2d Circuit: Merck Eprova AG v. Gnosis S.p.A Affirms the Use of Legal Presumptions of Consumer Confusion and Injury for the Purposes of Finding Liability in Certain Lanham Act Cases

The United States Court of Appeals for the Second Circuit recently held that, where literal falsity and deliberate deception have been proved in the context of a two-player market, it is appropriate to use legal presumptions of consumer confusion and injury for the purposes of finding liability in a false advertising case brought under the Lanham Act.[1]

I. Background and Procedural History

Since 2002, Merck & Cie ("Merck")[2] has sold a folate product under the name "Metafolin" to customers who utilize it in finished products for resale, such as vitamins and supplements. Metafolin is comprised of a naturally occurring form of Methyltetrahydrofolate ("5-MTHF"). Following decades of research and tens of millions of dollars in investments, Merck was the first company to manufacture a pure and stable stereoisomer of L-5-MTHF, a 6S Isomer Product, as a commercial source.

Isomers are chemical compounds that have the same composition but differ in chemical arrangement, while stereoisomers are chemical compounds that differ only in their spatial arrangement around a carbon atom. In the predominant naming conventions of compounds, isomers are labeled with either a "D" or an "L" based on the isomer's relation to the glyceraldehyde molecule or "R" and "S" based on the isomer's relation to the carbon atom. In the context of folates, "S" or "L" refers to the naturally occurring isomer, and "R" or "D" refers to the non-natural isomer. If manufactured synthetically, a folate is "mixed" and would be identified as having both "D" and "L," or "R" and "S," and thus be labeled as either "D,L" or "R,S."

In 2006, Gnosis S.p.a. and Gnosis Bioresearch S.A. (collectively, "Gnosis") started making a folate product named "Extrafolate," a tetrahydrofolate that is a mixture of the R isomer and the S isomer, or a D-5-MTHF product. D-5-MTHF does not occur in nature and does not have the same nutritional benefits to humans as Merck's L-5-MTHF product. Because it is a mixed product, Extrafolate sells at a much lower price than Metafolin.

Between 2006 and 2009, Gnosis printed marketing materials, including brochures and product specification sheets, using chemical descriptions, terms, and formulas attributed to the pure 6S Isomer for the sale and marketing of its 6R,S Mixture Product. Gnosis sold its product to six customers, both directly and indirectly, during this time. In 2007, Merck sued Gnosis for misleading advertising in connection with its use of the pure Isomer Product chemical name and properties in its marketing materials for Extrafolate.

Following a bench trial, the Southern District of New York held that Merck had established Gnosis' liability for false advertising under Section 43(a) of the Lanham Act,[3] and awarded damages, prejudgment interest, and attorney's fees as well as a corrective advertising injunction.

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[1] *Merck Eprova AG v. Gnosis S.p.A.*, 2014 WL 3715078 (2d Cir. July 29, 2014).

[2] Formerly Merck Eprova AG.

[3] 15 U.S.C. § 1125(a).

II. The Court's Decision

The Second Circuit affirmed both the district court's finding of liability under the Lanham Act and the damages awarded. On appeal, Gnosis challenged the district court's conclusion that consumer confusion and injury could be presumed in light of its factual findings. Gnosis also challenged the district court's award of damages, including awarding Merck three times Gnosis' profits from the time when Gnosis entered the market until the date of the opinion, on the basis of presumptions of injury and customer confusion as opposed to proof of these elements.

Liability under the Lanham Act

First, the Court addressed the district court's imposition of the consumer confusion presumption. A Lanham Act plaintiff may prove actual consumer confusion or deception resulting from the violation, or that a defendant's actions were intentionally deceptive thus giving rise to a rebuttable presumption of consumer confusion, in order to receive an award of damages. The majority of Gnosis' challenged marketing materials were literally false because they used the common name for the pure 6S Isomer Product to discuss and advertise Extrafolate, a mixed product.[4] The marketing materials were implicitly false as well because they were used to mislead consumers into believing that they were purchasing a pure product rather than a mixed product. [5] Accordingly, the burden of proof had been correctly shifted to Gnosis to demonstrate an absence of consumer confusion.

Although the district court had not specifically addressed why Gnosis had failed to rebut the presumption, the Court found that the record strongly supported the conclusion that a significant number of consumers had been misled by Gnosis' labeling, including testimony from direct and indirect buyers of Extrafolate who did not understand the composition of the product or mistakenly believed that it was the pure isomer.[6] Though the district court's failure to "squarely address" the rebuttal evidence as to Gnosis' impliedly false statements alone may have potentially warranted remand, the Court held that the findings of literal falsity and the "egregious nature" of Gnosis' deliberate intent were more than enough to support the district court's imposition of the consumer confusion presumption.[7]

Second, the Court rejected Gnosis' argument that a presumption of injury is only applicable to cases of comparative advertising mentioning the plaintiff's product by name. Previously, the Second Circuit had held that in cases involving misleading, non-comparative commercials which touted the benefits of the products advertised but made no direct reference to any competitor's product "'some indication of actual injury and causation' would be necessary in order to ensure that a plaintiff's injury is not speculative."[8] By comparison, injury could be presumed in false comparative advertising cases. While the Court acknowledged that this was "not the typical comparative advertising case" because Gnosis did not disparage its competitor by mentioning Merck in an advertisement, the Court analogized the situation to that in *Time Warner Cable Inc.* v. *DirecTV*, a more recent Second Circuit decision.[9] In *Time Warner*, a satellite television company criticized cable generally without mentioning plaintiff Time Warner by name. There the Second Circuit held that the district court had properly

[4] *Id.* at 17-18.

