IN THE UNITED STATES COURT FOR THE DISTRICT OF UTAH CENTRAL DIVISION

WORLD HEALTH PRODUCTS, LLC, a Utah limited liability company,

Plaintiff,

ORDER & MEMORANDUM DECISION

VS.

CHELATION SPECIALISTS, LLC, a Utah limited liability company, RONALD PARTAIN, JR., an individual, RONALD PARTAIN, SR., an individual, PATRICK HAYES, an individual, and DOES 1 through 5,

Defendants.

Case No. 2:06 CV 633

Plaintiff World Health Products, LLC, created and now markets a suppository product called Detoxamin. The Detoxamin suppository provides one method by which an individual can pursue chelation therapy. Chelation therapy involves the removal of heavy metals and other materials from the body.

Now before the court is World Health's motion for a preliminary injunction barring

Defendant Chelation Specialists, LLC, as well as other individually named defendants

(collectively "Chelation") from marketing a competing product, called Kelatox. World Health

alleges that Kelatox infringes a patent held by World Health and also claims that Chelation

misappropriated World Health's customer list in an effort to steal customers.

World Health is unable to establish that it will likely succeed on the merits of its case.

Additionally, consideration of the harm that an injunction would cause, as well as the public's interest, leads to the conclusion that an injunction is not warranted.

Background

People have utilized chelation therapy for many years. But until World Health went to market with its product, chelation therapy was confined to oral and intravenous administration. Seeking a more desirable administration solution, World Health developed Detoxamin, an anal suppository chelation treatment. This method of delivery had the advantage of a higher absorption rate than oral administration and was more attractive to some users of chelation therapy than intravenous delivery.

According to Kendal Svedeen, a managing member of World Health, the suppository market for chelation therapy was virtually created by World Health. As a result, World Health has spent considerable sums of money to test the efficacy of its product and to market its product to distributors, doctors, and individuals.

To aid in its sales and promotional activities, World Health associated itself with Patrick Hayes. World Health did not directly hire Mr. Hayes as an employee. Rather, World Health engaged Trident Consulting, LLC, a company that Mr. Hayes had previously created. Although the employment situation was structured in this somewhat unusual way, Mr. Hayes was essentially an employee of World Health. Mr. Hayes reported directly to Mr. Svedeen and was expected to be in World Health's office from eight to five each work day. While working at World Health, Mr. Hayes was constantly in contact with World Health customers. He fielded a high volume of telephone enquires and by all accounts served as the primary contact of World Health customers.

While Mr. Hayes was away on vacation, Mr. Svedeen received a phone call that caused

him great concern. The caller requested information about Kelatox, which the caller indicated was a chelation therapy product administered in suppository form. After finishing the phone conversation, Mr. Svedeen performed an Internet search and discovered that Kelatox was being offered as a low-cost alternative to Detoxamin. Further investigation revealed that Mr. Hayes, while working at World Health, had spent several months creating a new company that would directly compete with World Health.

Mr. Hayes had started the company, Chelation, with a former employee of World Health, Ronald Partain, Jr. Also involved was Ronald Partain, Sr., who had previously made suppositories on behalf of World Health and was a member of World Health's board of directors at the time of Chelation's creation. Mr. Svedeen confronted Mr. Hayes and immediately terminated Mr. Hayes's employment relationship with World Health.

World Health then filed this lawsuit, claiming that Chelation's product, Kelatox, infringes on a patent held by World Health. In addition to the patent infringement claim, World Health asserts several causes of action, including misappropriation of trade secrets, unfair competition, and tortious interference with business relationships. World Health also filed a request for a preliminary injunction prohibiting Chelation from infringing World Health's patent and requiring Chelation to return and discontinue using all misappropriated trade secrets.

Analysis

To obtain injunctive relief, the moving party must establish that: (1) it will likely prevail on the merits of the litigation; (2) it will suffer irreparable injury unless an injunction is issued; (3) its threatened injury outweighs any harm the proposed injunction may cause to the opposing party; and (4) an injunction, if issued, would not be adverse to the public interest. See Elam Const., Inc. v. Regional Transp. Dist. 129 F.3d 1343, 1346-47 (10th Cir. 1997). "Because a

preliminary injunction is an extraordinary remedy, the movant's right to relief must be clear and unequivocal." <u>Dominion Video Satellite, Inc. v. EchoStar Satellite Corp.</u>, 269 F.3d 1149, 1154 (10th Cir. 2001) (citing Kikumura v. Hurley, 424 F.3d 950, 955 (10th Cir. 2001)).

