

# United States Court of Appeals for the Federal Circuit

06-1169

PHG TECHNOLOGIES, LLC,

Plaintiff-Appellee,

v.

ST. JOHN COMPANIES, INC.,

Defendant-Appellant.

Lea Hall Speed, Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C., of Memphis, Tennessee, argued for plaintiff-appellee. With her on the brief was W. Edward Ramage, of Nashville, Tennessee.

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Appealed from: United States District Court for the Middle District of Tennessee

Judge Robert L. Echols

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DECIDED: November 17, 2006

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Before MICHEL, Chief Judge, DYK, and PROST, Circuit Judges.

PROST, Circuit Judge.

Defendant-Appellant, St. John Companies, Inc. (“St. John”), appeals the decision of the United States District Court for the Middle District of Tennessee granting a preliminary injunction in favor of Plaintiff-Appellee, PHG Technologies, L.L.C. (“PHG”). Because we find that St. John has raised a substantial question of the validity of the two patents at issue, the district court abused its discretion by granting PHG’s motion for a preliminary injunction. Therefore, we vacate the preliminary injunction.

## I. BACKGROUND

PHG and its predecessors have been in the business of selling certain medical patient identification labels as well as identification labeling software in the United States

since 1995. PHG owns the two design patents at issue in this case: United States Patent Nos. D496,405 (the “405 patent”) and D503,197 (the “197 patent”). The ’405 patent claims “[t]he ornamental design for the medical label sheet, as shown.” The ’197 patent claims “[t]he ornamental design for a label pattern for a medical label sheet, as shown.” Figure 1 from the ’405 patent and figure 1 from the ’197 patent appear below, respectively:

FIG. 1

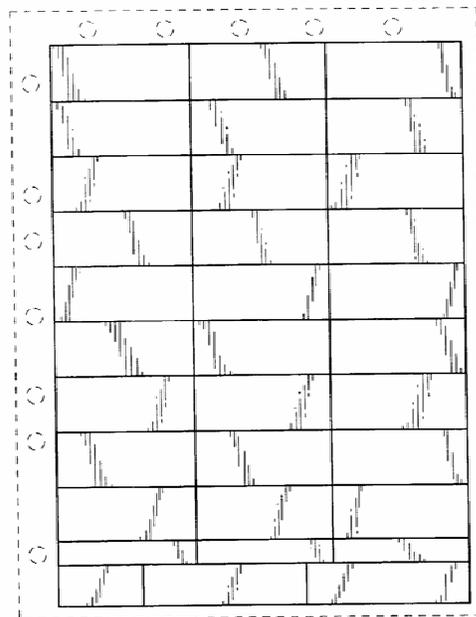
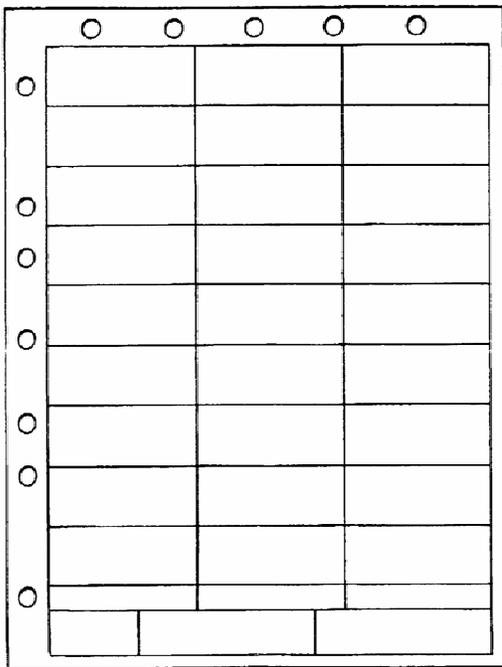


FIG.1

As can be seen, both designs include eleven rows of labels, with each row containing three labels. The first nine rows are depicted to contain three labels of equal size, the size being consistent with a standard medical chart label. The tenth and eleventh row each contain differently-sized labels which apparently correspond to the size of a pediatric and adult patient wristband respectively. The difference between the two patents is that the border is part of the design claimed in the ’405 patent but not part of

the design claimed in the '197 patent. The '405 and '197 patents depend from a utility parent application, No. 09/952,425 (the "425 utility application"), which is still pending at the United States Patent and Trademark Office.

