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This issue discusses the law of patent invalidity under 35 U.S.C. § 102, “anticipation.” In this month’s issue, we will look at how the “printed publication” requirement of § 102 has developed since we explored this topic in the inaugural issues of the *Federal Circuit Review*. We will discuss a recent case commenting on anticipation analysis in patent-by-process claims, and how claim construction impacts proper analysis of anticipation. We also will discuss recent cases that explore the relationship between the rules of anticipation and obviousness. Finally, we will examine cases elaborating on what elements a prior art reference must possess in order to anticipate a patent claim, including the arrangement of steps and the enablement of practicing the claimed invention.

THE “PRINTED PUBLICATION” REQUIREMENT: AN UPDATE

A patent claim is anticipated if every limitation of the claimed invention is found, expressly or inherently, in a single prior art reference. That reference must have been described in a “printed publication” in the U.S. or a foreign country prior to the patent applicant’s date of invention, or more than one year prior to the date of application in the U.S. In the September 2008 issue of the *Federal Circuit Review*, we discussed a line of decisions that have expanded the framework for determining when a work constitutes a “printed publication.” The test as set out in a 2004 decision, *In re Klopfenstein*, looks to 1. the length of time the reference was available, 2. the expertise of the target audience, 3. any reasonable expectations that the reference would or would not be copied, and 4. the ease with which the reference could be copied. See *In re Klopfenstein*, 380 F.3d 1345, 1350-52 (Fed. Cir. 2004). Because they are not media-specific, these four factors are suited to flex with emerging publication technologies. See, e.g., *SRI International, Inc. v. Internet Security Systems, Inc.*, 511 F.3d 1186 (Fed. Cir. 2008) (holding that paper published on an FTP site was not adequately accessible to the public to constitute a printed publication under § 102).

In a recent decision, the Federal Circuit has extended its reasoning in *Klopfenstein* to determine when and how documents filed with the U.S. Copyright Office become printed publications. See *In re Lister*, slip op. 2009-1060 (Fed. Cir. Sept. 22, 2009). Dr. Richard Lister claimed to have invented a method of playing golf featuring the use of tees for all

shots aside from play in hazard areas and greens. He described his method in a manuscript, which he submitted to the U.S. Copyright Office. After receiving a copyright registration certificate for the manuscript, Dr. Lister filed a patent application claiming his method of handicap play. *Id.* at 2. After years of prosecution Dr. Lister's application was rejected, in part because the trademark examiner found his claims anticipated by the disclosure of his method in the copyrighted manuscript. Dr. Lister unsuccessfully appealed the examiner's decision. *Id.* at 3. The Board of Patent Appeals affirmed that Dr. Lister's manuscript was publicly accessible, under the rule of *Klopfenstein*, because an interested researcher could have found it by searching for the terms "golf" and "handicap" in the Copyright Office catalogue, and could have obtained access to the manuscript by visiting the Library of Congress. *Id.* at 4.

Dr. Lister appealed to the Federal Circuit, arguing that the manuscript, despite being filed with the Copyright Office, was not sufficiently publicly accessible to an interested researcher to satisfy the printed publication requirement. First, he argued that the task of traveling to the Library of Congress was excessively burdensome. Second, he pointed to a lack of evidence that the manuscript was actually included in a proper index or catalogue before the critical date. *Id.* at 9.

Dr. Lister noted that reviewing the Copyright Office copy of the manuscript would require researchers to travel to Washington D.C., submit a formal request, and would then not entitle them to make any actual copies of the document. Further, he provided evidence that no one had ever requested to inspect the manuscript, demonstrating that it was effectively unavailable to the public. *Id.* at 9-10. The court quickly dismissed this argument. Access to the Copyright Office collection is freely available, and any required travel is irrelevant. Further, "cases have held that once accessibility is shown, it is unnecessary to show that anyone actually inspected the reference." *Id.* at 10. Finally, the court found that the technology involved was simple enough such that an interested researcher could "gain and retain" an understanding of the invention without needing to make a copy of the manuscript.

However, even though the manuscript was physically available, the printed publication requirement demands that concerned parties be able to *learn* of the manuscript's existence and potential relevance prior to the critical date. The record established that the manuscript was indexed in three databases: that of the Copyright Office, and commercial databases provided by Westlaw and Dialog. Dr. Lister argued that none of the databases indexed or catalogued the manuscript in a "meaningful way," as required by the case law. *Id.* at 12. Dr. Lister showed that the Copyright Office database can only be searched by the title of the work or the author's last name, and does not enable subject matter or keyword searching. *Id.* The U.S. Patent and Trademark Office ("USPTO") conceded that this catalogue alone would be insufficient to support a finding of public accessibility. *Id.* at 13.

