The Disclosure-Dedication Rule – Are Your Patents Affected?

By: Cliff Davidson, Esq.,
Davidson, Davidson & Kappel, LLC

Clifford M. Davidson, Esq.

Founding Partner, Davidson, Davidson & Kappel, LLC

Clifford M. Davidson, Esq., is a Founding Partner at Davidson, Davidson & Kappel, LLC, an Intellectual Property law firm with offices in New York City and Frankfurt, Germany. His practice includes counseling specialty pharma clients in patent-related matters, including patent prosecution, freedom to operate and infringement opinions, due diligence and tech-transfer, and litigation. He has assisted specialty pharma companies in the creation of patent portfolios covering their propriety technologies, which have added significant value to his clients' assets. Mr. Davidson's practice extends to all areas of pharmaceuticals and biologicals, including new chemical entities, new biologicals and biotech, new pharmaceutical formulations (all routes of administration), new combinations of previously known drugs, new methods of treatment, and methods of preparation. He has pioneered strategic patent focus on the pharmacokinetic profiles and the pharmacologic activity of drug/drug formulations. He can be reached via email at cdavidson@ddkpatent.com.

Introduction

Patents are the life-blood of the pharmaceutical industry, the means by which a company attempts to protect its products. To this end, many Specialty Pharma companies are alert to obtaining patent coverage that not only covers the precise formulation that they are attempting to commercialize, but to also attempt (through patents) to block competitors from gleaning important aspects of their technology and then developing "me-too" 505(b)(2) or ANDA products.

Patent claims define the metes and bounds of the property right awarded to the patentee. Patent attorneys put great care into drafting claims that encompass the invention (eg, the product to be commercialized), and often the patent claims do a good job of covering the actual product that is intended for commercialization. Sometimes, however, that mark is missed as a lack of continued communication between scientists and patent attorneys lead to a patent that nicely covers a predecessor to the commercialized product, but does not actually cover the commercialized product as well. An example of how this can happen is when changes are made to ingredients or proportions of ingredients during scale-up.

Another significant problem in obtaining patent protection concerns anticipating and obtaining patent protection for potential design-around strategies that may be utilized by competitors. In order to accomplish this goal, patent claims are often written with broad scope and are supported by a detailed patent specification that provides detailed information concerning not only the preferred embodiment of the invention, but alternative embodiments as well. These alternatives are, indeed, the very manner that the patentee believes competitors would turn to for easy design-around strategies.

What happens if the patent claims that eventually are granted are not as broad as the specification that supports the claims? For example, what happens if the patent examples include formulations that include a particular ingredient (A), the specification discloses alternatives for that ingredient, and the patent claims are specific to ingredient (A)? Are these alternatives covered by the patent and encompassed in the patent claims? Do the patent claims cover such alternatives under the doctrine of equivalents?[1] Are competitors free to utilize a design-around strategy that includes the use of an alternative ingredient that wasn't claimed?

There are at least two fact patterns whereby patent rights to an alternative ingredient (embodiment) set forth in a patent claim may be lost. Here, we discuss the basics of such situations, with the goal to alert inventors and decision-makers to potential pitfalls during patent prosecution, the process of obtaining a patent from the USPTO.

The Disclosure-Dedication Rule

The disclosure-dedication rule has been around for a long time, but has not generally been the mainstay of defenses against patent infringement. However, this defense has been asserted successfully in recent patent litigations, and has been relied upon (albeit unsuccessfully) in a recent pharma litigation. The disclosure-dedication rule "requires an inventor who discloses specific matter to claim it, and to submit the broader claim for examination. Otherwise, that matter is dedicated to the public and may not be recaptured under the doctrine of equivalents [*PSC v. Foxconn*, 355 F.3d 1353, 1360 (Fed. Cir. 2004)]." The intent of the inventor not to dedicate to the public is irrelevant [*Toro v. White Consolidated*, 383 F.3d 1326 (Fed. Cir. 2004)]. "The presumption is … that what is not claimed was not invented by the patentee, [or, if it was, he by] … his own act has made it public property (*PSC* at 1358)."

Accordingly, if an inventor discloses, for example, alternatives to a particular ingredient or aspect of a formulation, the patent claims must encompass that ingredient; otherwise the inventor risks dedicating that alternative to the public (and to design-around strategies). In other words, in some instances, it may be blatantly dangerous to disclose an alternative to a particular claimed ingredient in a patent claim, without including claims that specifically encompass that alternative ingredient.

A clear, precise disclosure of the dedication is not required to invoke the application of the disclosure-dedication rule (Id. at 1358); "If one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description, the alternative matter disclosed has been dedicated to the public (*PSC* at 1360)." "Nothing more [than this] is required to implicate the disclosure-dedication rule (*Toro* at 1334)."