St. John also sells medical patient identification labels in the United States in competition with PHG.<sup>1</sup> On May 13, 2004, before PHG's design patents issued, PHG informed St. John by letter that the design of St. John's medical label sheet infringed the intellectual property rights of PHG and that PHG anticipated that patents covering the accused design would be issued in the future. St. John did not respond to the May 13th letter and continued to sell its medical label sheet. After the two patents issued, PHG filed suit on August 11, 2005 alleging, inter alia, that St. John's medical label sheet infringed the '405 and '197 patents.

On August 26, 2005, two weeks after filing suit, PHG moved for a preliminary injunction against St. John's continued sale of its accused medical label sheet. The district court held an evidentiary hearing on November 22, 2005. St. John argued that the patented medical label sheets are primarily functional and presented evidence from the prosecution history of the '425 utility application and from an affidavit submitted by Adam Press, St. John's Chief Executive Officer, in support of its argument. PHG presented the testimony of Mr. Moyer, one of the inventors of the patents at issue. Mr. Moyer testified that he and Mr. Stewart, his co-inventor, experimented with different

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<sup>1</sup> Part of St. John's business model involves securing a contract with a large purchasing organization, performing a "label collect" in which every label used by any hospital within the organization is collected, copying those labels, and offering them at reduced prices to those hospitals.

configurations of the medical labels and chose the claimed designs because they were the “most aesthetically pleasing to us.”

On December 5, 2005, the district court granted PHG’s motion for a preliminary injunction and made, inter alia, the following findings with respect to the validity of the patents: (1) the design claimed is not dictated by its function; (2) the different sizes and arrangement of labels on PHG’s claimed design are primarily ornamental because there are other ways to arrange different sizes of labels on an 8 1/2” x 11” sheet; (3) the inventors of the design considered various arrangements and chose the patented design because it had “the best flow and look”; and (4) the novel features of PHG’s designs, particularly the placement of the various sizes of labels at the bottom of the sheet, distinguishes PHG’s designs from the prior art. Additionally, the district court made the following findings pertaining to infringement of the patents by St. John’s medical label sheet: (1) when compared, St. John’s medical label sheet and the patented design are identical and an ordinary observer would be “very hard-pressed” to identify any differences in the two designs; and (2) St. John’s accused design appropriates the novelty of PHG’s patented design, which distinguishes it from the prior art—the different sizes of labels and their placement on the sheet. Finally, the district court found that PHG is entitled to a rebuttable presumption of irreparable harm and the evidence confirms that PHG has suffered and will continue to suffer substantial damage in lost sales, business opportunities, and customer goodwill if St. John is not enjoined from continuing to market its accused design. See PHG Techs., L.L.C. v. St. John Cos., No. 03:05-0630 (M.D. Tenn. Dec. 5, 2005) (“Preliminary Injunction Opinion”). Based on these findings, the court concluded that PHG demonstrated a reasonable likelihood of

success on the merits, established that it would be irreparably harmed if an injunction did not issue and showed that the balance of hardships and the public interest weigh in favor of enjoining St. John from continuing to sell its accused design.

St. John appeals the district court's grant of the preliminary injunction against its accused medical label sheet design. We have jurisdiction pursuant to 28 U.S.C. § 1292(a)(1).

## II. DISCUSSION

### A. Standard of Review

This court reviews a district court's decision granting a motion for preliminary injunction for an abuse of discretion. Novo Nordisk of N. Am., Inc. v. Genentech, Inc., 77 F.3d 1364, 1367 (Fed. Cir. 1996). "To overturn the grant of a preliminary injunction, we must find that the district court made a clear error of judgment in weighing the relevant factors or based its exercise of discretion on an error of law or on clearly erroneous factual findings." Pfizer, Inc. v. Teva Pharms., USA, Inc., 429 F.3d 1364, 1372 (Fed. Cir. 2005). Whether a patented design is functional or ornamental is a question of fact.