Subject and keyword searching was available through the commercial databases, but Dr. Lister argued that an interested researcher would not have thought to search for "golf" and "handicap" when looking for pertinent art, because the term "handicap" was not found in his patent claims. The Federal Circuit disagreed, stating that diligent researchers would attempt "several searches using a variety of keyword combinations," including relevant colloquialisms like "handicap." *See id.* at 14.

The key question, then, was whether the manuscript was available in the commercial databases before the critical date. The USPTO argued that there was substantial evidence that this was the case: Dr. Lister's disclosed during patent prosecution that the information in the commercial databases came "directly" from the Library of Congress, which the USPTO interpreted to mean that the databases would have had displayed the information very shortly after the copyright had registered. The court found this insufficient. *Id.* at 15. Analogizing to paper and ink precedents, the court demanded proof comparable to "competent evidence of the general library practice" to specifically establish when the manuscript would appear online. *Id.* at 16. Without such proof, the USPTO failed to meet its burden in showing that the work was publicly accessible.

The inventor's victory before the Federal Circuit does not conclude the saga of his patent prosecution, which has now carried on for over thirteen years. But the *Lister* case posts several helpful markers for litigants evaluating the strength or weakness of a potential printed publication. In particular, the court has effectively established that Copyright Office records, without proof of additional access or distribution, are not "printed publications" for anticipation purposes. In such a fact-specific area of law, such clear boundaries are particularly helpful to both courts and litigants.

#### **Cases Referenced:**

*In re Klopfenstein*, 380 F.3d 1345 (Fed. Cir. 2004)

*In re Lister*, slip op. 2009-1060 (Fed. Cir. Sept. 22, 2009).

*SRI International, Inc. v. Internet Security Systems, Inc.*, 511 F.3d 1186 (Fed. Cir. 2008)

#### **PRODUCT-BY-PROCESS CLAIMS:**

##### **WHAT ANTICIPATES BEFORE MAY NOT NECESSARILY INFRINGE LATER**

The Federal Circuit recently issued an opinion in a long-running dispute over Amgen's erythropoietin ("EPO") biologic drug products Epogen and Aranesp. *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, slip op. 2009-1020, -1096 (Fed. Cir. Sept. 15, 2009). In *Amgen*, both parties appealed portions of a district court decision evaluating infringement and validity of five Amgen patents relating to the production of EPO, a protein that is useful in treating anemia and related diseases. Amgen's patented processes can create EPO from a culture of mammalian cells using recombinant DNA technology. *Id.* at 4. Roche planned to import its longer-lasting variation on EPO into the U.S., and Amgen sued for declaratory judgment of infringement. *Id.* at 7. Roche asserted that Amgen's patents were invalid or not infringed, in part due to the alleged anticipation of several claims. Roche relied upon the work and prior art publications of a clinician, Dr. Eugene Goldwasser, who had attempted to treat anemic patients with EPO isolated from human urine. After the time period of Dr. Goldwasser's research, Amgen's scientists discovered how to produce EPO by transfecting host hamster ovary cells with portions of the human EPO DNA sequence. *Id.* at 3-4.

Roche asserted that at least some of the EPO produced using the recombinant DNA method of Amgen's patents was identical to the EPO disclosed by Dr. Goldwasser. Although Amgen's claims included a new process for obtaining the EPO, Roche argued that the source limitations failed to impart a novel structure

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to the known EPO substance. *Id.* at 39. Amgen argued that the EPO produced through its patented process was structurally and functionally distinct from that produced by Dr. Goldwasser, and thus not anticipated. *Id.* Amgen prevailed before the district court. *Id.* at 8.

On appeal, Roche argued that Amgen's product-by-process claims essentially taught the creation of an old product (EPO) by a novel process (using recombinant DNA). *See id.* at 40. There is extensive precedent that an old product is not patentable even if it is made by a new process. *Id.* at 41 (citing cases). However, the Federal Circuit respected the district court's credence of Amgen's experts, who testified that the claimed EPO differed at the molecular level from the EPO in the prior art.