Although World Health alleges numerous causes of action in its complaint, it has only sought preliminary injunctive relief on its patent infringement and misappropriation of trade secrets claims.

I. Likelihood of Success on the Merits

A. Patent Infringement

"[F]or a court to find infringement, the plaintiff must show the presence of every element or its substantial equivalent in the accused device." Wolverine World Wide, Inc. v. Nike, Inc., 38 F.3d 1192, 1199 (Fed. Cir. 1994). When faced with a request for preliminary injunctive relief in a patent infringement dispute, a comprehensive and final claim construction is not required.

See Sofamor Danek Group, Inc. v. DePuy-Motech, Inc., 74 F.3d 1216, 1221 (Fed. Cir. 1996)

("[T]he trial court has no obligation to interpret [a] claim . . . conclusively and finally during a preliminary injunction proceeding."); cf. Black & Decker, Inc. v. Hoover Serv. Ctr., 886 F.2d 1285, 1296 n. 16 (Fed. Cir. 1989) ("Decisions on preliminary relief do not preclude trial on the merits . . . though preclusion may be appropriate when the evidence is the same . . .").

World Health alleges that Chelation is infringing patent number 5,602,180 (the "'180 patent"), which is held by World Health. The '180 patent claims: "A suppository for chelation therapy, said suppository comprising an inert meltable carrier containing dissolved or suspended disodium EDTA and a controlled-release matrix for releasing the complexes into the body over a period of three to four hours after anal administration of the suppository." (United States Patent Number 5,602,180, Feb. 11, 1997, attached as Ex. A to Memo. in Supp. of Defs.' Mot. for Part.

Summ. J. & in Opp'n to Plf.'s Mot. for Prelim. Injunc. (dkt. #32-1)[hereinafter Memo. in Opp'n]).

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks and quotation omitted). Words used in a patent claim "are generally given their ordinary and customary meaning." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The Federal Circuit has frequently stressed that claim construction should not occur in a vacuum and that courts should consider the language of the claims in light of the patent's specification and prosecution history. See Phillips, 415 F.3d at 1317. Indeed, in Phillips, the Federal Circuit highlighted the value of examining a patent's prosecution history when interpreting the patent's claims:

The prosecution history, which we have designated as part of the 'intrinsic evidence,' consists of the complete record of the proceedings before the [Patent and Trademark Office] [T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.

Id.

In this case, the claim language, when viewed in light of the patent's prosecution history, indicates that World Health is unlikely to successfully argue that Chelation's Kelatox product infringes the '180 patent. World Health alleges that Kelatox is identical to World Health's Detoxamin product. Further, and more importantly, World Health asserts that the '180 patent covers the Detoxamin formula and, by extension the Kelatox formula as well. The evidence does indicate that the two products are virtually identical. Both are anal suppositories designed to provide chelation therapy. Both utilize an inert carrier that contains calcium disodium ethylene

diamine tetraacetic acid. Both use a controlled-release matrix. And, although Chelation claims that Kelatox is distributed through the body at a slightly quicker rate than Detoxamin, the treatment times associated with the products are similar.

While World Health may be correct that Kelatox is virtually indistinguishable from Detoxamin, its claim of patent infringement is not likely to succeed because the products sold by both World Health and Chelation differ from the suppository claimed in the '180 patent. Specifically, both the Detoxamin and Kelatox suppositories deliver <u>calcium</u> disodium EDTA, while the '180 patent claims only delivery of disodium EDTA. While this distinction can be seen on the face of the patent itself, the prosecution history shows that the distinction between calcium disodium EDTA and disodium EDTA was recognized by the inventor of the '180 patent and that the inventor expressly disclaimed the use of calcium disodium EDTA in pursuing the patent.

