated statements by MIT during the course of the prosecution history as a clear and unmistakable disclaimer of claim scope." *Id.* at 1121.

Specification's repeated reference to cells of the invention as "parenchymal" or "functional" and its reference to the invention's advantage relating to "parenchymal" cells does not amount to clear and unmistakable surrender limiting invention to such cells.

The court also affirmed the district court's construction of "cells derived from a vascularized tissue" to include both parenchymal and non-parenchymal (e.g., bone-forming) cells, thus rejecting Shire's argument to limit the claims to parenchymal cells and exclude skin cells. Although the specification repeatedly refers to the cells of the invention as "parenchymal," "functional," or cells possessing the "necessary" or "desired" function, the court rejected Shire's argument that "these descriptions are synonymous, such that the invention should be limited to only parenchymal cells, especially in the face of the broad ordinary meaning of 'cells derived from a vascularized tissue.'" *Id.* at 1122. Similarly, "the specifications' reference to 'an advantage of the present method' being 'a means for selective transplantation of parenchymal cells' does not amount to a clear and unmistakable disclaimer restricting the claims to only parenchymal cells." *Id.*

Because prosecution statements limiting invention to "parenchymal" cells related specifically to such types of cells and were in response to an indefiniteness rejection, no unmistakable surrender applies to amended claims reciting vascular tissue cells.

Finally, Shire cited a statement from the prosecution of a related patent where MIT stated that "the types of cells described in the application are defined in Medical dictionaries and textbook[s] as 'parenchymal' cells." *Id.* at 1123. At that time, however, the claims recited "cells selected from the group consisting of parenchymal cells from vascularized tissue and cells forming bone," and MIT was responding to an indefiniteness rejection where the examiner directed MIT to identify support in the specification for the disclosure of "parenchymal cells from vascularized tissue. *Id.* Noting that MIT later shifted its prosecution strategy and removed the limitation of parenchymal cells in favor of "cells derived a vascularized tissue," the court held that it "would not read MIT's statement … directed to very different claim language—as limiting the term 'cells derived from a vascularized tissue' to parenchymal cells" *Id.*

This is the second instance where the court construed a claim in view of a proposed claim that the PTO rejected as reciting new matter. In *UCB, Inc. v. Yeda Research and Development Co., Ltd.*, 837 F.3d 1256 (2016), discussed earlier, the court cited Yeda's cancellation of a claim, in response to a PTO new matter rejection, in holding that Yeda could not obtain a claim construction that recovers the canceled claim scope. Here, by contrast, MIT's lack of success inured to its benefit, as acceptance of its non-skin amendment would have resulted in a claim excluding the infringing teaching. The cases are certainly distinguishable in that Yeda unsuccessfully sought to add language that would have covered the infringing product, whereas MIT unsuccessfully sought to add language that excluded the infringing product.

Inequitable Conduct

No "but-for materiality" regarding alleged discrepancies between patentee's litigation statements regarding a first narrower patent versus patentee's prosecution statements regarding related second and third broader patents, where both patentee and a third party highlighted such differences to PTO.

In *U.S. Water Services, Inc. v. Novozymes A/S*, 843 F.3d 1345 (Fed. Cir. 2016), Novozymes alleged inequitable conduct against U.S. Water based on purported inconsistences between what U.S. Water represented to the PTO during prosecution and what it represented to a district court during a litigation involving U.S. Water's claims directed to a method of making ethanol including adding phytase.

During prosecution of its first patent, U.S. Water narrowed its claims to add phytase specifically after fermentation to distinguish prior art where phytase is added before fermentation. However, during litigation of the first patent, in response to arguments that its claims were limited to adding phytase after fermentation, U.S. Water argued that adding phytase during fermentation was equivalent to adding phytase after fermentation—a discrepancy observed by the district court. During prosecution of a second patent, a continuation of the first patent, and after the district court noted the discrepancy, U.S. Water amended the second patent to broadly recite adding phytase to an ethanol processing fluid in the plant at any time during the process. The differences between the broadened amended claims and the narrowed claim of the first patent were identified by U.S Water. During prosecution of a third patent, likewise not limited by when the phytase was added, it was a third-party who identified this purported distinction with the narrower first patent to the PTO, which the examiner acknowledged.