A decision to grant or deny a preliminary injunction is based on the district court's consideration of four factors: "(1) the likelihood of the patentee's success on the merits; (2) irreparable harm if the injunction is not granted; (3) the balance of hardships between the parties; and (4) the public interest." Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1338-39 (Fed. Cir. 2003) (citing Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001)). "Our case law and logic both require that a movant cannot be granted a preliminary injunction unless it establishes both of the first

two factors, i.e., likelihood of success on the merits and irreparable harm.” Amazon.com, 239 F.3d at 1350. In order to establish the first preliminary injunction factor, PHG must show that it will likely prove that St. John infringes the ’405 and ’197 patents. However, in order to defeat the injunction on grounds of potential invalidity, St. John, as the party bearing the burden of proof on the issue at trial, must establish a substantial question of invalidity. See Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal, 126 S. Ct. 1211, 1219-20 (2006) (“[T]he burdens at the preliminary injunction stage track the burdens at trial.”); see also Ashcroft v. Am. Civil Liberties Union, 542 U.S. 656, 666 (2004).

## B. Analysis

On appeal, St. John challenges the district court’s findings with respect to only the first preliminary injunction factor—the likelihood of success on the merits. St. John argues that the district court erred by finding that (1) PHG will likely prove infringement and (2) St. John’s challenge to the validity of the patents at issue lacks substantial merit (i.e., does not raise a substantial question concerning the validity of the patents). We begin with St. John’s challenge to the validity of PHG’s asserted patents.

### 1. Substantial Question of Validity

St. John asserts that the district court erred in finding that the patented designs are primarily ornamental rather than merely a byproduct of functional considerations. In support of its assertion of functionality, St. John points to various statements made by PHG in the prosecution of the ’425 utility application and to statements made by Mr. Press in an affidavit submitted to the court. St. John argues that the statements made during prosecution and those submitted by Mr. Press constitute a clear and convincing

showing of functionality. Further, St. John asserts that because PHG presented no evidence to rebut St. John's showing of invalidity, the district court clearly erred in finding that the patented designs are primarily ornamental.

PHG responds that the district court correctly determined that St. John failed to raise a substantial question regarding the functionality of the designs because the patented designs were not dictated by the use or purpose of the article of manufacture—a medical label sheet. PHG concedes that the design has functional features but argues that the arrangement of the different sizes of labels on the sheet is primarily ornamental because, as found by the district court, “there are a multitude of ways to arrange different sizes of labels on an 8 1/2” x 11” sheet.” Further, PHG accuses St. John of focusing solely on the individual features of the claimed designs rather than analyzing the overall appearance to determine if the designs were dictated by functional considerations.

The district court determined that St. John failed to carry its burden of raising a substantial question of validity of PHG's design patents to defeat PHG's motion for preliminary injunction. The district court's sole finding with regard to St. John's assertion of invalidity was that the design was not dictated by its function because “[t]he testimony revealed [that] there are a multitude of ways to arrange different sizes of labels on an 8 1/2” x 11” sheet.” Preliminary Injunction Opinion, slip op. at 12. In support, the district court noted that “Brian Moyer testified that PHG considered various arrangements for medical label sheets and settled on the design ultimately patented because it had ‘the best flow and look.’” Id. In sum, the district court concluded that “[t]he different sizes of labels and the arrangement of those labels on PHG's Medical

Label Sheet are primarily ornamental because there are other ways to arrange different sizes of labels on an 8 1/2" x 11" sheet." Id., slip op. at 13-14.

"Whoever invents any new, original and ornamental design for an article of manufacture may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 171 (2006). As the statute indicates, a design patent is directed to the appearance of an article of manufacture. L.A. Gear, Inc. v. Thom McAn Shoe Co., 988 F.2d 1117, 1123 (Fed. Cir. 1993). "If the patented design is primarily functional rather than ornamental, the patent is invalid." Power Controls Corp. v. Hybrinetics, Inc., 806 F.2d 234, 238 (Fed. Cir. 1986). The design of a useful article is deemed to be functional when "the appearance of the claimed design is 'dictated by' the use or purpose of the article." L.A. Gear, 998 F.2d at 1123; see also Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1378 (Fed. Cir. 2000).

"[T]he determination of whether the patented design is dictated by the function of the article of manufacture must ultimately rest on an analysis of its overall appearance." Berry Sterling Corp. v. Pescor Plastics, Inc., 122 F.3d 1452, 1455 (Fed. Cir. 1997). Our cases reveal a "list of . . . considerations for assessing whether the patented design as a whole—its overall appearance—was dictated by functional considerations," including:

whether the protected design represents the best design; whether alternative designs would adversely affect the utility of the specified article; whether there are any concomitant utility patents; whether the advertising touts particular features of the design as having specific utility; and whether there are any elements in the design or an overall appearance clearly not dictated by function.

