

Novelty and Statutory Bars

§ 2:1 **Amgen, Inc. v. F. Hoffman-La Roche Ltd.**

A new product may be patented by reciting source or process limitations so long as the product is new and unobvious.

In *Amgen, Inc. v. F. Hoffman-La Roche Ltd.*,¹ Amgen's five patents-in-suit were drawn to the production of the erythropoietin (EPO) using recombinant deoxyribonucleic acid (DNA) technology. Amgen alleged that Roche's product, MIRCERA, would infringe Amgen's five patents if imported into the United States.

EPO is a naturally occurring protein (or polypeptide) that stimulates production of red blood cells, and is useful in treating anemia. In a clinical study performed in 1979–80, Dr. Eugene Goldwasser had attempted to treat anemic patients with EPO isolated from human urine. He had limited success because the EPO recovered from urine had a low yield and high impurity, and was unstable. Amgen researchers developed a way of producing usable amounts of EPO via recombinant DNA technology.

Roche contended that claim 1 of one of the patents-in-suit (patent A), and claims 3, 7, and 8 of a second patent-in-suit (patent B) were anticipated by the EPO purified from urine by Dr. Goldwasser. The Federal Circuit disagreed.

Claim 1 of patent A provided:

A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is purified from mammalian cells grown in culture.

1. *Amgen, Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009) (opinion by Circuit Judge Schall, joined by Circuit Judges Mayer and Cleverger).

At trial, the district court granted Amgen JMOL of no anticipation, concluding that claim 1 required EPO to be “purified from mammalian cells grown in culture.” On appeal, the Federal Circuit agreed.

Roche, relying on a statement in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*,² that “a claimed product shown to be present in the prior art cannot be rendered patentable solely by the addition of source or process limitations,” argued that claim 1 was not patentable based on the addition of the source limitation (“purified from mammalian cells grown in culture”) because the EPO recited in claim 1 was the same as urinary EPO. Roche argued that, even though Dr. Goldwasser’s EPO was purified from urine, it anticipated claim 1 because the “purified from mammalian cells grown in culture” source limitation failed to impart novel structure onto EPO.

The Federal Circuit, however, without directly addressing its earlier statement, concluded that “a new product may be patented by reciting source or process limitations so long as the product is new and unobvious.”³ According to the court, the issue was whether the production of EPO by recombinant technology resulted in a new product, so that claim 1 was not anticipated by the urinary EPO of Dr. Goldwasser, that is, whether the source limitation “purified from mammalian cells grown in culture” distinguished recombinant EPO from Dr. Goldwasser’s urinary EPO.”⁴ The Federal Circuit concluded that it did.

The Federal Circuit pointed to the specification and prosecution history of patent A that referred to studies indicating that recombinant EPO had a higher molecular weight and a different charge than urinary EPO, a declaration in the prosecution history explaining that recombinant EPO could be distinguished from urinary EPO based on its carbohydrate content, and trial testimony regarding differences in the carbohydrate composition of recombinant EPO and urinary EPO.

2. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 n.20 (Fed. Cir. 2003).

3. *Amgen*, 580 F.3d at 1366.

4. *Id.* at 1367.

§ 2:2 Callaway Golf Co. v. Acushnet Co.

To incorporate matter by reference, a host document must contain language clearly identifying the subject matter which is incorporated and where it is to be found.

In *Callaway Golf Co. v. Acushnet Co.*,⁵ Callaway owned four “Sullivan patents” drawn to a particular golf ball construction. The claimed golf balls had a core, a first or inner layer preferably made from a blend of low-acid ionomer resins, and a second or outer layer made of a relatively soft polyurethane material.

Typically, golf balls designed to travel long distances were relatively hard. On the other hand, golf balls designed for other shots, such as spin control for approach shots, or having a proper “click” and “feel,” were usually softer. The golf balls of the Sullivan patents were intended to have a “dual personality,” that is, capable of long distance shots, while retaining “playability” or “durability.”

Although the asserted claims varied, each called for a golf ball with (1) a core, (2) an ionomer resin (or ionomer blend) inner cover layer with a Shore D hardness of 60 or more, and (3) a polyurethane outer cover layer with a Shore D hardness of 64 or less. “Shore D hardness” referred to a hardness standard published by the American Society for Testing and Materials.

The parties disputed whether “cover layer having a Shore D hardness” required measuring hardness (1) on the ball, or (2) off the ball, for example, on a sample material. There was testimony that hardness could be affected by material under the layer. The district court held that the limitation required measurements “on the ball.” As a result, Acushnet stipulated that its accused balls infringed at least some of the asserted claims. The Federal Circuit, on appeal, agreed with that construction.

Acushnet argued, however, that the asserted claims were invalid for anticipation and/or obviousness. With respect to anticipation, Acushnet urged that the asserted claims were anticipated by a patent to

5. *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331 (Fed. Cir. 2009) (opinion by Circuit Judge Dyk, joined by Circuit Judges Linn and Prost).

Nesbitt that disclosed all of the claim limitations except for (1) a polyurethane outer cover and (2) a blend of ionomers in the inner cover. Callaway apparently did not contend otherwise. Acushnet argued that Nesbitt incorporated by reference another patent—Molitor—that taught both polyurethane and ionomer blends as cover materials and, Acushnet argued, inherently disclosed the necessary hardness limitations for those cover layers.

Acushnet, in support of its anticipation argument, prepared test golf balls combining the polyurethane outer cover described by Molitor with the core and ionomer-blend inner cover of Nesbitt and proffered measurements of the resulting balls. Acushnet provided the same in a motion for summary judgment of invalidity. Callaway filed a cross-motion for summary judgment arguing that (1) Nesbitt did not incorporate Molitor by reference, and (2) Nesbitt thus failed to disclose the necessary Shore D hardness limitation.