Beyond the facts of the case, however, the Federal Circuit opined on a more general issue of anticipation analysis with respect to product-by-process claims. Roche claimed that the court erred in holding that Amgen's claimed process limitations gave its EPO a novel structure, while not requiring Amgen to show whether Roche's accused product possessed such novel structure in order to infringe. Roche argued that "without the requirement to prove that recombination imparted novel structures to Amgen's EPO, urinary EPO anticipates recombinant EPO as a matter of law." *Id.* at 47.

The Federal Circuit was not persuaded. A product-by-process claim may be anticipated by a prior art product even if it is not produced in the same way as the claimed invention, because for validity analysis "the focus is on the product and not the process of making it." *Id.* With respect to infringement, however, "the focus is on the process of making the product as much as it is on the product itself." *Id.* at 48. Product-by-process claims thus allow exceptions to the rule that a product that would infringe an issued patent would necessarily anticipate the same patent if published more than a year before that patent's filing date. The court explained that this is because "a product in the prior art made by a different process can anticipate a product-by-process claim, but an accused product made by a different process cannot infringe a product-by-process claim." Therefore, because the recombinant DNA process created a novel type of EPO, the claims were not anticipated, and because Roche made its product using recombinant DNA technology, the claims were infringed.

### Case Referenced:

*Amgen Inc. v. F. Hoffman-La Roche Ltd.*, slip op. 2009-1020, -1096 (Fed. Cir. Sept. 15, 2009)

## CONSTRUING THE PRIOR ART

To determine if claim limitations are anticipated, the trier of fact must have a clear understanding of what those claim limitations actually are. Therefore, anticipation analysis must be predicated on some construction of the claimed invention that can be compared with the prior art. A recent decision, *In re Robert Skvorecz*, illustrates the risks of a faulty claim construction in the anticipation context. *See* 2008-1221, slip op. (Fed. Cir. Sept. 3, 2009).

Robert Skvorecz's invented a wire chafing stand designed not to stick to other stands when nested together. He accomplished this by adding an offset to the wire legs of the stand, such that the legs were



laterally indented close to where each leg met the rim of the stand. During patent prosecution, he claimed (in part) “[a] wire chafing stand comprising a first rim of wire steel . . .” and went on to describe the configuration of the wire legs and lateral offsets found on each leg. The examiner rejected this claim as anticipated by a prior patent on a similar wire stand that included claims to “a plurality of offsets . . . welded to said wire legs at the separation of the upright sections into segments.” *Id.* at 5. Skvorecz appealed, arguing that his claims required each wire leg to have a laterally displacing offset, a limitation not found in the prior art. The Board of Patent Appeals affirmed the examiner’s decision.

Before the Federal Circuit, the PTO argued that Skvorecz’s invention was anticipated because it could be construed to include wire legs *without* offsets, because the key claim used the word “comprising.” *Id.* at 7. Therefore, “because the signal ‘comprising’ is open-ended, not every wire leg is required by claim 1 to include offsets.” *Id.* The Federal Circuit dismissed this theory: “[t]he signal ‘comprising’ does not render a claim anticipated by a device that contains less (rather than more) than what is claimed.” *Id.* at 8. The PTO incorrectly interpreted “comprising” to mean that not all of the legs of the Skvorecz needed to have offsets, even though the claim when read as a whole confirmed that was not the case. Because “[a]nticipation cannot be found, as a matter of law, if any claimed element or limitation is not present in the reference,” the Federal Circuit reversed the rejection. *Id.* at 9. This case illustrates how contesting claim construction may be a useful way to ward off a rejection on anticipation grounds.

#### **Case Referenced:**

*In re Robert Skvorecz*, slip op. 2008-1221 (Fed. Cir. Sept. 3, 2009)

#### ANTICIPATION: THE “EPITOME OF OBVIOUSNESS”?

Anticipation sets a high threshold—that each and every limitation of a claim be found within the four corners of a single document. Obviousness may be proved by combining multiple prior art references and drawing connections between them. It seems logical that prior art that anticipates a claim also should render that claim obvious to a person of ordinary skill in the art. However, a recent Federal Circuit decision teaches that a claim may be found nonobvious, and yet be anticipated.

*In Cohesive Technologies, Inc. v. Waters Corporation*, 543 F.3d 1351 (Fed. Cir. 2008), the court provided guidance on strategically using anticipation and obviousness contentions. Plaintiff Cohesive alleged that Waters’ products infringed two of its patents. *Id.* at 1358. During the subsequent jury trial, Waters presented evidence that certain disputed claims were anticipated by seven prior art references. *Id.* at 1358-59. Waters also alleged that the same claims were obvious, in light of each of the seven references independently, and taken in combination. *Id.* at 1359.