On review, the Federal Circuit found no error in the district court's determination that Novozymes failed to demonstrate a genuine dispute over materiality, and that the law did not require a finding of inequitable conduct. The court rejected Novozymes' argument of "but-for materiality" regarding the information disclosed in the litigation because the amendment of the continuation application highlighted the differences with the narrower patent such that it "would have been amply clear to the examiner that the patentees were seeking a claim that was broader in the sense that the after-fermentation limitation was removed." *Id.* at 1354. The court also agreed with the district court that the third-party submission provides another reason why the examiner knew she had to evaluate the allowability of the broader claims over the prior art distinguished in the narrower first patent. The court thus found that the examiner was aware of the differences between the pending claims of the second and third broader patents and the narrower claims of the first patent, "but found that the evidence did not affect the ultimate patentability determination." *Id.*

The most significant takeaway of this case is how much less of an issue inequitable conduct has become in a post-*Therasense* world. Indeed, this is the only published Federal Circuit case in 2016, at least in the chemical/pharmaceutical/biotech space, addressing inequitable conduct. What a change from past years!

Biologics Price Competition and Innovation Act of 2009 (BPCIA)

A biosimilars applicant under the BPCIA must provide a reference product sponsor with 180 days' post-licensure notice before commercial marketing begins, regardless of whether the applicant provided the reference product sponsor with the (2)(A) notice of FDA review.

In *Amgen, Inc. v. Apotex, Inc.*, 827 F.3d 1052 (Fed. Cir. 2016), Apotex appealed the granting of a preliminary injunction against it under the Biologics Price Competition and Innovation Act of 2009 (BPCIA) regarding the sale of its "biosimilar" to Amgen's FDA-approved Neulasta®. Citing the Federal Circuit's earlier decision in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357–58 (Fed. Cir. 2015), holding that the biosimilar application must give 180-day notice after receipt of a license from the FDA for the purpose of information exchange, the district court issued the injunction because Apotex had failed to follow this procedure. In so holding, the district court rejected Apotex's argument that the *Amgen* holding was distinguishable because, unlike Sandoz who had entirely skipped the statutory process of information exchange and patent litigation channeling, Apotex had launched the statutory process of information exchange under section 2(A) of the statute.[20]

The Federal Circuit affirmed. Citing the use of the word "shall" in the statute, the court found that the requirement under (8)(A) of the statute of 180 days' post-licensure notice before commercial marketing is a mandatory one enforceable by injunction ***whether or not*** notice was given under section (2)(A) of the statute. The court noted that when it ruled in *Amgen v. Sandoz* that this language is, indeed, "mandatory," it did not say that it was mandatory only in no-(2)(A)-notice circumstances. To the contrary, (8)(A) contains no words that make the applicability of its notice rule turn on whether the applicant took the earlier step of giving the (2)(A) notice that begins the information-exchange process. Further, *Amgen v. Sandoz* stated that (8)(A) was a "standalone notice provision" not dependent on the information–exchange processes that begin with (2)(A). Rather, the purpose of (8)(A) is to ensure that, starting from when the applicant's product, uses, and processes are fixed by the license, the necessary decision-making regarding further patent litigation is conducted such that the reference product sponsor has time to make a decision about seeking relief based on yet-to-be litigated patents.

20 Section 2(a) states that within 20 days after the FDA notifies the applicant that its application has been accepted for review, the applicant is to give notice to the reference product sponsor by providing the application as well as information describing the manufacturing process.

The BPCIA does not limit a reference product sponsor's remedy to a Declaratory Judgment Action against a biosimilars applicant who violates the statute's 180 days' post-licensure notice provision under section 8(A) before commercial marketing.

The court also rejected Apotex's argument that paragraph (9) of the statute makes a declaratory-judgment action, discussed in (9)(B), the exclusive remedy for violations of the notice provision of section (8)(A). Apotex argued that the only remedy for an applicant's unilateral denial to the reference product sponsor of the 180-day period for post-licensure litigation decision-making is a declaratory-judgment action on a patent–which (9)(B) permits if the applicant "fails to complete" any one of several steps, including the giving of the (8)(A) notice. The court disagreed, holding that "[w]e cannot infer such an exclusive-remedy conclusion from paragraph (9)." Citing Supreme Court precedent, the court noted that its equitable jurisdiction "is not to be denied or limited in the absence of a clear and valid legislative command," whether "in so many words, or by a necessary and inescapable inference." Under that standard, or indeed under a straightforward understanding of paragraph (9) as it relates to (8)(A), the court did not find "that paragraph (9) establishes that a declaratory judgment action is the sole remedy for violating (8)(A)."