The district court granted Callaway's motion for summary judgment that Nesbitt did not anticipate as a matter of law because Nesbitt did not describe use of polyurethane or blends of ionomer resins in Molitor with sufficient particularity to effectuate an incorporation by reference of those features. On appeal, the Federal Circuit reversed.

Regarding obviousness, Acushnet contended that various claim limitations were disclosed in the prior art. A jury returned a verdict that dependent claim 5 of one of the patents-in-suit was invalid for obviousness, but the remaining eight asserted claims, including claim 4 from which claim 5 depended, were not invalid. The district court nevertheless entered judgment on the jury's verdict. On appeal, the Federal Circuit held that the jury's verdict on obviousness was irreconcilable, and required a new trial.

Regarding anticipation, the Federal Circuit reiterated that a patent claim is invalid for anticipation if, within the "four corners of a single, prior art document," every element of the claimed invention is described expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation. That includes, the Federal Circuit explained, material not explicitly contained in the single, prior art document if that material is incorporated by reference into the document.

The Federal Circuit further reiterated that whether material was incorporated was a question of law and that to incorporate matter by

reference, a host document must contain language clearly identifying the subject matter incorporated and its location. In other words, the Federal Circuit explained, the host document must identify with “detailed particularity” what specific material it incorporates and clearly indicate where that material is found in the various documents.

The Federal Circuit concluded that the Nesbitt reference properly incorporated by reference the Molitor reference by identifying with specificity both the material being incorporated by reference (foamable polymeric compositions suitable for golf ball cover layers) and where it could be found (the Molitor patent).

The district court, however, had held that Nesbitt satisfied the requirements for incorporation only with regard to the ionomer resins disclosed in Molitor, not polyurethane. The Federal Circuit disagreed, reasoning that although Molitor stated that ionomer resins were preferable, Nesbitt’s reference to Molitor was not limited to those resins.

That alone, of course, was sufficient to reverse the district court’s grant of summary judgment. However, the Federal Circuit additionally addressed the district court’s exclusion of evidence regarding the “test ball.” Although the issue of anticipation was not tried to the jury, Acushnet had proffered such evidence in connection with its obviousness argument. The district court in deciding summary judgment had refused to consider the test ball evidence on the issue of anticipation in light of its holding that Nesbitt did not incorporate the Molitor reference.

The district court had also excluded the test ball evidence at trial to prevent the jury from giving undue weight to Acushnet’s arguments *vis-à-vis* motivation to combine and obviousness. On appeal, the Federal Circuit affirmed the district court’s decision *vis-à-vis* obviousness, but reached a different conclusion *vis-à-vis* anticipation. The Federal Circuit reasoned that the district court’s refusal to allow the test ball evidence at trial was inapplicable to Acushnet’s anticipation argument, where motivation to combine was not an issue.

The Federal Circuit also noted that the district court had excluded testimony from Acushnet’s expert on the ground that he had not been involved in the preparation and testing of the test balls. Although the Federal Circuit concluded that there was no error in excluding that testimony *vis-à-vis* the obviousness issue, the Federal Circuit noted that in light of other authenticating testimony, the district court could consider that evidence on remand.

§ 2:3 Clock Spring, L.P. v. Wrapmaster, Inc.

A use may be experimental only if it is designed (1) to test claimed features of the invention or (2) to determine whether an invention will work for its intended purpose— itself a requirement of patentability. Durability testing under City of Elizabeth is limited to testing to allow filing of a patent application, not to satisfy industry requirements.

In *Clock Spring, L.P. v. Wrapmaster, Inc.*,⁶ the Federal Circuit further narrowed “experimental use” negation of the “in public use” bar. Clock Spring’s patent-in-suit was drawn to methods for repairing damaged high-pressure gas pipes, which involved cleaning the surface of the pipeline, applying a filler material to fill in any pits, gauges or dents (the filler material had a “pasty fluid consistency” which thereafter cured to a rigid state), applying a layer of adhesive, while the filler material and adhesive were both in their uncured states, installing a reinforcement band around the outer surface of pipe over the defective region to form a coil, tightening convolutions of the coil until the innermost convolution of the coil was in contact with the outer surface of the pipe to remove any void spaces, and placing one or more strips of tape around the coil to hold the coil in place until the adhesive cured. According to the Federal Circuit, the “main distinctive feature over the prior art” was wrapping the pipe while the filler was in an uncured state to provide smooth and continuous contact between the wrap and the pipe.

Clock Spring sued Wrapmaster for infringement as well as for a claim under the Lanham Act. Wrapmaster moved for summary judgment, inter alia, asserting that all claims of the patent-in-suit were invalid based on (1) an alleged prior public use under section 102(b) in October 1989 in Cuero, Texas, more than one year before the filing date in 1992, and (2) obviousness based on seven patents, all issued to the same inventor as the patent-in-suit—Fawley.

6. *Clock Spring, L.P. v. Wrapmaster, Inc.*, 560 F.3d 1317 (Fed. Cir. 2009) (opinion by Circuit Judge Dyk, joined by Circuit Judge Bryson and District Judge Patel, United States District Court for the Northern District of California, sitting by designation).

With respect to the alleged prior “public use,” Wrapmaster relied on a 1994 Gas Research Institute (GRI) report regarding a demonstration made by Fawley. GRI was a nonprofit research and development organization which was entitled to receive royalty payments from Clock Spring on the patent-in-suit.