After reviewing the evidence, the district court concluded that Waters’ anticipation case was “iffy,” and that “declining to charge on anticipation would not cause ‘any real harm to the defendant,’ and would not ‘make very much difference because it comes in in obviousness’” [sic]. *Id.* The court entered a directed verdict, finding the patent not anticipated. The jury subsequently found the patent

claims nonobvious and infringed by Waters' product. *Id.* After further litigation on other issues, both parties appealed portions of the district court decision. Waters appealed the court's judgment on anticipation. *Id.*

On appeal, the Federal Circuit took the opportunity to elaborate on the overlap between anticipation and obviousness. "Despite the often quoted maxim that anticipation is the 'epitome of obviousness' . . . novelty under 35 U.S.C. § 102 and nonobviousness under 35 U.S.C. § 103 are separate conditions of patentability and therefore separate defenses available in an infringement action." *Id.* (citing *In re Kalm*, 378 F.2d 959, 962 (C.C.P.A. 1967)).

Anticipation requires all elements of a claim to be found within a single reference. By contrast, an obviousness defense relies on a hypothetical scenario in which all of the relevant prior art is immediately available, and may be interpreted and combined as a skilled artisan would think to do. As set forth by the Supreme Court in *Graham v. John Deere Co.*, the trier must assess (1) the scope of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art and (4) secondary indicia of nonobviousness). See 383 U.S. 1, 17-18 (1966). While obviousness is grounded in these factual considerations, the final determination is a question of law. In *Cohesive Technologies*, the Federal Circuit pointed out that an anticipated claim could still be nonobvious when secondary considerations are taken into account. See *Cohesive Technologies*, 543 F.3d at 1364.

Anticipation may be proven inherently when "a limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure in the prior art." *Schering Corp. v. Geneva Pharmaceuticals, Inc. et al.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). While inherent anticipation requires the fact finder to look beyond the unambiguous text of a reference, it is not a determination about whether the reference makes the invention obviousness. Importantly, inherent anticipation does not require a skilled artisan to recognize the inherent characteristics in the prior art that anticipate the claimed invention. *Id.* at 1377. Therefore, a claim that is technically anticipated may not have been obvious at the time of filing. See *Cohesive Technologies*, 543 F.3d at 1364.

To illustrate these points, the Federal Circuit gave an example of a claim directed to a particular metal alloy.

The claimed metal alloy may have all the hallmarks of a nonobvious invention--there was long felt but unresolved need for an alloy with the properties of the claimed alloy, others may have tried and failed to produce such an alloy, and, once disclosed, the claimed alloy may have received high praise and seen commercial success. Nevertheless, there may be a centuries-old alchemy textbook that, while not describing any metal alloys, describes a method that, if practiced precisely, actually produces the claimed alloy. While the prior art alchemy textbook inherently anticipates the claim under § 102, the claim may not be said to be obvious under § 103.

*Id.* at 1364 n.2.

In dissent, Judge Mayer disputed the wisdom of the majority's decision: "[a]lthough a claimed invention can be obvious but not anticipated, it 'cannot have been anticipated and not have been obvious.'" *Id.* at 1376 (emphasis in original) (citing *In re Fracalossi*, 681 F.2d 792, 794 (C.C.P.A. 1982)). Resting on the court's precedents for the statement that "anticipation is the epitome of obviousness," Judge Mayer described the majority's approach as a "fallacy." *Id.*

The majority, however, ultimately rebuked the district court, stating that it "is for the litigants--not the court--to make the strategic decision as to whether to assert one, both, or neither of these defenses in a jury trial." *Id.* at 1365. Notably, while a district court's findings on obviousness are reviewed *de novo* on appeal, a jury's verdict on anticipation is reviewed with greater deference. Therefore, it is important that defendants and their attorneys, particularly in jury trials, study this distinction and strategize accordingly to maximize the opportunity to persuade the trial court and prepare for an appeal.

#### **Cases Referenced:**

*Cohesive Technologies, Inc. v. Waters Corporation*, 543 F.3d 1351 (Fed. Cir. 2008)

*Graham v. John Deere Co.*, 383 U.S. 1 (1966)

*In re Fracalossi*, 681 F.2d 792 (C.C.P.A. 1982)

*In re Kalm*, 378 F.2d 959 (C.C.P.A. 1967)

*Schering Corp. v. Geneva Pharmaceuticals, Inc. et al.*, 339 F.3d 1373 (Fed. Cir. 2003)

#### ARRANGEMENT OF LIMITATIONS: *NET MONEYIN* V. *VERISIGN*

The Federal Circuit also recently clarified the requirements for an anticipatory prior art reference in *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008).