[5] *Id.* at 19.

[6] *Id.* at 20-23.

[7] *Id.* at 24.

[8] *Id.* at 26 (quoting *McNeilab, Inc.* v. *American Home Prods. Corp.*, 848 F.2d 34, 28 (2d Cir.1988)).

[9] *Id.* at 27 (citing *Time Warner Cable Inc.* v. *DirecTV*, 497 F.3d 144 (2d Cir. 2007)).

accorded plaintiff a presumption of irreparable harm because "Time Warner *is* cable in the areas where it is the franchisee." As it was the only cable provider in the region, "consumers … would undoubtedly understand the derogatory statement [criticizing cable] as referring to [Time Warner]."[10] The Court found this decision to be instructive particularly because it involved a two-player market. Similarly, the Court concluded that, because Gnosis and Merck were the only direct competitors in the folate market, Merck was damaged by Gnosis' false advertising of the product and there was no risk of speculative injury. Thus, the Court extended its reasoning in *Time Warner* and held that where a plaintiff has met its burden of proving deliberate deception in the context of a two-player market, it is appropriate to utilize a presumption of injury, even when a plaintiff's advertisement does not mention a competitor's product by name.[11]

Damages

Gnosis challenged the entire scope of the district court's damages award, which included requiring Gnosis to pay Merck three times its profits, as well as prejudgment interest, attorney's fees and costs, and the imposition of a corrective advertising injunction. Specifically, Gnosis took issue with the award of damages on the basis of presumptions of customer confusion and injury, as opposed to proof of actual confusion and injury. Because the district court had properly found willful deception, which is a prerequisite for awarding profits under any theory, and had reasoned that a profits award was necessary to deter future unlawful conduct, this type of relief was found not to be an abuse of discretion. Further, the Court held that, as a general matter, the presumptions of injury and consumer confusion may be used for the purposes of awarding both injunctive relief and monetary damages to a successful plaintiff in false advertising cases in which parties in a two-player market are direct competitors and where literal falsity and willful, deliberate deception have been proved. The Court was also satisfied with the district court's justification for the trebling of damages, which was meant to reflect the intangible benefits Gnosis enjoyed as a result of its false advertising and deter future deceptive conduct.

As for Gnosis' challenges to the other forms of relief, the Court further affirmed the district court's judgment. It was noted that prejudgment interest is typically reserved only for "exceptional" cases, but that the finding of Gnosis' willful conduct in the two-player market context supported the conclusion that this was an exceptional situation and justified the award. Similarly, attorneys' fees may be awarded in exceptional cases under the Lanham Act, but given the circumstances of the case and proof that Gnosis had hampered the litigation process, the Court affirmed the award of attorney's fees as well as the district court's calculation of those fees. The Court took no issue with the corrective advertising campaign, as it was narrow in scope, designed to explain the difference between the pure and mixed products, and provided only the basic background of the case on its face. Lastly, the Court refused to award Merck fees and costs associated with the appeal because Gnosis had already been sanctioned and the appeal was non-frivolous.

III. Significance of the Decision

With this decision, Lanham Act plaintiffs are afforded a presumption of injury in cases where the plaintiff has met its burden of proving deliberate deception in the context of a two-player market, even where a plaintiff's advertisement does not mention a competitor's product by name. Prior to this decision, the presumption was only afforded to plaintiffs in comparative advertisement cases and plaintiffs in misleading, non-comparative commercials in which disparaging remarks were clearly targeting a particular competitor, regardless of whether they explicitly name the competitor.

[10] *Id.* at 26-27 (citing *Time Warner Cable Inc.* v. *DirecTV*, 497 F.3d 144 (2d Cir. 2007)(internal quotations omitted)).

[11] *Id.* at 29-30.

The Court also expanded the use of presumptions of injury and confusion in the context of awarding damages. Previously these presumptions were only explicitly allowed to be used to award injunctive relief. With this decision, the Court has opened the door to allow the award of monetary damages on the basis of these presumptions as well, at least in cases where the parties are direct competitors in a two-player market and where literal falsity and willful deception have been proved.

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If you have any questions about the issues addressed in this memorandum or if you would like a copy of any of the materials mentioned, please do not hesitate to call or email Charles A. Gilman at 212.701.3403 or cgilman@cahill.com; Jon Mark at 212.701.3100 or jmark@cahill.com; John Schuster at 212.701.3323 or jschuster@cahill.com; or Cynthia Smuzynska at 212.701.3832 or csmuzynska@cahill.com.