Clock Spring did not dispute that the 1989 demonstration was public, or that it involved the limitations of the patent-in-suit, except that Clock Spring urged that the 1989 demonstration had not involved the application of the wrap with an uncured filler. Clock Spring also urged that the use fell within the scope of “experimental use.” A magistrate judge recommended that the district court grant summary judgment of invalidity based both on the alleged “in public use” and obviousness in light of two of the seven asserted patents. With respect to the “in public use” issue, the magistrate judge concluded that the 1994 GRI report showed that the filler was uncured when applied to the pipe, and that the use was not “experimental.”

On review by the district court, Clock Spring urged that the 1989 demonstration lacked three limitations of the claims, namely the uncured state limitation, the requirement that the pipe have a “cavity,” and the requirement that the “filler” be applied to the “cavity.” Clock Spring also submitted additional evidence in support of its “experimental use” argument, namely additional GRI reports (some of which mentioned the 1989 demonstration) and a twenty-eight-page report by NCF Industries, Inc. concerning the 1989 demonstration. Fawley was president of NCF Industries, Inc.

The district court concluded that Clock Spring had raised a fact issue *vis-à-vis* “experimental use,” and thus rejected the magistrate judge’s recommendation on the “in public use” issue. The district court, however, agreed with the magistrate judge’s recommendation on obviousness, and accordingly granted summary judgment of invalidity. The district court also granted summary judgment on the Lanham Act claim. On appeal, the Federal Circuit did not discuss the obviousness issue. Rather, the court concluded that the prior “public use” invalidated the claims.

The Federal Circuit noted that there was no dispute that the 1989 demonstration was “public.” Second, there was no dispute that the demonstration involved all limitations of claim 1, except (1) “defined by at least one cavity extending from an outer surface of said pipe toward the center of said pipe” be involved; (2) that “filler material” be

used to fill the “cavity”; and (3) that the pipe be wrapped while the filler material was in an “uncured state.”

The Federal Circuit concluded that photograph captions in the NCF report showed that the demonstration met the “cavity” limitation. The court also concluded that although the report did not expressly mention using a filler, the same would have been obvious, especially in view a disclosure in the NCF report that the filler compound was intended to be “used to fill in pitted areas of pipe corrosion,” and that the purpose was to demonstrate a method of “spot repair” of pipelines.

The Federal Circuit further concluded that the 1989 demonstration involved uncured filler, replying on an IDS filed during prosecution of the patent-in-suit stating “[e]mployees of Texas Eastern then installed the CLOCK SPRING bands around the pipeline before the filler material had cured to a rigid state.” According to the Federal Circuit, the 1994 GRI report also described the process as involving filler in an uncured state. The court found further support for that conclusion in the NCF report because of the short time (three minutes) elapsed between application of the filler and adhesive, and wrapping with a coil. The compound used required an hour to cure.

With respect to “experimental use,” the Federal Circuit explained that the doctrine was not separate or apart from the public use bar, but public use may not be invalidating if it qualified as an experimental use. The court noted that *Allen Engineering Corp. v. Bartell Industries, Inc.*⁷ listed some of the relevant factors, and although *Allen Engineering* involved a prior commercial sale and not a prior public use, the factors were “equally relevant” to the experimental use analysis.

On the factor of control by the inventor, the Federal Circuit found that there was no evidence that Fawley had controlled the demonstration. However, the court expressly did not rely on Fawley’s lack of control. Rather, the court concluded that the demonstration could not qualify as “experimental use.”

The court emphasized that a use was experimental only if designed (1) to test claimed features of the invention or (2) to determine whether an invention would work for its intended purpose. In other

7. *Allen Eng’g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1353 (Fed. Cir. 2002).

words, the Federal Circuit explained, an invention may not be ready for patenting if claimed features or overall workability were being tested. But there would be no experimental use unless claimed features or overall workability were being tested for purposes of the filing of a patent application.

According to the Federal Circuit, Clock Spring did not argue that the 1989 demonstration was directed to refining features that were part of the claim limitations, but rather argued that the demonstration was to test durability. The court was not persuaded.

In particular, the court wrote that the NCF report described the purpose of the demonstration as showing to Panhandle Eastern attendants and guests the steps of application and the ability of minimally trained crews to make Clock Spring installations. The 1994 GRI report stated that “the demonstration was designed to familiarize pipeline personnel with the Clock Spring technology, and to begin training of maintenance personnel in the use of the coil pass installation method.” During prosecution, the applicant stated that the purpose of the demonstration was to seek “input from people in the industry on the performance of the bands and the practicality of their installation techniques.”

The Federal Circuit noted that the 1994 GRI report could be read as suggesting that the 1989 demonstration was for durability testing because it stated that “recovery and analysis of installed composite after several years of exposure in pipeline settings was the only means of verifying the long-term performance of [the clock spring’s] composites in moist soils.”

Nevertheless, according to the Federal Circuit, no report in the record suggested that the 1989 demonstration was designed to test durability for the purposes of the patent application to the PTO. Rather, the reports made clear that the durability testing was for “acceptance by regulators and the pipeline industry,” and that the 1989 installation was not dug up and examined until almost a year after the 1992 patent application was filed.

The Federal Circuit reasoned that even if durability were being tested, it was not for purposes of the patent application, and could bring the experimental use exception into play.

§ 2:4 Cordis Corp. v. Boston Scientific Corp.

Functional language may define over the prior art.

In *Cordis Corp. v. Boston Scientific Corp.*,⁸ Cordis sued Boston Scientific asserting infringement of two patents, A and B, drawn to intravascular stents. Boston Scientific counterclaimed, asserting infringement of one of its patents also drawn to such stents. A jury concluded that a claim of patent A was not invalid as anticipated or obvious. On appeal, the Federal Circuit agreed and affirmed.

