

# United States Court of Appeals for the Federal Circuit

2009-1018

IOVATE HEALTH SCIENCES, INC.  
and UNIVERSITY OF FLORIDA RESEARCH FOUNDATION, INC.,

Plaintiffs-Appellants,

v.

BIO-ENGINEERED SUPPLEMENTS & NUTRITION, INC.  
(doing business as BSN, Inc.),

Defendant-Appellee,

and

MEDICAL RESEARCH INSTITUTE,

Defendant-Appellee.

Charles A. Weiss, Kenyon & Kenyon LLP, of New York, New York, argued for plaintiffs-appellants. With him on the brief were Elizabeth A. Gardner and Cynthia Lambert Hardman.

Philip D. Segrest, Jr., Husch Blackwell Sanders Welsh & Katz, of Chicago, Illinois, argued for defendant-appellee Bio-Engineered Supplements & Nutrition, Inc. With him on the brief was Joseph E. Cwik. Of counsel on the brief was Jonathan J. Krit, Amin Talati, LLC, of Chicago, Illinois.

Robert P. Latham, Jackson Walker L.L.P., of Dallas, Texas, argued for defendant-appellee Medical Research Institute. With him on the brief was David T. Moran. Of counsel were Sara K. Borrelli and Alan B. Daughtry.

Appealed from: United States District Court for the Eastern District of Texas

Judge Ron Clark

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Appeal from the United States District Court for the Eastern District of Texas in Case No. 9:07-CV-46, Judge Ron Clark.

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DECIDED: November 19, 2009

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Before MAYER, LOURIE, and PROST, Circuit Judges.

Opinion for the court filed by Circuit Judge LOURIE, in which Circuit Judges MAYER and PROST join. Concurring opinion filed by Circuit Judge MAYER.

LOURIE, Circuit Judge.

Iovate Health Sciences, Inc. (“Iovate”) and the University of Florida Research Foundation, Inc. (the “Foundation”) appeal from the summary judgment order of the United States District Court for the Eastern District of Texas holding claims 1, 2, 5, 7, 8,

9, and 18 of U.S. Patent 6,100,287 ("the '287 patent") invalid as anticipated under 35 U.S.C. § 102(b). Iovate Health Sciences, Inc. v. Bio-Engineered Supplements & Nutrition, Inc., No. 9:07-CV-46 (E.D. Tex. Aug. 27, 2008) ("Summary Judgment Order").

Because the invention claimed in the '287 patent was disclosed in a printed publication before the critical date, we affirm the district court's decision.

## BACKGROUND

The Foundation is the assignee and Iovate the exclusive licensee of the '287 patent, which claims 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 reads as follows:

1. A method for enhancing muscle performance or recovery from fatigue wherein said method comprises administering a composition comprising a ketoacid and an amino acid wherein said amino acid is cationic or dibasic.

Claims 2, 5, 7, and 8 all depend, directly or indirectly, from claim 1 and further define the composition: claim 2 requires that the composition further comprise a compound selected from glutamate, glutamine, or glycine; claim 5 requires that the composition contain alpha-ketoisocaproic acid, or a salt thereof; claim 7 requires that the composition contain arginine; and claim 8 requires that the amino acid and ketoacid be conjugated. Dependent claim 9 limits claim 1 to oral administration, and claim 18 limits claim 1 to use on a human. The '287 patent was filed on November 13, 1998, and claims priority from a provisional application filed on November 13, 1997.

In March 2007, Iovate brought suit in the Eastern District of Texas against Bio-Engineered Supplements & Nutrition, Inc., d/b/a BSN, Inc. and Medical Research Institute (collectively, "BSN"), claiming infringement of the '287 patent by certain of

BSN's nutritional products. The allegedly infringing products contain arginine alpha keto-glutarate and are advertised to, inter alia, enhance muscle strength or resistance to muscle fatigue.<sup>1</sup> 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." BSN then moved for summary judgment of invalidity, asserting that the '287 patent was anticipated or rendered obvious by a number of amino acid/ketoacid dietary supplements advertised in certain fitness periodicals.