The disclosure-dedication rule is only applicable to unclaimed subject matter that has been clearly deemed to be an alternative in the specification of the patent in question to a claimed embodiment (eg, ingredient). Recent case law has clarified that "before unclaimed subject matter is deemed to have been dedicated to the public, that unclaimed subject matter must have been identified by the patentee as an alternative to a claim limitation [*Pfizer Inc. v. Teva Pharmaceuticals USA Inc.*, No. 05-1331, Opinion at p.21 (Fed. Cir. 2005)]."

Application of the Rule

In *Toro*, claim 1 read in part "said cover including means for increasing the pressure developed by" blower. The specification stated that the invention is "advantageous in that it automatically restricts the size of the inlet … without having the operator manually insert or remove a replaceable ring." At issue was the question of whether a separate ring/structure would be considered to be an infringement of claim 1. According to the Court of Appeals for the Federal Circuit (CAFC), "there [was] no doubt that the specification … disclose[d] the separate ring/structure… it d[id] so by noting inferiority of a device in which the operator manually insert[ed] or remove[d] a replaceable ring (*Toro* at 1334)." However, the disclosed separate ring/structure was not claimed. The subject matter directed to the blower wherein the operator manually inserts or removes a replaceable ring was held to be dedicated to the public (Id.).

In *PSC*, the patentee claimed a retainer strip that included "an elongated, resilient metal strap." The specification stated that the strap is "made of a resilient metal, such as stainless steel, although other resilient materials may be suitable for the strap," and that "other prior art devices use molded plastic and/or metal parts (*PSC* at 1356)." The CAFC held that retainer strip made from plastic was dedicated to the public.

In a significant case of interest, *Johnson & Johnston Associates Inc. v. R.E.Serv. Co.*, 285 F.3d 1046 (Fed. Cir. 2002), the patentee had claimed a substrate for printed circuit boards comprising "a laminate constructed of … a sheet of aluminum." The specification had a broader definition of that substrate, stating that "while aluminum is currently the preferred material for the substrate, other metals, such as stainless steel or nickel alloy, may be used." The claims pending before the patent office always were limited to the aluminum material, and the patent examiner never had the opportunity to consider whether another material would still render the claims patentably distinct from the prior art. RES used a steel substrate instead of aluminum. At the district court level, the jury found RES guilty of willful infringement under the doctrine of equivalents. The CAFC, in an *en banc* decision, reversed the

decision. The bases for the reversal were clearly stated by the CAFC: (1) it is the claims that define the invention; (2) "a patentee cannot narrowly claim an invention to avoid prosecution scrutiny by the PTO, and then, after patent issuance, use the doctrine of equivalents to establish infringement because the specification discloses equivalents; (3) to avoid "the problem of extending the coverage of an exclusive right to encompass more than properly examined by the PTO (Id. at 1054)."

In making its decision in the *Johnson* case, the CAFC clarified an apparent conflict between two prior decisions. In *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098 (Fed. Cir. 1996), Maxwell avoided examination of an unclaimed alternative, which was distinct *YBM Magnex, Inc. v. Int'l Trade Comm'n*, 145 F.3d 1317 (Fed. Cir. 1998), the CAFC stated that the *Maxwell* decision did not create a new rule of law that the doctrine of equivalents could never encompass subject matter disclosed in the specification but not claimed (Id. at 1321). In *YBM Magnex*, the patent claim specifically covered a magnet alloy that included 6,000 to 35,000 ppm oxygen, and the accused infringer used similar magnet alloys with an oxygen content between 5,450 and 6,000 ppm.

Although the aforementioned cases do not involve pharmaceuticals, the CAFC has recently considered the application of the disclosure-dedication rule as it applies to pharmaceutical formulations. In the aforementioned *Pfizer* case, Ranbaxy teamed up with first ANDA filer, Teva, to bring to market Ranbaxy's version of a generic version of Accupril®, using a product that it believed would not infringe the patent in question in view of the meaning of the claimed term "saccharide" as stipulated in a previous Pfizer/Warner-Lambert-Teva litigation concerning the product Teva sought to commercialize. The patent in question claimed a pharmaceutical composition containing "a suitable amount of saccharide to inhibit hydrolysis. Ranbaxy's product included microcrystalline cellulose, which is a polysaccharide. In the prior Warner-Lambert-Teva litigation, it had been stipulated by the litigants that the word "saccharide" as used in the claims meant "a sugar, and specifically includes only lower molecular weight carbohydrates, specifically, mono- and disaccharides and their simple derivative, including such substances as lactose, sucrose, mannitol, and sorbitol," under which definition microcrystalline cellulose would not be literally encompassed.[2] Pfizer sued Ranbaxy and Teva after marketing had begun. In this litigation, the district court construed "saccharide" differently than the previously (non-binding) stipulated definition, to include "mono-, di-, tri-, and polysaccharides," which encompassed microcrystalline cellulose, and proceeded to enter a preliminary injunction against Ranbaxy marketing its product, finding that Warner-Lambert (Pfizer) was likely to provide infringement and validity of its patent claims. Ranbaxy appealed to the CAFC.