Boston Scientific urged that patent B anticipated dependent claim 2 of patent A. The parties agreed that patent B disclosed all limitations of dependent claim 2 except for functional language in parent claim 1, namely, “such that the links and bands define an expandable structure having axial flexibility in an unexpanded configuration.” Boston Scientific argued that such functional claim language could not serve to distinguish the claim over the prior art. The Federal Circuit disagreed, reiterating that “functional language can be a claim limitation.”⁹

§ 2:5 Cordis Corp. v. Boston Scientific Corp.

There may be a reasonable expectation of privacy even though written agreement expressly disclaims any obligation of confidentiality.

In *Cordis Corp. v. Boston Scientific Corp.*,¹⁰ Cordis sued Boston Scientific asserting infringement of two patents, A and B, drawn to intravascular stents. Boston Scientific counterclaimed asserting infringement of one of its patents also drawn to such stents.

The district court on summary judgment held that two claims of patent B were not invalid as anticipated by two monographs prepared

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8. *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319 (Fed. Cir. 2009) (opinion by Circuit Judge Dyk, joined by Circuit Judge Mayer, and District Judge Huff, United States District Court for the Southern District of California, sitting by designation).
 9. *Id.* at 1335.
 10. *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319 (Fed. Cir. 2009) (opinion by Circuit Judge Dyk, joined by Circuit Judge Mayer, and District Judge Huff, United States District Court for the Southern District of California, sitting by designation).

by the inventor. The district court concluded that those monographs did not constitute “printed publications.” On appeal, the Federal Circuit agreed and affirmed.

Dr. Palmaz, the inventor, had prepared a ten-page paper in 1980 discussing his work on stents. That was the “1980 monograph.” Dr. Palmaz at the time was a resident at a hospital in California. He gave copies of the paper to approximately six of his instructors at an oral presentation and to other colleagues. Palmaz later gave copies of the 1980 monograph to two companies, Vascor, Inc. and Shiley, Inc., under written agreements, while attempting to commercialize his stent technology. Neither agreement required confidentiality, and the Shirley agreement provided that Shirley “shall not be committed to keep secret any idea or material submitted.”

Dr. Palmaz revised the paper in 1983 (the “1983 monograph”). He gave a copy of both monographs to Werner Schultz, a technician providing him assistance, in 1983. He also gave a copy to a doctor at the University of Texas, San Antonio, when he joined the faculty in 1983, who gave the copy to a technician setting up Dr. Palmaz’s laboratory. Dr. Palmaz also gave a copy of the 1983 monograph to the university as part of a research proposal. The filing date of patent B was 1985.

The Federal Circuit explained that public accessibility turned on whether interested members of the relevant public could obtain the information if they wanted to.

The court noted that many cases concerned whether treatises available in libraries were sufficiently indexed to be publicly accessible, while other cases concerned whether widespread distribution resulted in allowing the public access to copies. According to the court, the monograph disclosures involved a somewhat different question, that is, “whether the distribution to a limited number of entities without a legal obligation of confidentiality rendered them printed publications under § 102(b).”

The court observed that in *In re Klopfenstein*,¹¹ the Federal Circuit had noted a reluctance to find something a printed publication where professional and behavioral norms entitled a party to a reasonable

11. *In re Klopfenstein*, 380 F.3d 1345, 1350–51 (Fed. Cir. 2004).

expectation that information would not be copied or further distributed. In *Klopfenstein*, the court also recognized the importance of preserving the incentive for inventors to participate in academic presentations or discussions, noting that professional norms may support expectations of confidentiality.

With respect to Dr. Palmaz's disclosure of the monographs to university and hospital colleagues, the Federal Circuit held that the record contained "clear evidence" that such academic norms gave rise to an expectation that disclosures will remain confidential. In particular, the court quoted Cordis's expert's testimony that the "code of practice which occurs worldwide in academic circles, in departments, in medicine" includes treating a document describing scientific research in the "same confidential manner as you would if you had been given it directly by the author."

Boston Scientific argued, however, that the distribution of the monographs to the two commercial companies rendered them "printed publications." The Federal Circuit disagreed, finding that the evidence was sufficient to support a conclusion that there was an expectation of confidentiality between Dr. Palmaz and each of the two commercial entities. The court noted that while the Shiley legal agreement, executed before development discussions, disclaimed a confidentiality requirement, Dr. Palmaz testified that he requested confidentiality during subsequent discussions and was "surprised" when shown the language of the agreement. Further, there was no suggestion that the request for confidentiality was not honored, and Dr. Palmaz confirmed that the entities kept their copies of the monograph confidential, whether or not they were legally obligated to do so. The Federal Circuit reasoned that there was no showing that similar documents in the past became available to the public as a result of disclosure by these or similar commercial entities, that these or similar commercial entities typically would make the existence of such documents known and would honor requests for public access, or that these or similar commercial entities had an incentive to make the document available, etc. The court concluded that the "mere fact that there was no legal obligation of confidentiality" was not by itself sufficient to show that Dr. Palmaz's expectation of confidentiality was not reasonable.

§ 2:6 Ecolab, Inc. v. FMC Corp.

Clear and convincing evidence of anticipation may come from expert witness testimony.

In *Ecolab, Inc. v. FMC Corp.*,¹² Ecolab and FMC sold chemical products used by beef and poultry processors to reduce pathogens, such as *E. coli* and salmonella, on uncooked beef and poultry. Those products included an antimicrobial compound peracetic acid (PAA), which the food processing and food service industries had used as a surface sanitizer. Ecolab and FMC had both obtained patents drawn to the use of PAA as a sanitizer in beef and poultry processing.