On August 27, 2008, the district court granted BSN's motion, holding claims 1, 2, 5, 7, 8, 9, and 18 invalid under § 102(b) as anticipated by advertisements for TwinLab® Mass Fuel and Weider's VICTORY™ Professional Protein published in Flex magazine before the November 13, 1996, critical date.<sup>2</sup> Each ad includes a list of ingredients, directions for administering the dietary supplement orally to humans, and marketing claims and testimonials from bodybuilders extolling the virtues of the product. The Mass Fuel ad appeared in the June 1995 issue of Flex and describes a supplement that contains ornithine alpha-ketoglutarate, keto-isocaproate, glutamine, and alpha-ketoglutarates and that is designed to "help promote muscle protein synthesis and

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<sup>1</sup> Flamma SpA initially joined Iovate as a plaintiff but was dismissed from the suit on October 4, 2007, after selling to Iovate all of its right, title, and interest in a second asserted patent, U.S. Patent 5,973,199 ("the '199 patent"), which claims certain hydrosoluble creatine salts. After the district court denied BSN's motion for summary judgment that the '199 patent is invalid for obviousness, the parties stipulated that the '199 patent is not invalid, is not unenforceable, and is infringed by BSN's products.

<sup>2</sup> The district court denied summary judgment with respect to claims 10 and 12 of the '287 patent. The parties stipulated to a dismissal of those claims.

growth"; "build[] thick, dense muscle mass"; and accelerate muscle recovery when taken mixed with water after weight-training. The ad urges athletes to look for the product at "fine health food stores" and gyms or to write for a free catalog, and it offers a free training video with purchase. The Professional Protein ad appeared the next year in the June 1996 issue of Flex. This ad describes a supplement that contains arginine aspartate, ornithine-alpha-ketoglutarate, alpha-ketoisocaproic acid, and glutamine and that is 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 describes how the product is made, including the four steps used to isolate the protein components from milk whey; lists a price of \$24.99; states that the product is available at GNC and other health food stores or by phone; instructs the user on the amount to take; and offers a manufacturer's rebate of \$5.00 for mailing in a coupon with proof of purchase before July 31, 1996.

The district court held that the ads established a public use and offer for sale under § 102(b), as they show an actual product and state that it is available for purchase in health food stores, gyms, or by catalog. The court determined that the ads disclose all of the limitations of the asserted claims, including each of the claimed chemical components as well as the stated function of oral administration to a human to speed muscle recovery. And the court held that, assuming they needed to be, the ads were enabled under § 102(b) because a person of skill in the art would, combining his or her knowledge with the ads' suggestions, consider them to be enabled despite their failure to give precise amounts for each chemical component contained in the product.

On September 24, 2008, the district court entered a consent judgment and order of dismissal disposing of all the parties' claims and counterclaims. Iovate timely appealed the district court's grant of summary judgment of invalidity. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

## DISCUSSION

We review the district court's grant of summary judgment *de novo* under the same standards applied by the district court. Enzo Biochem, Inc. v. Gen-Probe, Inc., 424 F.3d 1276, 1280 (Fed. Cir. 2005). Summary judgment is appropriate if there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). Patents enjoy a presumption of validity, 35 U.S.C. § 282 (2006), and a party seeking to invalidate a patent must overcome this presumption by facts supported by clear and convincing evidence. Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1374 (Fed. Cir. 2001). While the district court's decision and the parties' arguments discuss three of the grounds listed in § 102(b)—printed publication, public use, and on sale—we need affirm the district court's decision on only a single ground, and we conclude that the Professional Protein advertisement clearly constitutes an anticipatory printed publication.<sup>3</sup>

Section 102(b) provides that “[a] person shall be entitled to a patent unless . . . the invention was . . . described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States.” 35 U.S.C. § 102(b). To qualify as a printed publication, the Professional Protein ad

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<sup>3</sup> Because it is undisputed that the Mass Fuel ad does not disclose a composition containing arginine as required by dependent claim 7, we rely solely on the Professional Protein ad.

must have been disseminated or otherwise made accessible to persons interested and ordinarily skilled in the subject matter to which the ads relate prior to the critical date.

Kyocera Wireless Corp. v. Int'l Trade Comm'n, 545 F.3d 1340, 1350 (Fed. Cir. 2008).