On December 12, 2016, the Supreme Court denied certiorari in *Amgen, Inc. v. Apotex, Inc.* The Supreme Court, however, has granted certiorari for the Federal Circuit's earlier decision in *Amgen v. Sandoz*. Because *Amgen v. Sandoz* dealt with the Federal Circuit's interpretation of the BPCIA's 180-day notice of commercial marketing and its patent dispute resolution process, the Supreme Court's decision in that case will likely affect whether *Amgen v. Apotex* remains good law at the Federal Circuit. Arguments at the Supreme Court in *Amgen v. Sandoz* are set for April 26, 2017.

Conclusion

So what's in store for 2017?

On the chemical and life science front, we expect more § 101 eligibility challenges as the Federal Circuit works its way through defining the contours of the Supreme Court's *Myriad* and *Mayo* cases. Absent legislative intervention – which seems unlikely – the Federal Circuit's *Ariosa* and *Rapid Litigation Management Ltd.* decisions set up the need for case-by-case resolution of patent eligibility questions for cases arguably involving laws of nature or natural phenomena.

The Supreme Court will hear argument in *Amgen v. Sandoz* in April 2017, and thus weigh in on the operation of the Biologics Price Competition and Innovation Act of 2009 (BPCIA). At stake is whether a biosimilar applicant must provide a reference product sponsor with a copy of its biological license application and related manufacturing information under the statute, and whether the sponsor may seek a declaratory judgment action to obtain that information. Other issues of importance at the Supreme Court include infringement for supplying component parts, laches, patent exhaustion, and venue.

The Federal Circuit's forthcoming decision in *WiFi One*, on the scope of what is appealable from an IPR institution decision, could provide patent owners with additional avenues to challenge adverse PTAB rulings. Also, since the number of IPR filings in the chemical and life sciences fields increased in recent years, we expect next year to provide additional Federal Circuit guidance in these fields. Importantly, chemical and life science IPRs often introduce secondary considerations and issues with respect to unexpected results not often presented in the electrical and mechanical cases dominating much of the court's earlier IPR jurisprudence. We also expect to see decisions interpreting the American Invents Act (AIA). For example, the Federal Circuit will decide whether only "public" sales are subject to the on-sale bar under the AIA.

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Jeff Vockrodt is a partner in Arent Fox's Intellectual Property group, where he focuses on global patent procurement and enforcement strategies, with an emphasis on chemical and pharmaceutical industries. He represents both patent owners and challengers in disputes involving a wide range of technologies, including semiconductors, medical devices, pharmaceuticals, biotechnology, and chemical processing. Jeff serves as lead counsel in inter partes review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB), and has substantial experience throughout all aspects of ex parte and inter partes reexaminations in addition to interference proceedings before that tribunal including appeals to the Court of Appeals for the Federal Circuit (CAFC).

Jeff is a registered patent attorney with a chemical engineering background. He served for four years as patent examiner before the United States Patent and Trademark Office and a law clerk in the United States International Trade Commission Office of Unfair Import Investigations before entering private practice.

Client Work

Recent matters include:

- Preparing and prosecuting patent applications with an emphasis on ensuring adequate protection vis-à-vis the product under development and known competitive threats taking into account recent developments in patent jurisprudence.
- Preparing patent and market exclusivity defense strategies involving portfolio development to fend off challenges by way of Abbreviated New Drug Applications (ANDAs); 505(b)(2), or New Drug Applications related to competing products.
- Negotiate and counsel client as to license agreements including issues with respect scope, duration and patent term issues.
- Counsel clients as to all issues related to patent term including patent term adjustment (PTA) and patent term extension (PTE) including filing related petitions the Patent Office or challenges in District Court.
- Defend company's patent portfolio and respond to questions about the portfolio by parties conducting due diligence as part of a financing round or prospective merger.
- Conduct due diligence, freedom-to-operate, validity and patentability analyses, and prepare formal legal opinions of counsel as to third-party patents and in connection with transactions including providing an opinion of counsel to underwriters as to the company's patent issues in an initial public offering and subsequent financing rounds.

Practices

Food, Drug, Medical Device & Agriculture

Intellectual Property

Life Sciences

Bar and Court Admissions

District of Columbia Bar

District of Maryland

US Patent and Trademark Office

Education

The George Washington University Law School, JD

University of Arizona, BS (Chemical Engineering)

- As lead counsel to a global medical device company, obtained PTAB decision invalidating all challenged claims of a competitor's patents through IPR in a decision affirmed by the CAFC.
- Served as counsel in several IPR and CBM proceedings on behalf of the patent owner and challenger from pre-investigation, filing of the petition, litigation before the PTAB, and appeal to the CAFC.
- Represented patent owners and challengers in inter partes reexamination proceedings (the predecessor of IPR) many of which were litigation-related and included complex Patent Office petitions. One of the inter partes reexaminations Jeff handled was relied on by the Patent Office in its rulemaking related to the PTAB proceedings, Office Patent Trial Practice Guide, In re Arviv, Control No. 95/001,526 (Petition Decision April 18, 2011).
- Represented patent owners and petitioners in ex parte reexamination proceedings in cases related to pending or threatened litigation.
- Served as counsel before the Interference Trial Section on several interference proceedings to determine the party first to invent or resolve inventorship disputes among competing entities. issued with claims covering commercially important subject matter.

