

IDEAS ON INTELLECTUAL PROPERTY LAW

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Al works shut out from copyright protection

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Isn't it obvious?

Presumption of obviousness knocks out patent

Patents that specify ranges — for example, a range of concentrations in a topical composition — can run into a presumption of obviousness that results in their inventions being deemed unpatentable. A pharmaceutical company ran into just that problem when the ranges cited in its patent for a skin treatment overlapped with those in some so-called "prior art."

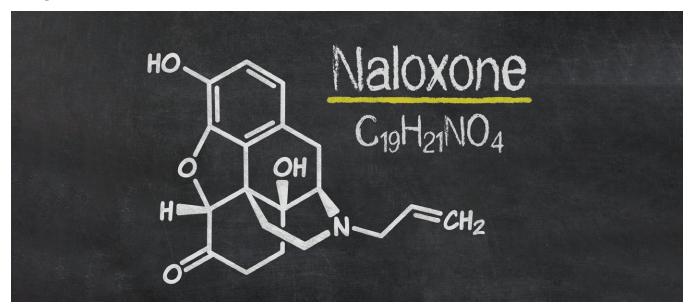
SKIN IN THE GAME

The case involved a patent for methods of treating acne or rosacea with a topical composition. The patent's formulations for the composition contain certain concentrations or concentration ranges of dapsone, as well as a type of thickening or gelling agent known as A/SA. The patent also includes a "negative limitation" stating that the composition doesn't include adapalene.

A rival pharmaceutical company filed a petition for inter partes review (IPR) with the U.S. Patent Trial and Appeal Board (PTAB). Under IPR, the board can reconsider and cancel an already-issued patent based on certain types of prior art. Prior art includes printed publications showing that the invention was anticipated or obvious. The PTAB held that the patent would have been obvious in light of three pieces of prior art: two earlier international patent applications for topical compositions (referred to as Garrett and Nadau-Fourcade, for their respective inventors) and a journal article. All three disclosed thickeners within the ranges claimed in the patent.

The PTAB found that the combination of Garrett and Nadau-Fourcade "teach" or suggest every claim limitation at issue in this case. It further found that a person of ordinary skill in the relevant field would have been motivated to incorporate the A/SA gelling agents used in Nadau-Fourcade into Garrett's formulations, which had called for a type of thickener known as carbomers. The court reached the same conclusion regarding the combination of the journal article, which used A/SA agents, and Garrett.

The board ultimately concluded that several of the patent claims were unpatentable. The patentee turned to the U.S. Court of Appeals for the Federal Circuit for relief.



OBVIOUSNESS DOESN'T REQUIRE "ABSOLUTE PREDICTABILITY"

The court in *Almirall* (see main article) also considered whether a skilled artisan in the relevant field would have had a reasonable expectation of success in substituting a thickener from an earlier patent application for a topical composition (the A/SA gelling agents) for the thickener used in the formulations of another application (carbomers). A finding of obviousness requires, among other things, that a skilled artisan would have had a reasonable expectation of success in combining or modifying prior art.

The U.S. Court of Appeals for the Federal Circuit explained that the requisite reasonable expectation of success can exist without "absolute predictability of success." It cited expert testimony that a skilled artisan would have understood that the substitution would have been routine and predictable because the A/SA agents were known for use in topical compositions with water-insoluble drugs.

The two kinds of thickeners were recognized as interchangeable gelling agents for topical formulations with dapsone that could be used in the same concentration range. This fact supported the reasonable success determination.

A TOPICAL APPLICATION

On appeal, the patentee contended that the PTAB shouldn't have applied a presumption of obviousness. The presumption arises when the ranges of a variable in a patent overlap the ranges cited (or "disclosed") in prior art.

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But the Federal Circuit found it wasn't improper to apply the presumption. In the absence of evidence that there's something special about the range in a challenged patent, the court said, an overlap with prior art suffices to show that the claimed range was obvious. And, absent a reason to conclude otherwise, the PTAB was justified in concluding that the range disclosed in Garrett disclosed the range in the challenged patent. That, the appellate court said, was enough to create a presumption of obviousness as to the claimed amounts in the patent — a presumption the patentee failed to overcome.

Moreover, the Federal Circuit found that the outcome would be the same even if the presumption didn't apply. The case didn't turn on overlapping ranges. Rather, it was a simply a case of substituting one known gelling agent for another. As the board found, a skilled artisan would have been motivated to make the substitution.

ONE MORE FIGHT TO PICK

The patentee also argued that the PTAB failed to account for the negative adapalene claim limitation. Garrett didn't indicate that any of its formulations included adapalene, but the patentee argued that wasn't enough to disclose or teach the negative limitation in its patent.