Here the parties do not dispute that the Professional Protein ad was published in Flex and that the magazine was accessible to those interested in the art of nutritional supplements prior to November 13, 1996. To be anticipatory, the ad must also describe, either expressly or inherently, each and every claim limitation and enable one of skill in the art to practice an embodiment of the claimed invention without undue experimentation. In re Gleave, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

#### A. Disclosure of Each and Every Claim Limitation

On appeal, Iovate argues that there are genuine issues of material fact regarding whether the Flex ads disclose all the limitations of the asserted '287 patent claims and, specifically, whether the Professional Protein ad discloses an effective method of "enhancing muscle performance or recovery from fatigue."<sup>4</sup> Iovate points to the testimony of its expert, Dr. Ivy, who opined that the Mass Fuel ad's disclosure of "promot[ing] muscle synthesis and growth" is not synonymous with "enhancing muscle performance" and that the Professional Protein ad's general concepts of muscle "recuperation" and "post-workout recovery" do not address the claim term enhancing "recovery from fatigue" as construed to mean "increasing muscle performance after muscle performance has been decreased by exercise" but rather as recovery from one

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<sup>4</sup> Iovate also argues that there are genuine issues of material fact regarding whether the advertisements meet the "conjugated" limitation of dependent claim 8. Because Iovate admitted that the listed ingredient ornithine-alpha-ketoglutarate is an amino acid conjugated with a ketoacid in its opposition to BSN's motion for summary judgment of invalidity, we decline to address this argument on appeal.

workout to the next. Furthermore, according to Dr. Ivy, those skilled in the art do not ordinarily rely on advertisements in muscle magazines to prove the effectiveness of a nutritional supplement because of the lack of scientific testing and the existence of false advertising in the industry.

BSN responds that the claim preamble is either non-limiting or expresses only the purpose for which the composition is taken, not a functional or effective result. Specifically, BSN points to the fact that the claims (1) recite a “method for” rather than a “method of enhancing muscle performance or recovery from fatigue”; (2) are not limited to “an effective amount” or any particular range, amount, or concentration of ingredients; and (3) do not include a step in which the intended effect is either measured or achieved. Furthermore, BSN contends, there is no genuine issue of material fact that both prior art supplements were advertised for exactly the same purpose as claimed in the '287 patent.

We agree with BSN that the Professional Protein ad discloses each and every limitation of the claims asserted by Iovate. There is no dispute that the Professional Protein ad discloses a composition comprising a cationic or dibasic amino acid (ornithine) and a ketoacid (alpha-ketoglutarate) as well as the additional limitations found in claims 2 (glutamine), 5 (alpha-ketoisocaproic acid), 7 (arginine), 8 (conjugated amino acid and ketoacid, here ornithine-alpha-ketoglutarate), 9 (administered orally), and 18 (used on a human). It is also undisputed that the ad discloses the administration of the nutritional supplement for the purpose of enhancing muscle performance or recovery from fatigue (by building muscle strength, promoting muscle growth, and achieving faster recuperation and post-workout recovery).

To avoid anticipation, Iovate relies on conclusory expert testimony and attempts to increase the specificity of the language used in the claims' preamble. But even assuming that the preamble limits the claims, there is no evidence that those skilled in the art of nutritional supplements used the term "enhancing muscle performance"—and thus "increasing the ability of muscle to maintain required or expected force or power output"—to exclude increasing muscle strength. Such an argument borders on the frivolous. In fact, both the patent specification and Iovate's infringement allegations refer to muscle strength as a proxy for this term. Specifically, the specification describes the invention as directed to "methods and compositions for enhancing muscle performance . . . [and m]ore specifically . . . a unique metabolic intervention to improve athletic dynamic muscle strength and muscle work." '287 Patent col.5 l.66–col.6 l.3 (emphasis added). And Iovate repeatedly includes BSN's advertising claims of enhancing muscle strength to support its allegations of infringement by BSN's products. See Bristol-Myers, 246 F.3d at 1378 ("[I]t is axiomatic that that which would literally infringe if later anticipates if earlier."). Moreover, although only one of the stated purposes needs to be disclosed for anticipation, we also can discern no error in the district court's finding that the Professional Protein ad's statements regarding faster post-exercise muscle recuperation and recovery are synonymous with "increasing muscle performance after muscle performance has been decreased by exercise," especially given the absence of any time limit for recovery in the claims.