Ecolab filed suit alleging that FMC had infringed three of its patents. FMC counterclaimed for infringement of one of its patents. The jury found that (1) several claims of Ecolab's asserted patents were invalid as anticipated or obvious, (2) FMC willfully infringed valid claims of two of Ecolab's patents, (3) Ecolab infringed valid claims of FMC's patent, and (4) neither party induced infringement of any claims. The jury awarded reasonable royalty damages, and the district court entered judgment on the jury's verdict. Both parties filed post-trial motions for JMOL, etc., which the district court denied.

One of the post-trial motions was FMC's motion for JMOL that claim 7 of one of Ecolab's patents was invalid as anticipated by a prior art publication. The jury had concluded that claim 7 was not invalid and was infringed. The Federal Circuit reversed, finding that there was insubstantial evidence to support the verdict, relying on FMC's expert witness testimony.

The Federal Circuit held that FMC had borne its burden of showing anticipation by clear and convincing evidence through the testimony of its expert witness, Professor Russell. According to the Federal Circuit, Russell explained how the prior art publication met each of the limitations of claim 7.

Ecolab argued that there was substantial evidence to support the jury's verdict despite Russell's testimony, because the claimed method was directed in the "complex setting" of a processing plant. The Federal

12. *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335 (Fed. Cir. 2009) (opinion by Circuit Judge Gajarsa, joined by Circuit Judges Rader and Dyk).

Circuit rejected that argument, noting that claim 7 was broadly written and was not limited to PAA treatment in a meat processing plant.

The Federal Circuit also rejected Ecolab's argument that there was "voluminous evidence of undue experimentation." According to the court, Ecolab had not presented any evidence that experimentation would be required to practice claim 7 using the PAA treatment disclosed by the publication. Second, according to the court, the evidence that Ecolab relied on used a less concentrated form of PAA than that disclosed in the publication.

The Federal Circuit further rejected Ecolab's argument that claim 7 distinguished over the publication because the publication taught that each of two PAA treatment steps was following by a trimming step, that is, the PAA-treated meat was trimmed away and discarded. That is, according to the court, Ecolab argued that the publication did not disclose that PAA treatment alone was sufficient to reduce microbial population on a meat surface. The Federal Circuit disagreed, concluding that no reasonable jury could conclude that the publication's disclosure of PAA treatment for a two-minute period was not "in an amount and time sufficient to reduce the microbial population," as called for by claim 7.

§ 2:7 **Exergen Corp. v. Wal-Mart Stores, Inc.**

Broad claims and inherent manner of use may lead to finding of anticipation through inherency.

In *Exergen Corp. v. Wal-Mart Stores, Inc.*,¹³ Exergen's three patents-in-suit were drawn to infrared thermometers for measuring human body temperature. Exergen sued, inter alia, S.A.A.T. Systems Application of Advanced Technology, Ltd. for infringement. A jury found willful infringement and awarded lost profits damages. S.A.A.T. appealed, urging that the district court had erred in failing to grant its motion for JMOL. On appeal, the Federal Circuit reversed the finding of infringement, concluding that all asserted claims of one of the

13. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009) (opinion by Circuit Judge Linn, joined by Chief Judge Michel and District Judge St. Eve, United States District Court for the Northern District of Illinois, sitting by designation).

patents-in-suit were invalid for anticipation under section 102, and that Exergen had failed to introduce substantial evidence that the other two of the patents-in-suit were infringed.

Exergen's patents disclosed a thermometer (referred to as a "radiation detector") that included a housing, a display, and an on/off switch. A probe was designed to be positioned in an ear canal, but as the Federal Circuit noted, the claims were broader than that in referring to "biological tissue." The thermometers initially detected infrared radiation from the surface of the human body—for example, the eardrum or the skin of the forehead—to determine surface temperature. The instruments then calculated internal temperature.

Claim 1 called for, *inter alia*, "electronically detecting the peak radiation from the multiple areas to obtain a peak temperature signal."

The asserted prior art was drawn to a method and apparatus for measuring internal body temperature using infrared emissions. A probe unit mated with a "chopper unit." When a user removed the probe unit from the chopper unit, the system began taking radiation measurements and a user had ten seconds to insert the probe into the external ear canal and press a SCAN key. When the SCAN key was pressed, "[t]he maximum reading from the beginning of the removal of the probe unit from the chopper unit is displayed as the tympanic temperature."

Exergen's expert, the inventor of the patent-in-suit, conceded that the prior art disclosed all limitations of claim 1 except "electronically detecting the peak radiation from the multiple areas to obtain a peak temperature signal."

On appeal, Exergen presented two arguments why the prior art did not anticipate claim 1: (1) the prior art heated the probe unit to 98°F and detected that radiation in addition to radiation detected from the patient, and (2) the prior art detected radiation from only a single spot in the ear canal after the SCAN key was depressed, not "multiple areas" as required by the claim. The Federal Circuit was not persuaded.

With respect to the first argument, claim 1 used the open-ended transition term "comprising," and the Federal Circuit commented that nothing in claim 1 required the detector to detect radiation solely from biological tissue.

With respect to the second argument, the Federal Circuit viewed Exergen's expert as having conceded that the limitation was inherently disclosed in the prior art. Exergen's expert testified that when the

probe was removed from the chopper unit, it was measuring infrared radiation even though the SCAN key was not depressed. The expert also testified that the unit was measuring radiation when the probe was moved along the side of a patient's face. The Federal Circuit reasoned that because the unit would "necessarily" detect radiation from the patient's face, outer ear, and ear canal at a rate of seven times per second while inserting the probe unit into the ear canal, the prior art inherently disclosed the "multiple areas" limitation.