In the specification of the patent in question, the definition of the term "saccharides" did not affirmatively state what saccharides are, but rather negatively defined what they are not. The district court found that the one of ordinary skill in the art reading the specification would understand "saccharides" to include polysaccharides, and the CAFC agreed. Ranbaxy contended that as a matter of law, microcrystalline cellulose could not be an equivalent of a "saccharide" because the patentee dedicated microcrystalline cellulose to the public by disclosing, but not claiming, its use in the patent in question. One alleged disclosure of microcrystalline cellulose was a listing of "modified cellulose derivatives" as examples of disintegrating agent, and another alleged example was a comparative example included in the patent that contained microcrystalline cellulose. However, it was not stated in the specification or in that example that microcrystalline cellulose was considered to be an alternative to a saccharide as set forth in the claims.

In pertinent part, the CAFC was not convinced that one of ordinary skill in the art would have come to the conclusion that the inventors identified microcrystalline cellulose to be an alternative to a saccharide that prevents hydrolysis. The CAFC further found that microcrystalline cellulose, being a polysaccharide, could be fairly characterized as an insubstantial change when compared to "sugars," and that the doctrine of equivalents was not precluded in this case. Accordingly, the CAFC held that disclosure-dedication rule did not apply.

What Can be Gleaned From the Case Law?

According to the recent decision in the Pfizer case, one might expect that where an alternative to a particularly claimed embodiment of an invention is disclosed in a manner such that one of ordinary skill in the art can understand that it is considered an alternative by the inventor, such alternative subject matter that is not claimed may be considered to be dedicated to the public (and to present a possible design-around strategy). The CAFC in the Pfizer case did take the position that subject matter that is not specifically identified as being an alternative to a claim limitation is not dedicated to the public under the "disclosure-dedication rule."

However, this does not necessarily mean that the claims should be construed to encompass that alternative embodiment, for any number of reasons. The determination of the meaning of the words and phrases of the claims (referred to as "claim construction") is often made during a pretrial hearing conducted by the court, which is referred to as a "Markman Hearing" after the court determination in *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). In

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interpreting the claims of a patent, the judge will look to the claim language itself, to the patent specification, and the prosecution history of the patent (*Markman*, 52 F.3d at 979). In interpreting claims, the words of a claim are typically given their ordinary and customary meaning to a person of ordinary skill in the art, at the time of the invention, and after reading the entire patent, including the specification, and prosecution history, ie, the intrinsic record [*Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005)].

When a patentee narrows an originally broad claim in response to the Office Action, the disclosure-dedication rule does not apply to the subject matter disclosed but eliminated by the amendment [*Rosby v. Stoughton*, 2003 U.S. Dist. LEXIS 17034 (Northern District Il. 2003)]. However, prosecution history estoppel is applicable (Id.). Once an estoppel is created, there is a presumption that prosecution history bars a finding of equivalents for the amended claim element, and the patentee bears the burden of showing that the amendment does not surrender the particular equivalent in question [*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002)].

Even if the claim is not narrowed during prosecution, it is well-established that the doctrine of equivalents may not be used to broaden the scope of the claim to encompass what was already in the public domain, ie, found in the prior art. *Wilson Sporting Goods, Co. v. David Geoffrey & Assoc.*, 904 F.2d 677 (Fed. Cir.) cert. denied, 498 U.S. 992 (1990), overruled on other grounds, *Cardinal Chem. Co. v. Morton Int'l.*, 508 U.S. 83 (1993). Therefore, even if an alternative embodiment is not carved out during prosecution of the patent, the claims, nevertheless, cannot encompass that embodiment if doing so would render the claims invalid.

How Can You Prevent Disclosure-Dedication?

There are three ways to avoid the application of disclosure-dedication rule to the subject matter disclosed, but not claimed in the application. First, a patentee can claim the subject matter in a copending application before the patent issues [*Johnson & Johnson v. R.E. Service Co.*, 285 F. 3d 1046 (Fed. Cir. 2003)]. Second, after the patent issues, a patentee can file a broadening reissue within 2 years after issuance (Id.). In alternative, a patentee can file another "application within the 1-year grace period following the issuance of the patent before the patent has become a statutory bar under § 102 (b) [*In re Gibbs*, 437 F. 2d 486 (CCPA 1971)]."

Conclusion

There are a lot of issues that go into the analysis of whether a patent limitation encompasses a potential design-around strategy. The issues are complex, and taking short-cuts in the analysis is a risky business. Patent litigation in the pharmaceutical field tends to be more lengthy and even more costly than other technologies. It is highly recommended that when faced with such a situation, one must obtain the advice and assistance of patent counsel early during product development in order to maximize the chances for successfully navigating around or through patent litigation. ■

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References

1. *For a claim to be infringed under the doctrine of equivalents, the accused product must contain elements identical or equivalent to each claimed element of the patented invention. See Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997).*
2. *The district court eventually granted summary judgment against Teva, finding the patent in question not invalid and infringed, and not unenforceable due to inequitable conduct. The CAFC affirmed in part, but had reversed and remanded the case to the district court, leading to the cooperation between Teva and the subsequent filer Ranbaxy.*