Iovate also seeks to avoid anticipation by reading an effectiveness requirement into the preamble, which, it argues, the ads fail to disclose. But the '287 patent claims do not restrict the administration of the claimed amino acid and ketoacid composition to

any specific dosage or amount, or even an “effective amount.” The claims also do not require any further measurement or determination of any result achieved by administering the claimed composition. Thus, the ad’s disclosure of a certain composition taken for a certain purpose suffices for the purpose of anticipation. Bristol-Myers, 246 F.3d at 1378; see also Gleave, 560 F.3d at 1336 (“[W]here the claims themselves do not require a particular activity, we have no call to require something more from the anticipating reference.”). But even if the claims did require an effective amount, the Professional Protein ad instructs the reader that “active athletes need up to 2.0 g protein per 1 kg of body weight daily” and that Professional Protein should be taken once, two to three hours before and once about one hour after exercise. And, according to the users quoted in the ad, “I rely on Professional Protein as I strive to increase strength and size” and “I take [Professional Protein] one hour before my workout, and it . . . helps me recuperate faster from my workouts.” Thus, regardless of any questions about false advertising, the ad teaches that taking a supplement containing the claimed ingredients as advertised is effective for increasing muscle performance and recovery after exercise. As such, we find that the Professional Protein ad discloses each and every claim limitation as a matter of law.

#### B. Enablement

We next consider whether the Professional Protein ad enabled one of skill in the art to practice an embodiment of the claimed invention in June of 1996. Iovate argues that the district court erroneously focused on whether a person of ordinary skill in the art could have made the advertised supplements rather than the claimed invention. Furthermore, Iovate contends, the record lacks any evidence that the ad taught a skilled

artisan how to make a composition effective for enhancing muscle performance or recovery from fatigue because the ads lack any guidance on appropriate ingredient dosages.

BSN responds that because the claims are not directed to any particular concentrations, ratios, or percentages, one of skill in the art could practice the invention by buying the individual ingredients, or more simply the product itself, and administering them as directed by the ad for the purposes recited. BSN argues in the alternative that determining the relative amounts and dosages of the disclosed compounds would not amount to undue experimentation.

We agree with BSN that all one of ordinary skill in the art would need to do to practice an embodiment of the invention is to mix together the known ingredients listed in the ad and administer the composition as taught by the ad. We have already rejected Iovate's argument that the claims require administering an effective amount of the claimed composition. But even if the claims did require an effective amount, one of skill in the art would have been able to determine such an amount based on the ad and the knowledge in the art at the time. Again, the ad teaches the amount of protein an active athlete needs per day per kilogram of body weight and that Professional Protein should be taken once before and once after exercise. In addition, the '287 patent specification lists numerous pre-1996 publications that teach acceptable clinical dosages of the two claimed components. '287 Patent col.8 ll.21-53. It also lists pre-1996 publications that teach the effects of the components' administration on humans, including, for example, (1) a dietary intervention with analogs of ketoacids and diabasic amino acids that aids patients with eroding muscle mass, id. col.2 ll.50-58; and (2) ketoacid/amino acid

complexes that, inter alia, improve muscle trauma recovery time and alter muscle protein synthesis following exercise, id. col.2 l.65–col.3 l.10. Thus, contrary to Iovate's assertions, the district court correctly concluded, as do we, that a person of skill in the art, combining his or her knowledge of the art with the advertisement's suggestions, would have considered the advertisement to be enabled. See Bristol-Myers, 246 F.3d at 1379.

Because no reasonable fact-finder could conclude other than that the Professional Protein ad discloses each limitation of the claimed method in an enabling manner, it qualifies as a printed publication that invalidates the asserted claims.

#### CONCLUSION

The Professional Protein advertisement constitutes an anticipatory printed publication under § 102(b) that invalidates the asserted claims of the '287 patent. We therefore affirm the district court's grant of summary judgment in favor of BSN.

AFFIRMED

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MAYER, Circuit Judge, concurring.

I join the opinion of the court. I also believe the products were on sale more than one year before the critical date as contemplated by 35 U.S.C. § 102(b).