For example, after the patent application was initially rejected, the applicant responded with an amendment to the application, hoping to allay the concerns that prompted the initial rejection. The applicant took great pains to stress that the presence of calcium in the EDTA preparation would severely hamper the purpose of the suppository, rendering it ineffective for its intended purpose. For example, the applicant stated that "[i]n the lower bowel, the disodium EDTA would be a highly effective chelating agent for a suppository, whereas Calcium EDTA would not be." (Amendment 2, attached as Ex. C. to Memo. in Opp'n.) The applicant also stated that "[t]he use of Calcium EDTA, as in the Rosenberg patent, would be completely ineffective in an anal suppository." (Id. at 3.) Most tellingly, the applicant stressed the ineffectiveness of calcium disodium EDTA considering the purpose the suppository was designed to serve. "The disease target of the present invention is atherosclerosis. The disease ...

. is a chronic metabolic disorder in which calcium ion plays a role in the formation of arterial plaque EDTA administration relieves the disorder by removing calcium from the blood stream." (Id. at 3-4.) The parties' filings with the court indicate that calcium disodium EDTA would not effectively remove calcium from the blood stream because calcium is already present in the compound, which would prevent the compound from attaching itself to additional calcium found in the bloodstream.

In short, the plain language of the patent, combined with the prosecution history, support the conclusion that the claims of the '180 patent are expressly limited to disodium EDTA and that the use of calcium disodium EDTA is not covered. Accordingly, it is not likely that World Health can exclude Chelation's production of Kelatox by relying on the '180 patent.

B. Trade Secret Misappropriation

World Health claims that its customer list is a trade secret and that Chelation misappropriated World Health's customer information to facilitate the solicitation of World Health customers. Chelation maintains that it has no copies, tangible or otherwise, of the customer information. More fundamentally, Chelation argues that World Health's customer list cannot be characterized as a trade secret because World Health did not make a reasonable effort to keep the list secret.

The threshold issue in determining whether a trade secret has been misappropriated is "whether, in fact, there is a trade secret to be misappropriated." Envirotech Corp. v. Callahan, 872 P.2d 487, 494 (Utah Ct. App. 1994) (quoting Microbiological Research Corp. v. Muna, 625 P.2d 690, 696 (Utah 1981)). A trade secret is information that: "(a) derives independent economic value from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and (b) is the

subject of efforts that are reasonable under the circumstances to maintain its secrecy." Utah Code Ann. § 13-24-2. "The burden is on the plaintiff to prove the existence of a trade secret, and there is no presumption in his favor." MedSpring Group, Inc. v. Feng, 368 F. Supp. 2d 1270, 1276 (D. Utah 2005).

Chelation argues that World Health cannot met its burden because the evidence establishes that no reasonable efforts were made to maintain the secrecy of the customer list. Evidence indicating that a company did not require its employees to sign confidentiality agreements or otherwise restrain access to sensitive corporate information weighs against the conclusion that such information is a trade secret. Cordell v. Berger, 2:01-CV-710C, 2001 WL 1516742, at * 3 (D. Utah, Nov. 27, 2001) (plaintiff did not use confidentiality agreements or limit employee and volunteer access to allegedly secret information contained in a database). Another relevant factor is whether tangible copies of the allegedly secret information were marked as confidential or otherwise contained an indication of the sensitive nature of the information. See id. ("Neither the Graduate Base nor print-outs made from it are marked in any manner to indicate their confidentiality.").

At the time the events giving rise to this litigation occurred, World Health did not require its employees to sign any type of confidentiality or non-competition agreement. The evidence indicates that World Health employees were free to pursue other projects while employed by World Health. Further, print outs of the customer list were regularly made and placed on the desk of Mr. Hayes. Print outs of the customer list were typically thrown in the garbage without first being shredded. The list itself was not marked as confidential in both its electronic and tangible form and did not otherwise contain an indication that its contents were secret. Also, while the computer database containing the customer list was password protected, the testimony

at the preliminary injunction hearing established that the various passwords were known by all employees and that employees commonly wrote down the passwords of other employees. In addition, World Health would regularly provide the names of customers that served as distributors of Detoxamin when they received telephone inquires requesting that information. World Health also imported a significant portion of its customer list into a separate database that was not password protected.