Id. at 1456 (emphasis added). In particular, we have noted that "[t]he presence of alternative designs may or may not assist in determining whether the challenged design can overcome a functionality challenge. Consideration of alternative designs, if present,

is a useful tool that may allow a court to conclude that a challenged design is not invalid for functionality.” Id. “When there are several ways to achieve the function of an article of manufacture, the design of the article is more likely to serve a primarily ornamental purpose.” Rosco, 304 F.3d at 1378.

Our case law makes clear that a full inquiry with respect to alleged alternative designs includes a determination as to whether the alleged “alternative designs would adversely affect the utility of the specified article,” such that they are not truly “alternatives” within the meaning of our case law. Id. In this case, while the district court relied exclusively on its finding that there were a multitude of alternative designs, the court did not make any findings with respect to whether any of the alternatives would adversely affect the utility of the medical label sheet. One might presume that the district court’s findings with respect to alternatives implicitly include the additional finding that the alternatives did not adversely affect the utility of the medical label sheet. The difficulty in doing so in this case, however, is that the district court makes no reference to St. John’s evidence that the overall arrangement of the labels on the medical label sheet was dictated by the use and purpose of the medical label sheet and that alternative designs lacking that arrangement would adversely affect the utility of the sheet. Specifically, St. John presented Mr. Press’s affidavit, in which he stated:

The labels for use on the wristbands themselves are located on the bottom two rows of the sheet as these are usually the first labels used when a patient is admitted to a medical facility. The lower right hand corner is the easiest location for a right-handed user to remove the label as it is flush to an edge and unencumbered by a file or binder clip along the top or left hand margins. By placing the labels for the wristbands at the bottom of the page, the subsequent removal of additional labels adjacent to the removed label is facilitated.

(Press Aff. ¶ 5.d.)

Mr. Press's affidavit constitutes evidence that alternative designs, which do not include the "novel feature" of PHG's design—the placement of various sizes of medical labels at the bottom of the sheet—would adversely affect the utility of the medical label sheet. It articulates a clear functional reason why the use and purpose of the article of manufacture dictated that the "wristband" labels be located at the bottom of the sheet. Additionally, PHG's statements during prosecution of the '425 utility application indicate that there were functional reasons for each of the other features of the medical label sheet, including: for creating one sheet containing labels of different sizes; for the particular sizes of each differently-sized label; for the size of the sheet itself; and for including holes along the side and top of the sheet.

While a district court's determination as to whether a design is primarily ornamental is reviewed for clear error, in this case there is no explicit finding by the court on whether the alleged alternatives are in fact functionally equivalent (i.e., that the alternatives do not adversely affect the utility of the medical label sheet), or any mention or finding whatsoever with respect to the evidence presented in Mr. Press's affidavit. The evidence presented by St. John, in our view, was sufficient to raise a substantial question of invalidity. The only evidence presented by PHG and relied upon by the district court was Mr. Moyer's testimony that he and his co-inventor chose the patented designs because they had "the best flow and look." PHG did not offer testimony refuting the assertions made in Mr. Press's affidavit—that functional considerations dictated the medical label design, specifically the "novel feature" of the differently-sized labels being placed at the bottom of the sheet. In fact, on cross-examination Mr. Moyer testified that the original intent in designing a medical label sheet with differently-sized labels was

“functional.” Therefore, this case is clearly distinguishable from L.A. Gear, in which the patentee introduced evidence indicating that “a myriad of athletic shoe designs” could achieve the same functions that were achieved by the patented designs and “[i]t was not disputed that there were other ways of designing athletic shoes to perform the functions of the elements of the [patented] design.” 988 F.2d at 1123.