Publications & Presentations

Recent publications:

- Co-author, Chemical & Life Sciences Year in Review, 2016
- "PTAB Markush Rejection Practice and What it Means for Biotech Applicants," Law360 (March 16, 2017)
- "3 Reasons Why Supreme Court Should Grant Cert in Critical Biotech Case" (April 26, 2016)
- "The Limitations and Advantage of IPR for Design Patents," Law360 (April 12, 2016)
- Quoted Source "Three years after its passage, the AIA has brought IPRs and CBMs in front of the USPTO" Inside Counsel Alphabet Soup, Ed Silverstein (Sept. 1, 2015)
- Four Takeaways from the Federal Circuit's First Inter Partes Review Decision, *In Re Cuozzo,* BNA Intellectual Property Technology and Law Journal (February 9, 2015)
- Co-Editor, *Inter Partes* Review Year in Review 2014
- "5 Things You Should Know About Post-Grant Review," Law360 (Sept. 19, 2014)
- Guest Lecturer on Post-Grant Proceedings, Georgetown University Advanced Patent Law Course (2014).
- Are the Board's Institution Decisions on § 315 Eligibility for *Inter Partes* Review Appealable? (April 1, 2014)

Recent presentations:

- Speaker, "Post-Grant Strategies: Inter Partes Review and Post-Grant Review," organized by Biomeridies and StartingBloch, Nimes, France (June 2015)
- Panelist, "Recent Trends in Patent Office Litigation before the Patent Trial and Appeal Board," Northern Virginia Technology Council, Tech Law and Procurement Committee Event (May 2015)
- Speaker, VIB (Flemish Biotech Institute)–US Patent One-Day Workshop, "Proceedings before the Patent Trial and Appeal Board" Sint-Martens-Latem, Belgium (November 2014)
- Keynote Speaker, "Trends for University Patent Monetization in the Post American Invents Act Era," VirginiaTech, College of Science Academy of Integrated Science's Science, Technology and Law Program (October 2014)

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Dr. Yelee Y. Kim specializes in the chemical, pharmaceutical, biotechnology, medical device, and software arts. Her practice consists primarily of patent prosecution, patent litigation, and client counseling.

Client Work

Yelee's patent prosecution experience includes drafting and prosecuting applications in the fields of chemicals, pharmaceuticals, biotechnology, software, and the mechanical arts. She regularly counsels companies in all aspects of intellectual property, such as patent procurement strategy, patent portfolio management, and trade secrets. Yelee works closely with domestic and international companies, from startups to large corporations, especially in the areas of medical devices, pharmaceuticals, nutraceuticals and dietary supplements, cosmetics, software, and sportswear. Yelee also has significant experience in the preparation of patent validity, freedom-to-operate, and non-infringement opinions; due-diligence analysis for patent licensing and corporate transactions; and various other patent counseling matters. Yelee has litigation experience in the areas of chemicals, computer science, and medical devices.

Previous Work

While attending law school, Yelee worked as a clinical pharmacist, utilizing her extensive knowledge in the areas of drug discovery, pharmaceutical chemistry, biotechnology, and the therapeutic application of pharmaceuticals. Prior to joining Arent Fox, Yelee was an associate at an intellectual property boutique in New York, where she focused on patent counseling and due diligence analysis in the biotechnology and pharmaceutical arts.

Publications & Presentations

Recent publications:

- Co-author, Chemical & Life Sciences Year in Review, 2016
- Co-author, "The Collection and Analysis of 2,3-Dimethyl-2,3-Dinitrobutane Vapor," *American Industrial Hygiene Association Journal* (1998)

Recent presentations:

- "Goodbye Seagate, Hello Halo: Effects of the Evolving Willfulness Standard on Life Sciences Patent Filings," 15th ACI Advanced Summit on Life Sciences Patents (February 2017)
- "Practical Strategies for Dealing with the Ever-Expanding Interpretation of Obviousness-Type Double Patenting," ACI Advanced Summit on Life Sciences Patents (January 2015)
- "Protecting Your Intellectual Property: Trade Secrets and Patents," Personal Care Products Council, Legal and Regulatory Meeting (May 2012)

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Alex Spiegler is a registered patent attorney whose practice focuses on all aspects of patent law. He has extensive experience with the US Patent & Trademark Office, specializing in patent prosecution and post-grant proceedings (e.g., *inter partes* reviews), in a wide variety of technologies, including biotechnology, agricultural technology, and pharmaceuticals. Alex also provides advice on claim construction, infringement and validity issues in litigation.