Mr. Sveeden testified that draconian efforts to maintain secrecy were not needed because World Health is a small company and he trusted his employees. But, even considering the small size of World Health, the evidence establishes that next to no meaningful effort was made to maintain the secrecy of the customer list. Accordingly, it is unlikely that World Health can establish the existence of a trade secret and its likelihood of successfully pursuing its trade secret misappropriation claim is not high.

II. Other Preliminary Injunction Factors

The conclusion that World Health is not likely to succeed on the merits of its patent infringement and trade secret misappropriation claims affects the consideration of the final three preliminary injunction factors: the presence of irreparable harm, a weighing of the balance of potential harms, and the public's interest, see Medspring Group, 368 F. Supp. 2d at 1276. Consideration of these factors does not weigh in favor of issuing an injunction in this case.

A. Irreparable Harm

World Health claims that it will suffer irreparable harm in the form of lost business and damage to its reputation and good will if an injunction is not issued. "To constitute irreparable harm, an injury must by certain, great, and actual." <u>Chemical Weapons Working Group, Inc. v. U.S. Dep't of the Army</u>, 963 F. Supp. 1083, 1095 (D. Utah 1994). Damage to a company's

reputation or good will is frequently considered irreparable because of the difficulties involved in adequately compensating such loss monetarily. See Dominion Video Satellite, 269 F.3d at 1156-57. But in this case, it is unlikely that World Health has suffered a legally cognizable injury flowing from Chelation's marketing of calcium disodium EDTA or from Chelation's alleged misappropriation of World Health's customer list. See Holly Sugar Corp. v. Goshen County Coop. Beet Growers Ass'n, 725 F.2d 564, 568 (10th Cir. 1984) ("A court cannot grant a remedy, legal or equitable, unless there has been a legal injury; mere damage is insufficient."); Cordell, 2001 WL 1516742, at *4 ("As the Graduate Base is not a trade secret, the Bergers' actions do not violate Harmony's legal rights, and, accordingly, do not cause Harmony irreparable harm.").

B. Balance of Injuries to the Parties

World Health will certainly be harmed if Chelation is allowed to continue its marketing of Kelatox. But Chelation will undoubtedly be harmed if it is enjoined from marketing and selling its product. The evidence shows that World Health enjoys a healthy rate of gross monthly sales, bringing in approximately ten times the amount of money earned by Chelation. The effect of enjoining Chelation's operations would potentially result in the death of the company. While the negative effect of Chelation's business on World Health cannot be ignored, the balance of the harms weighs against issuing an injunction in this case.

C. Public Interest

The public has a substantial interest in assuring free competition in the marketplace. World Health has not established that Chelation has impermissibly gained a marketplace advantage either through patent infringement or trade secret misappropriation. Accordingly, the public interest weighs against enjoining Chelation's activities on those grounds. See Abbott Labs. v. Andrx Pharms., Inc., 452 F.3d 1331, 1348 (Fed. Cir. 2006) ("Although the public

interest inquiry is not necessarily or always bound to the likelihood of success on the merits . . . we agree . . . that the public interest is best served by enforcing patents that are likely valid and infringed. As Abbott did not establish a likelihood of success on the merits, we conclude that the public interest is best served by denying the preliminary injunction."); Cordell, 2001 WL 1516742, at *5 ("The free exchange of information in the public domain drives competition and our economy. An injunction prohibiting the Bergers' use of the Graduate Base would act to restrain trade without any accompanying benefit. The public interest weighs in favor of the Defendants.").

Conclusion

World Health has failed to meet the heavy burden applicable to preliminary injunctive relief. While World Health may ultimately prevail on some, or perhaps even all, of its claims, it is has not established the likelihood of its success on its patent infringement and trade secret misappropriation claims. Further, consideration of both the balance of the parties' potential harms and the public's interest support the conclusion that a preliminary injunction is inappropriate in this case. Accordingly, World Health's Motion for Preliminary Injunction is DENIED.

DATED this 28th day of August, 2006.

BY THE COURT:

TENA CAMPBELL

United States District Judge