The court disagreed. It reiterated that prior art doesn't need to state the absence of a feature to disclose a negative limitation. It was reasonable for the board to find that a skilled artisan would recognize that Garrett discloses a complete formulation that excludes the possibility of an additional active ingredient, such as adapalene.

CLEARED UP

The PTAB and Federal Circuit's holdings provide valuable guidance on the applicability of the presumption of obviousness and what's required to disclose a negative limitation. They also reinforce the importance of carefully reviewing prior art and drafting patents accordingly.

Patent's on-sale bar drains damages

here can be a fine legal line between providing a quote and an offer for sale. An inventor recently learned this lesson the hard way in *Junker v. Medical Components, Inc.* — and it resulted in the invalidation of his patent and the reversal of a hefty infringement damages award.

COMMUNICATIONS ABOUND

Larry Junker sued Medical Components, Inc. (MedComp) for infringement of his design patent on a handle for so-called "introducer sheaths" used during catheter insertion. He had filed the application for the patent on his "peelable" handle on February 7, 2000.



By the time Junker had filed the application, he'd already developed a business relationship with the founder of a medical device company. In early 1999, the company produced a prototype of Junker's design. Around that same time, the founder of the company began communicating with another company about a peelable introducer sheath product. In response to a request from that company, the founder sent a letter detailing bulk pricing information for variously sized peelable introducer sheaths.

Junker sued MedComp in 2013. The trial ended in Junker's favor, and he was awarded damages of more than \$1.2 million. MedComp appealed, arguing, among other things, that the patent was invalid under the on-sale bar because of the 1999 letter.

COURT PEELS APART THE LETTER

Under the law, a patent can be deemed invalid by a tribunal if, more than one year before the application date for the patent, the invention was the subject of a commercial sale or offer for sale by the inventor.

The invention was ready for patenting, so the only question for the Court of Appeals was whether the 1999 letter was a commercial offer for sale meaning the recipient could create a binding contract by simply accepting the offer (assuming consideration is paid). According to the appellate court, relevant factors when determining whether such an offer has been made include:

- The terms of any previous inquiry,
- The completeness of the terms of the suggested bargain, and
- The number of persons to whom a communication is addressed.

The letter here directly responded to a request for a quotation and was addressed solely to the company that made the request. The Federal Circuit took this as a signal that the letter wasn't an unsolicited price quotation or invitation to negotiate but rather a specific offer to the company to take further action.

Moreover, the letter included several terms typically necessary for a commercial contract. For example, it provided specific delivery conditions (shipped in "bulk" and "non-sterile").

It also indicated that shipment would be "free on board," or FOB, a standard commercial term that allocates the risks and responsibilities of the buyer and seller regarding delivery, payment and loss of the product. It provided a payment term of "net 30-day basis." And the court highlighted the fact that the letter specified multiple different purchase options.

The Federal Circuit acknowledged that the letter concluded with an invitation for further in-person discussion of the recipient's specific requirements. It explained, though, that expressing a desire to do future business doesn't negate the commercial character of the transaction then under discussion.

Overall, the court said, the completeness of the relevant commercial sale terms indicated that the letter was multiple offers for sale. The recipient could have accepted any one or more of the offers to bind the parties in a contract. Therefore, the on-sale bar applied, the patent was invalidated, and the damages award was reversed.

Finally, the Federal Circuit wasn't persuaded by the three uses of the word "quote" in the letter.

The court said the precise label is relevant but not controlling. Where a purported quote includes detailed terms, it may well be deemed an offer.

> A commercial offer for sale means the recipient could create a binding contract by simply accepting the offer (assuming consideration is paid).

CAREFUL WRITING

The upshot of this case? Protecting a patent is more than confronting infringers after the patent issues. You need to be careful with actions that can be interpreted as commercializing your invention prior to seeking patent protection. The life of your patent depends on it.

Package it up Bakery's trade dress claim falls

hen designing product packaging, you generally want it to clearly identify your product. In *Bimbo Bakeries USA, Inc. v. Sycamore*, the U.S. Court of Appeals for the Tenth Circuit has ruled that a baking company's trade dress used elements so customary in the industry that it was generic and not subject to trademark protection under the federal trademark law known as the Lanham Act.