Net MoneyIN (NMI) held two patents for automated credit card payment systems suitable for Internet use. Earlier systems for online payment processing required customers to forward private payment information directly to an unknown merchant, and subjected merchants to high credit card company fees. NMI's payment models used a new way of routing these transactions between customers, merchants and banks. *See id.* at 1363.

NMI sued VeriSign and other credit card processors for infringing its patented payment processing methods. *Id.* at 1364. The defendants claimed that both patents in suit were anticipated, asserting a reference that explained two protocols for enabling Internet-based secure electronic payments. *Id.* Each of the steps, or "links," claimed in NMI's method could be found in one of the two protocols described in the prior art reference, although neither protocol disclosed all of the links. The district court concluded that although "no specific example within [the reference] contains all five links," the reference was anticipatory. *Id.* at 1369.

On appeal, NMI argued that the district court's combination of the two protocols within the single reference was improper. The Federal Circuit focused on the arrangement of the steps taught in the prior art reference. Anticipation requires that a single prior art document disclose every element of a claimed invention, but this rule "does not tell the whole story." *Id.* To anticipate, the reference also must teach all of the limitations "arranged or combined in the same way as recited in the claim." *Id.* at 1370. This is clearly of import when ingredients must be mixed stepwise in a claimed procedure. But the Federal Circuit's holding is relevant for all claims because it "refers to the need for an anticipatory reference to show all of the limitations of the claims arranged or combined in the same way as recited in the claims, not merely in a particular order." *Id.*

It followed, then, that the prior art reference asserted by the defendants was not anticipatory, because it did not disclose each of the claimed elements combined within a single protocol. Although the prior art and the claimed system were very similar, "differences between the prior art reference and a claimed invention, however slight, invoke the question of obviousness, not anticipation." *Id.* at 1371.

The *Net MoneyIN* decision confirms the challenge of obtaining an anticipation rejection. However, litigants may assert an obviousness defense relying on a single reference, and may be more inclined to do so in the wake of this decision. It is also important to note that although the Federal Circuit takes the arrangement requirement seriously, it has subsequently confirmed that a reference need not "satisfy an *ipsissimus verbis* test" (i.e., state word-for-word) in order to anticipate. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (discussed below). Anticipation is a question of fact, and adversaries may dispute how a person of ordinary skill in the art would have interpreted a piece of prior art, including the extent to which a reader would have cross-referenced separate sections of an article or patent.

For example, in *Ortho-McNeil Pharmaceutical, Inc. v. Teva Pharmaceuticals Industries, Ltd.*, the parties disagreed as to whether the teachings of two working examples within the same reference could be applied together. See Slip Op. 2008-1549, -1550 (Fed. Cir. Aug. 26, 2009). The claim in question taught a mixture of the pain medications tramadol and acetaminophen at a particular ratio. The defendants pointed out that one example of a prior art patent taught that tramadol may be administered in a 25 mg or 50 mg dose. A second example of the same patent taught 25 mg of tramadol in combination with acetaminophen. Defendants argued that using the combination of the second example, but substituting the 50 mg of tramadol from the first example, would fit the ratio limitation of the disputed claim. The patentee countered that the dosing ranges of the first example pertained to tramadol alone, and did not teach using the same doses in combination with other drugs, so that the examples in the prior art reference did not anticipate.

The Federal Circuit found that these considerations amounted to a dispute of a genuine issue of material fact, and as such could not be disposed of on summary judgment before trial. The parties disputed how the prior art patent's teachings about variable dosing would apply to its teachings about multi-drug combinations, and as to how a skilled artisan would read the lessons of one example into another. Defendants asserting an anticipation defense with complex prior art should work closely with experts to determine all possible interpretations of the reference as a whole in order to prevent an unwanted summary judgment motion.