§ 2:8 *In re Gleave*

Reference disclosing every fifteen-base-long sense oligodeoxynucleotide in the IGFBP-2 gene—more than 1400 sequences—anticipated claim to specific sequence of a twenty-base oligodeoxynucleotide: In re Wiggins narrowed to facts.

In *In re Gleave*,¹⁴ the application contained claims to (1) antisense oligodeoxynucleotides, (2) methods of making pharmaceutical compounds containing the oligodeoxynucleotides, and (3) methods of treating endocrine-regulated cancers by using the oligodeoxynucleotides to prevent the formation of IGFBP-2 and IGFBP-5. The rejected composition claims were drawn to antisense oligodeoxynucleotides.

The technology was based on the understanding that certain antisense oligodeoxynucleotides can simultaneously bind to and prevent the translation of mRNA into two types of human Insulin-Dependent Growth Factor Binding Protein (IGFBP). In antisense technology, complementary molecules bind to mRNA, which block the step of protein production. mRNA is the nucleic acid molecule that carries genetic information from DNA during protein production. Binding mRNA to antisense molecules can be used to interrupt and inhibit the production of certain disease-related proteins. "Sense" refers to the original sequence of the DNA or RNA molecule. "Antisense" refers to the complementary sequence of the DNA or RNA molecule.

14. *In re Gleave*, 560 F.3d 1331 (Fed. Cir. 2009) (opinion by Circuit Judge Prost, joined by Chief Judge Michel and Circuit Judge Moore).

Oligodeoxynucleotides are short segments of single-stranded DNA that are complementary to mRNA. Some oligodeoxynucleotides are “bispecific,” meaning they can bind to mRNAs transcribed from two distinct genes and prevent the formation of both proteins.

Claim 1 was drawn to a “bispecific antisense oligodeoxynucleotide,” and dependent claim 4 further required that the oligodeoxynucleotide “consists essentially of a series of bases as set forth in any of Seq. ID. Nos. 3 through 7.” Those sequences range from eighteen to twenty-two DNA bases in length. Gleave elected Sequence No. 5, a twenty-base oligodeoxynucleotide.

The examiner initially rejected the claims over a published PCT application, Wright, which listed every fifteen-base-long sense oligodeoxynucleotide in the IGFBP-2 gene, and disclosed more than 1400 sequences. The board concluded that Wright anticipated claim 1, and also affirmed a rejection under section 103.

The issue on appeal was “whether a reference that lists every fifteen-base sense oligodeoxynucleotide in a known nucleic acid sequence anticipates or renders obvious claims to specific antisense sequences having particular properties.” The Federal Circuit answered yes.

Gleave, though, argued that the issue was “the meaning of the term ‘described’ in 35 U.S.C. § 102(b) and the type of disclosure that is therefore required for a reference to be anticipatory.” Gleave argued that Wright did not describe any particular individual antisense species, because Wright 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.”

In response, the Federal Circuit emphasized that an anticipatory reference need not disclose a utility. The court further noted that Gleave’s claims were to compositions of matter—oligonucleotides—and Wright satisfied the enablement requirement of section 102(b) by showing that one of skill in the art would know how to make the relevant sequences that it (Wright) disclosed. According to the Federal Circuit, the fact that Wright provided “no understanding of which of the targets would be useful” was of no import, because Gleave admitted that it was well within the skill of an ordinary person in the art to make any oligodeoxynucleotide sequence.

According to the Federal Circuit, Gleave's primary argument was rooted in policy, that is, Gleave argued for collapsing the distinction between a list and a genus disclosure. Gleave cited the CCPA's 1973 decision in *In re Wiggins*,¹⁵ arguing that "a list of compounds, 'without any direction as to selection among the targets, is not a description of any one of these targets.' "

The Federal Circuit disagreed, stating that Gleave's conclusion ignored the *Wiggins* facts. The Federal Circuit noted that in *Wiggins*, there was no evidence that a person of ordinary skill in the art could make the compounds disclosed in the alleged anticipatory reference at the time of disclosure. The Federal Circuit further explained that *Wiggins* mentioned by name two compounds that fell within the scope of *Wiggins*'s claims, but noted that the synthesis of these compounds had been unsuccessful; further, the only publication of record that disclosed a method of making the compounds was not published until two years later.

The Federal Circuit agreed with *Wiggins*'s statement that the mere naming of a compound in a reference "without more," could not constitute a description of the compound. The Federal Circuit reasoned that the "without more" phrase was "key" and that *Wiggins* made clear that the something "more" was the ability of a person of ordinary skill in the art to make the claimed compound. According to the Federal Circuit, *Wiggins* underscored the point by three times pointing out that its discussion was in the context of "potential or theoretical" compounds.

The Federal Circuit also noted that lists and genus-species relationships are treated differently, comparing *Perricone v. Medicis Pharm. Corp.*¹⁶ with *Atofina v. Great Lakes Chem. Corp.*¹⁷ According to the court, that distinction collapses when the class of compounds falling within the genus is so limited that a person of ordinary skill in the art can immediately envisage each member of the class.

15. *In re Wiggins*, 488 F.2d 538, 543 (C.C.P.A. 1973).

16. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005) (rejecting "the notion that [a compound] cannot anticipate because it appears without special emphasis in a longer list").

17. *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006) ("It is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus.").

The Federal Circuit concluded that Gleave’s arguments failed for two reasons: (1) Wraight expressly listed every possible fifteen-base-long oligodeoxynucleotide sequence in IGFBP-2, and that was sufficient to anticipate Gleave’s claims, and (2) even accepting Gleave’s arguments regarding Wraight, a person of ordinary skill in the art equipped with an IGFBP sequence was admittedly capable of envisioning how to make any antisense sequence. Thus, the Federal Circuit explained, even if Gleave’s policy position was adopted, Gleave would not be entitled to a patent over Wraight.