RECIPE FOR LITIGATION

Bimbo Bakeries owns, makes and sells Grandma Sycamore's Home-Maid Bread, a popular brand in Utah. It obtained the right to the recipe from a baker named Leland Sycamore, who later opened his own bakery. U.S. Bakery, a competitor of Bimbo, hired Sycamore's bakery to make another homemade bread called Grandma Emilie's. After their relationship soured, U.S. Bakery developed a new formula for Grandma Emilie's and created packaging that resembled Grandma Sycamore's packaging.

Bimbo sued U.S. Bakery on multiple grounds, including trade dress infringement. The district court dismissed that claim before trial and Bimbo appealed.

INFRINGEMENT INGREDIENTS

Trade dress refers to an object's total image and overall appearance. It can include features such as size, shape, color or color combinations, texture, graphics, and even particular sales techniques.



To establish trade dress infringement, a plaintiff must show:

- Its trade dress is "inherently distinctive" or has become distinctive,
- There is a likelihood of confusion among consumers about the source of the competing products, and
- The trade dress is nonfunctional.

Trade dress is inherently distinctive if its intrinsic nature identifies its source. Trade dress that isn't inherently distinctive can nonetheless gain legal protection if it has developed secondary meaning — in other words, if, in the minds of the public, the primary significance of the trade dress is to identify the product's source, rather than the product itself.

Courts use five categories when determining whether trade dress is inherently distinctive: fanciful, arbitrary, suggestive, descriptive and generic. The first three are entitled to legal protection; descriptive trade dress can acquire protection through secondary meaning. Generic trade dress isn't protectible.

SLICING ANALYSIS

As the appeals court noted, where it is industry custom to package products in a particular manner, trade dress in that style is generic. Ultimately, this principle doomed Bimbo's appeal.

The court agreed with the district court that the trade dress for Grandma Sycamore's product was customary for homemade bread products. Bimbo's competitors in that sector all tended to use a horizontal label with a design at the top center of the end; the word "white" in red letters; and a red, yellow and white color scheme. They generally also used a stylized font below the design, outlined in white.

Trade dress refers to an object's total image and overall appearance and can include features such as size, shape, color or color combinations, texture, graphics, and even particular sales techniques.

The court concluded, therefore, that Bimbo's purported trade dress was generic and not protected. It affirmed the district court's judgment in favor of U.S. Bakery.

NOT TOTALLY COOKED

All hope wasn't lost for Bimbo following the court's ruling. The Tenth Circuit concluded that Bimbo "may well have a protectable Grandma Sycamore's trade dress." Its trade dress claim in this case, however, was too broad and extended far beyond its product's more specific attributes.

Al works shut out from copyright protection

rtificial intelligence (AI) has made inroads in a wide array of areas, but it has yet to break down the barriers to copyright protection. The U.S. Copyright Office continues to refuse to register a copyright on works created by AI. The Review Board of the U.S. Copyright Office (board) explained its reasoning earlier this year.

DOES NOT COMPUTE

In 2019, the Copyright Office refused to register Steven Thaler's two-dimensional artwork. According to Thaler, the work was autonomously created by AI, without any creative contribution from a human. He sought to register the work as the owner of the "Creativity Machine" that made the work.



The Copyright Office denied registration because the work lacked human authorship. Thaler requested reconsideration, and the Copyright Office came to the same conclusion. He then submitted a second request for reconsideration. The result was the same.

LACKS THE HUMAN TOUCH

Copyright law protects only "the fruits of intellectual labor" that "are founded in the creative powers of the

[human] mind." Thus, Thaler had to provide evidence that the work was the product of human authorship.

But Thaler instead argued that the human authorship requirement is unconstitutional and unsupported by statute or court precedent. The board disagreed, finding that courts — including the U.S. Supreme Court — interpreting the Copyright Act have "uniformly" limited copyright protection to works created by humans.

Although it conceded that it knew of no U.S. court that has weighed whether AI can be the author for copyright purposes, the board determined that courts have been consistent in finding that non-human expression is ineligible for copyright protection. The board also found that federal agencies have followed the courts' lead on this issue.

The board cited a recent report from the U.S. Patent and Trademark Office (USPTO) for further support. The USPTO sought public comment on whether a work produced by AI, without the involvement of a "natural person," qualifies as a work of authorship under the Copyright Act. The vast majority of commenters acknowledged that existing law doesn't allow non-humans to be authors and that this should remain the law.

ALTERNATIVE REALITY FAILS, TOO

The board also rejected Thaler's second argument — that the work-for-hire doctrine allows for non-human, artificial persons such as companies to be authors.

The board pointed out that a work-for-hire is created as the result of a binding legal contract, and the Creativity Machine can't enter such contracts. Moreover, the doctrine addresses only the identity of a work's owner, not whether it's protected by copyright.

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