Further, we reject PHG’s assertion that St. John’s analysis focuses solely on the individual features of the designs rather than their overall appearance. The evidence presented by St. John not only addresses the individual features of the designs, but also their overall appearance.<sup>2</sup> Mr. Press’s statements directly pertain to the overall arrangement of the designs as a whole and indicate that the use and purpose of the

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<sup>2</sup> Although our case law recognizes that the relevant inquiry with respect to a design patent is the overall appearance of the design, this court invariably also considers whether the elements of the design are themselves dictated by the purpose or use of the article of manufacture. See Power Controls, 806 F.2d at 240 (“In determining whether a design is primarily functional, the purposes of the particular elements of the design necessarily must be considered.”); see also L.A. Gear, 988 F.2d at 1123 (noting that the record showed “the existence of a myriad of athletic shoe designs in which each of the functions identified by [the alleged infringer] as performed by the [patented] design elements was achieved in a way other than by the design of the . . . patent” (emphasis added)).

Therefore, St. John’s evidence that the particular elements of PHG’s designs were dictated by the use or purpose of the medical label sheet “necessarily must be considered.” St. John’s evidence in this regard includes PHG’s statements during prosecution of the ’425 utility application indicating that the particular elements of the designs are dictated by the use or purpose of the medical label sheet. While PHG argues that a utility application may be drawn to different features of the same product, a statement with which we whole-heartedly agree, PHG has not done so in this case. Its statements in prosecution are directed to the same features of the medical label sheet as the design. For example, the medical label sheet itself is ideally of standard-size, 8 1/2” x 11”, and the three different label sizes are all standard-sized as well, one size being standard for medical charts and record books, another for adult patient wristbands, and a third for pediatric patient wristbands. Therefore, PHG’s statements during prosecution are relevant to whether the elements of the design are primarily ornamental, and as discussed infra, are also relevant to whether the designs’ overall appearance was “dictated by” its use and purpose.

medical label sheet dictate that the wristband-sized labels be located at the bottom of the sheet. See supra. His statements reasonably indicate that once the location of the wristband-sized labels has been dictated by the use and purpose of the medical label sheet, the location of the remaining labels is necessarily dictated as well. This is because the remaining labels, as well as the medical label sheet itself, are of standard size. Therefore, in order to maximize the efficient use of space on the sheet, the location and number of the medical chart and record labels is dictated by the placement of the wristband-sized labels at the bottom of the sheet. St. John's evidence thus directly pertains to, and is sufficient to raise a substantial question with respect to, whether the overall appearance of the patented designs is "dictated by" the medical label sheet's use and purpose. Because St. John has satisfied its burden of raising a substantial question of invalidity, the district court's finding that PHG was likely to show that the patented designs were primarily ornamental is clearly erroneous.

We also note that, contrary to PHG's assertion, the facts in this case are distinguishable from those presented in Rosco. In Rosco, this court reversed the district court's finding of invalidity based on functionality because the record indicated that other mirror designs "that have non-oval shapes also offer that particular field of view . . . and the record shows that other non-oval shaped mirrors have the same aerodynamic effect." 304 F.3d at 1378. In this case, however, the evidence of record at this preliminary stage indicates that other medical label designs would adversely affect the utility of the medical label sheet, and the district court made no findings to the contrary.

## 2. Infringement

St. John's argument on infringement is that the patented designs do not have any non-functional features to identify in claim construction and therefore there is nothing to compare in an infringement analysis. Alternatively, St. John asserts that the "contrasting grid-like pattern" is ornamental and the "point of novelty" that must be found in the accused design for infringement to occur.

In light of our conclusion—that St. John has raised a substantial question of the design patents' validity—we need not reach St. John's arguments with respect to infringement to conclude that St. John has failed to show that it will likely succeed on the merits. Therefore, the first preliminary injunction factor weighs in favor of St. John.

## III. CONCLUSION

St. John's challenge to the district court's grant of PHG's motion for a preliminary injunction was based solely on its assertion that PHG could not establish the first preliminary injunction factor—the likelihood of success on the merits. St. John has shown, based on the evidence of record at this preliminary stage, that the district court clearly erred in concluding that PHG met its burden of proving that it is likely to succeed on the merits. Because PHG has not established that at least the first preliminary injunction factor—likelihood of success on the merits—weighs in its favor, see Amazon.com, 239 F.3d at 1350, the district court abused its discretion in granting PHG's motion for a preliminary injunction.

Accordingly, we vacate the district court's grant of a preliminary injunction.

## COSTS

Each party shall bear its own costs.

## VACATED