§ 2:9 Iovate Health Sciences, Inc. v. Bio-Engineered Supplements & Nutrition, Inc.

Prior art need only teach the claimed invention to anticipate.

In *Iovate Health Sciences, Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*,¹⁸ Iovate was the exclusive licensee of the patent-in-suit drawn to the use of nutritional supplements containing a ketoacid and an amino acid that is either cationic (positively charged) or dibasic (containing two basic groups) to enhance muscle performance or recovery from fatigue. Claim 1 was drawn to a “method for enhancing muscle performance or recovery from fatigue.”

The district court construed “enhancing muscle performance” to mean “increasing the ability of muscle to maintain required or expected force or power output” and construed enhancing “recovery from fatigue” to mean “increasing muscle performance after muscle performance has been decreased by exercise.” The district court also granted BSN’s motion for summary judgment that the claims of the patent-in-suit were invalid as being anticipated by a number of amino acid/ketoacid dietary supplements advertised in fitness periodicals. On appeal, the Federal Circuit affirmed.

18. *Iovate Health Sciences, Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*, 586 F.3d 1376 (Fed. Cir. 2009) (opinion by Circuit Judge Lourie, joined by Circuit Judges Mayer and Prost, concurring opinion by Circuit Judge Mayer).

The prior art the Federal Circuit relied on was an advertisement for Weider's VICTORY Professional Protein published in *Flex* magazine before the November 13, 1996, critical date. The ad described a supplement containing arginine aspartate, ornithine-alpha-ketoglutarate, alpha-ketoisocaproic acid, and glutamine and that was taken with water before and after training to increase muscle strength, size, and mass; to help muscles recuperate faster after exercise; and to "decrease[] the breakdown of muscle proteins" to "provide[] greater potential for post-workout recovery." The ad also described how the product was made, including four steps used to isolate the protein components from milk whey; listed a price of \$24.99; stated that the product was available at GNC and other health food stores or by phone; instructed the user on the amount to take; and offered a manufacturer's rebate of \$5.00 for mailing in a coupon with proof of purchase.

The district court held that the ad (and another ad that the Federal Circuit did not rely on) established a public use and offer for sale under section 102(b). The district court also held that the ads were enabling despite a failure to give precise amounts for each chemical component. The Federal Circuit deemed the ad an invalidating printed publication.

Iovate argued, *inter alia*, that there was a genuine issue of fact in dispute whether the Professional Protein ad disclosed all of the claim limitations, including a method of "enhancing muscle performance or recovery from fatigue." Iovate's expert testified that the Professional Protein ad's references to muscle "recuperation" and "post-workout recovery" were not the same as "recovery from fatigue" as claimed. The Federal Circuit rejected that argument, concluding that the district court had not erred in finding that the ad's statements were synonymous with the claims as construed, especially given the absence of any time limit for recovery in the claims.

With respect to enablement, Iovate argued that the ad did not teach one of ordinary skill in the art how to make a composition effective for enhancing muscle performance or recovery from fatigue because the ad lacked guidance on appropriate dosages. The Federal Circuit noted that all one of ordinary skill in the art had to do to practice an embodiment of the invention was mix together the known ingredients listed in the ad and administer the composition as taught by the ad. The Federal Circuit rejected Iovate's argument that the claims required administering an effective amount of the claimed composition, but explained

that even if the claims did require an effective amount, an artisan would have been able to determine such an amount based on the ad and the knowledge in the art at the time.

§ 2:10 *In re Lister*

A deposit copy with the U.S. Copyright Office becomes “accessible” when its title is searchable through Lexis or Westlaw.

In *In re Lister*,¹⁹ Dr. Lister, a clinical psychologist and sportsman, competed regularly in organized golf tournaments, but grew tired of the slow pace of the game. He concluded that the game could be improved by allowing players to tee up the ball on the fairway, or anywhere else other than designated hazard areas or on the green.

He described that method of playing golf in a manuscript entitled “Advanced Handicap Alternatives for Golf” and submitted the manuscript to the U.S. Copyright Office on July 4, 1994, and the Office issued a certificate of registration on July 18, 1994. Dr. Lister later learned that he must file a patent application to protect his invention, and he did so on August 5, 1996. The prosecution then continued over the next thirteen years, including rejections, amendments, and two appeals to the board.

The board had sustained a rejection under section 102(b) concluding that Dr. Lister’s claims were anticipated by the manuscript he filed with the Copyright Office. On appeal, the Federal Circuit reversed and remanded.

The question was whether the manuscript was “accessible.” The Federal Circuit rejected Dr. Lister’s arguments that the manuscript was not “publically accessible” because an interested researcher would have to travel to Washington, D.C., and inspecting the manuscript at the Copyright Office was too burdensome. However, the court concluded that there was no evidence that prior to the critical date the manuscript was included in a catalog or index that would allow an interested researcher to find it.

19. *In re Lister*, 583 F.3d 1307 (Fed. Cir. 2009) (opinion by Circuit Judge Prost, joined by Circuit Judges Gajarsa and Linn).

Dr. Lister based his first argument on *Northern Telecom, Inc. v. Datapoint Corp.*,²⁰ in which the Federal Circuit held that documents relating to a military system were not “printed publications” under section 102(b) because they were not “generally available” to the interested public. The Federal Circuit rejected the argument finding that his manuscript at the Copyright Office was available to the general public, while the documents involved in *Datapoint* were not. The court also rejected Dr. Lister’s argument that the fact that the Copyright Office would not allow researchers to make copies precluded a finding of public access. The court agreed with the board that the nature of the manuscript was such that a researcher could readily understand the explanation of the game without having to make a copy.