Client Work

Recent matters include:

- Prepare and prosecute patent applications in the biotechnology, agricultural, pharmaceutical, and chemical arts, including inventions related to plants, herbicides, fertilizers, nucleic acids, proteins, antibodies, diagnostics, methods of treatment, and chemical processes.
- Conduct due diligence, freedom-to-operate, validity and patentability analyses in the biotechnology, agricultural, chemical and pharmaceutical arts, and prepare formal legal opinions reflecting conclusions of such analyses. Served as IP opinion counsel to pharmaceutical company in IPO.
- Represent agricultural company in *inter partes* review involving herbicidal compositions.
- Represented lawn care company in litigation and patent office proceedings. Successfully obtained summary judgment on competitor's trade secret claim. Obtained favorable *Markman* ruling against competitors' patents, leading to dismissal of the patent infringement suit. Successfully provoked *inter partes* reviews and reexaminations against competitors' patents, and obtained decisions that competitors' patents are unpatentable.
- Represented inventor against reexamination of patent directed to methods for treating achondroplasia. Reexamination Certificate confirmed patentability of all original claims.
- Represented agricultural biotechnology company against reexamination of patent directed to methods of treating genetically modified plant with an herbicide. Reexamination Certificate issued with claims covering commercially important subject matter.
- Represented life sciences company with patents covering DNA sequencing technology. Obtained favorable *Markman* ruling.
- Represented life sciences company in patent office proceedings (interferences and reexaminations) relating to nucleic acid technology (e.g., sequencing, amplification).

Practices

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US Patent and Trademark Office

Education

Columbus School of Law at The Catholic University of America, JD

Rutgers University, BS (Biotechnology)

- Represented pharmaceutical company in a Hatch-Waxman litigation brought against it by owner of patents covering leading attention hyperactivity disorder drug.

Previous Work

Alex was an associate at an international law firm prior to joining Arent Fox. From 2000 to 2004, he was a Biotechnology Patent Examiner at the US Patent and Trademark Office.

Publications & Presentations

Recent publications:

- Co-author, Chemical & Life Sciences Year in Review, 2016
- Co-author, "3 Reasons Why Supreme Court Should Grant Cert in Critical Biotech Case," April 26, 2016
- Co-author, Pharmaceutical, Chemical and Biotech Year in Review, 2015
- Co-author, Thinking Twice About "Comprising," AIPLA's *Biotech Buzz*, June 2015
- Co-author, *Inter Partes* Review Year in Review, 2014
- Co-author, Pharmaceutical, Chemical and Biotech Year in Review, 2014
- Co-author, Pharmaceutical, Chemical and Biotech Year in Review, 2013
- Co-author, "Patent Reform Stalled by Tech and Pharma/Biotech Debate," Daily Business Review (2010)
- Co-author, "Recent Trends in Patent Practice: The Federal Circuit's Treatment of Pharmaceuticals," BNA Life Sciences Law & Industry (2007)

Recent presentations:

- "Intellectual Property in the United States," organized by StartingBloch, Montpellier, France (2016)
- "Intellectual Property in the United States," organized by Biomeridies and StartingBloch, Nimes, France (2015)
- "Subject Matter Eligibility of Biotech and Pharmaceutical Inventions," organized by Biomeridies and StartingBloch, Clapiers, France (2015)
- "Recent Developments in the Patent Office and Courts Affecting Life Sciences and Computer Patents in the United States," Flanders Institute for Biotechnology U.S. Patent Seminar, Gent, Belgium (2014)
- "Developments in Biotechnology, Chemical and Pharmaceutical Law," CLE Seminar, New York, NY (2012)
- "Legislative and Judicial Developments Affecting Patenting of Biotech Inventions in the United States," DeClerq & Partners IP Seminar, Sint-Martens-Latem, Belgium (2011)

Questions? Need More Info?

We have answers.

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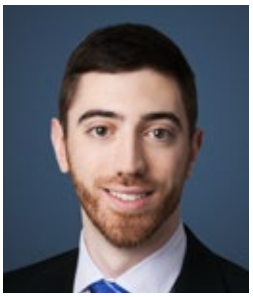

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