## Cases Referenced:

*In re Gleave*, 560 F.3d 1331 (Fed. Cir. 2009)

*Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008)

*Ortho-McNeil Pharma., Inc. v. Teva Pharms. Inds., Ltd.*, Slip Op. 2008-1549, -1550 (Fed. Cir. Aug. 26, 2009)

## DESCRIPTION AND ENABLEMENT IN ANTICIPATING REFERENCES

As previously discussed, an anticipating reference must disclose each element of the claimed invention, either expressly or inherently. Additionally, per the *Net MoneyIN* decision, the elements must be arranged or combined in the same way as in the claim. Finally, the prior art reference must enable a person of ordinary skill in the art to make the invention without undue experimentation. See *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008). A sufficiently enabling anticipatory reference must put the invention “in the possession” of the person of ordinary skill in the art. See *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1315 (Fed. Cir. 2008). The reference will not satisfy this test if it requires “undue experimentation” to lead the skilled artisan to the result.

The standard of enablement required of an anticipatory reference is different from the statutory enablement standard for claims during prosecution. Under 35 U.S.C. § 112, a patent specification must contain a written description of the invention sufficient to enable any person skilled in the art to make and use it. “Claim-supporting disclosures” under § 112 can be distinguished from “claim-anticipating disclosures” under § 102, because patentees should be held to a high standard to earn their limited monopolies. The description in an anticipating reference might not entitle its author to a patent, even if it could allow a person of skill in the art to practice the invention. As the Court of Claims and Patent Appeals indicated in *In re Lukach*, “the description of a single embodiment of broadly claimed subject matter constitutes a description of the invention for anticipation purposes . . . whereas the same information in a specification might not alone be enough to provide a description of that invention for purposes of adequate disclosure.” 442 F.2d 967, 970 (C.C.P.A. 1971).

The Federal Circuit recently addressed the enablement requirement of an anticipatory reference in *In re Gleave*, 560 F.3d 1331 (Fed. Cir. 2009). Inventor Gleave appealed from a decision of the Board of Patent Appeals and Interferences rejecting his patent application as anticipated. Gleave’s application claimed a type of polymer believed to be useful in treating endocrine-regulated cancers, called an antisense oligodeoxynucleotide, that could bind to and halt the translation of mRNA in certain proteins. *Id.* at 1333.

The patent examiner rejected Gleave’s claims over a prior art reference listing over 1,400 sequences of oligodeoxynucleotides. *Id.* at 1333-34. On appeal, the Federal Circuit was asked to determine whether the expansive reference could anticipate Gleave’s specific sequences, which had particular properties. *Id.* at 1334.

Gleave argued that the prior art reference failed to anticipate his invention because it did not describe any particular individual species, but merely gave the public “ink, formed into strings of letters, without inventive thought and without placing the public in possession of anything new. There is no guidance to make particular selections, and no understanding of which of the targets would be useful, and what the properties of the related antisense would be.” *Id.* at 1335.

The court explained that enablement in anticipation requires that a person of ordinary skill be able to make and use the invention based on the disclosure, *i.e.*, to make or to use based upon the type of claim at issue. “This does not mean, however, that the prior art reference must demonstrate the invention’s *utility.*” *Id.* (emphasis in original). For example, when the claimed invention is a method of treating a disease, “a prior art reference need not disclose ‘proof of efficacy’ to anticipate the claim.” *Id.* (citing *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d at 1315 (Fed. Cir. 2008)). Gleave’s key claims pertained to compositions of matter. Therefore, an anticipatory reference could satisfy the enablement requirement of § 102 merely by showing that a skilled artisan could make the sequences disclosed in the prior art. The fact that the prior art wouldn’t necessarily inspire one to single out the key sequence is irrelevant. *Id.* at 1336.

Gleave pointed out that none of the sequences listed in the prior art were shown to have the desired activity that would make them attractive for pharmaceutical uses. Gleave’s patent claimed an “oligodeoxynucleotide . . . of sufficient length to act as an antisense inhibitor” of a particular protein. *Id.* The court, however, pointed out that Gleave did not claim that the composition actually worked for its intended purpose. Therefore, “where the claims themselves do not require a particular activity, we have no call to require something more from the anticipating reference.” *Id.*

The court concluded that Gleave had, at best, discovered only a new use for the compounds. The prior art reference was anticipating, even though it may have failed to describe the key compounds with the rigor that was required of Gleave in his patent application. This more generous understanding of what it means for a document to speak to a person of ordinary skill is important to keep in mind in evaluating a possibly anticipatory document.

### **Cases Referenced:**

*Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323 (Fed. Cir. 2008)

*In re Gleave*, 560 F.3d 1331 (Fed. Cir. 2009)

*Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312 (Fed. Cir. 2008)

*In re Lukach*, 442 F.2d 967 (C.C.P.A. 1971)



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