With respect to indexing, Dr. Lister argued that (1) the records of the Copyright Office were not sufficiently searchable to lead an interested researcher to his manuscript, and (2) even if so, there was no evidence that the manuscript was available in searchable databases prior to the critical date.

It was undisputed that there were three relevant databases: the Copyright Office’s automated catalog and two commercial databases, Westlaw and Dialog. The automated catalog was not sorted by subject matter and could only be searched by either the author’s last name or the first word of the title of the work. Westlaw and Dialog obtained the automated catalog data from the Copyright Office and entered it into their own databases. Users of the Westlaw and Dialog databases could perform keyword searches of the titles, but not the full texts, of the works.

The PTO conceded at oral argument that the Copyright Office’s automated database was insufficient to render the manuscript “publicly accessible” because of the limited search available. The first word of the title, for example, was “Advanced.” With respect to the Lexis and Westlaw databases, unlike that of the Copyright Office, one could search key words in the title, and thus could search “handicap” and “golf.” Dr. Lister argued such key words would have been insufficient to uncover his manuscript. The Federal Circuit disagreed, finding that “[a] reasonably diligent researcher with access to a database that

20. *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 936–37 (Fed. Cir. 1990).

permits the searching of titles by keyword would be able to attempt several searches using a variety of keyword combinations.”²¹

However, the Federal Circuit concluded that the record did not contain any evidence of when the manuscript was entered into the Lexis or Westlaw databases. The court rejected the PTO’s argument that Dr. Lister bore the burden of proof on the issue. Accordingly, the court reversed and remanded.

§ 2:11 Martek Biosciences Corp. v. Nutrionova, Inc.

An abandoned patent application may provide evidence of conception, but not reduction to practice, and therefore is insufficient by itself to corroborate testimony of prior invention under section 102(g).

In *Martek Biosciences Corp. v. Nutrionova, Inc.*,²² Martek’s patents-in-suit related to microorganisms that were useful in producing commercial quantities of DHA, an omega-3 fatty acid.

Lonza sought to introduce evidence of prior invention under section 102(g), namely, the testimony by a Dr. Long that he had previously made the claimed invention. The district court excluded that evidence based on a lack of corroboration. On appeal, the Federal Circuit affirmed.

As “evidence” of corroboration, Lonza offered (1) Dr. Long’s 1987 abandoned patent application and (2) evidence that examples originally disclosed in that abandoned application were later reproduced, generating the results described in the application. The Federal Circuit held that neither was sufficient.

The Federal Circuit noted that “[d]ocumentary or physical evidence that is made contemporaneously with the inventive process provides the most reliable proof that the inventor’s testimony has been

21. *Lister*, 583 F.3d at 1315.

22. *Martek Biosciences Corp. v. Nutrionova, Inc.*, 579 F.3d 1363 (Fed. Cir. 2009) (opinion by Circuit Judge Gajarsa, joined by Circuit Judges Newman and Moore, dissenting-in-part opinion by Circuit Judge Lourie, joined by Circuit Judge Rader).

corroborated,”²³ and that “[s]uch contemporaneous documentary evidence could include an abandoned patent application.”²⁴

However, the Federal Circuit noted, “while an abandoned patent application is evidence of conception, it is insufficient to corroborate testimony that an alleged prior inventor reduced the invention to practice.”²⁵ The Federal Circuit concluded that in prior cases involving abandoned patent applications, other evidence from a time prior to or contemporaneous with the alleged invention was offered.

The Federal Circuit rejected the evidence regarding reproduction of the examples as not qualifying as evidence from a time prior to or contemporaneous with the alleged prior invention.

§ 2:12 *In re Skvorecz*

The word “comprising” does not render a claim anticipated by a device that contains less (rather than more) than what is claimed.

In *In re Skvorecz*,²⁶ Skvorecz’s reissue application was drawn to a wire chafing stand. Such stands were stored with multiple units nested together. That tended to cause the stands to wedge together making them difficult to separate. The invention included an indent or “offset” located adjacent to the upper legs of the stand which served to displace each leg laterally which resulted in reduced wedging. Claim 1 and other claims were rejected, inter alia, as being anticipated by a patent to Buff.

The PTO argued on appeal that claim 1 was anticipated because it could be construed to include wire legs without offsets because the claim used the open-ended transition term “comprising.” In other words, according to the PTO, not every wire leg was required to include offsets—despite that claim 1 referred to “said wire legs” and

23. *Id.* at 1375 (quoting *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1350–51 (Fed. Cir. 2001)).

24. *Id.*

25. *Id.*

26. *In re Skvorecz*, 580 F.3d 1262 (Fed. Cir. 2009) (opinion by Circuit Judge Newman, joined by Circuit Judges Friedman and Mayer).

that “each wire leg” had offsets. The PTO argued that Buff showed offsets that laterally displaced a wire leg, and it was irrelevant whether Buff’s wire leg had an offset. The Federal Circuit disagreed.

The Federal Circuit explained that “[t]he signal comprising” does not render a claim anticipated by a device that contains less (rather than more) than what is claimed. The Federal Circuit explained that the examiner had incorrectly applied the examination expedient of “broadest reasonable interpretation” to interpret “comprising” to mean that not all the Skvorecz wire legs need have offsets, despite the claims that state that “each wire leg” had an offset. According to the Federal Circuit the Buff device did not have an offset located in each wire that served as a leg to support the device.

