IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS
TEXARKANA DIVISION

ST. JUDE MEDICAL, INC., a Minnesota Corporation, and ST. JUDE MEDICAL PUERTO RICO LLC, a Puerto Rico Limited Liability Company. PLAINTIFFS

VS. CASE NO. 08-CV-4101

ACCESS CLOSURE, INC., a Delaware Corporation DEFENDANT

FINDINGS OF FACT AND CONCLUSIONS OF LAW

At the jury trial in this case, the jury found that AccessClosure, Inc. ("ACI") is infringing St. Jude Medical, Inc.'s ("St. Jude") U.S. Patent No. 7,008,439 ("the '439 patent"). However, the jury also rendered an advisory opinion on the issue of double patenting and found that the claims of the '439 patent were not patentably distinct from claim 7 of another St. Jude patent, U.S. Patent No. 5,725,498 ("the '498 patent"), which was filed by the same applicants as the '439 patent. In other words, the jury found that the '439 patent is invalid for obviousness-type double patenting over the '498 patent. The issue before the Court today, which was not submitted to the jury, is whether the safe harbor provision of 35 U.S.C. § 121, protects the '439 patent from any double patenting challenge based on the '498 patent.

A. The Janzen Patent Family

The '439 and '183 patents are part of a family of patents directed to various inventions that relate to ways of plugging holes in arteries after medical procedures, such as angioplasty. Ernst Janzen is the lead inventor. Janzen and his colleagues came up with a number of inventions that were important to the vascular closure industry. These inventions included precisely guiding a plug

to a vascular hole, on a guidewire, without requiring a dilator. Other inventions by Janzen included using a dilator as part of the process of delivering the plug to the vascular hole. The U.S. Patent and Trademark Office ("PTO") held that these two approaches constituted patentably distinct inventions and required the applicants to pursue them in separate patent applications.

1. Prosecution of the '183 and '130 patents

On August 16, 1991, the Janzen applicants filed a U.S. Patent Application that would later issue as U.S. Patent No. 5,351,183 ("the '183 patent"), which is the grandparent patent to the two patents at issue here today. On September 25, 1992, the PTO notified the applicants that it would require the claims of the '183 application to be restricted. The restriction requirements included multiple levels. First, the applicants were required to elect between method and device claims: I) claims drawn to a device for use in sealing a puncture in a wall of a blood vessel, and II) claims drawn to a method of sealing a puncture in a wall of a blood vessel. After electing a device or method, the Janzen applicants were further required to elect one of three different species: A) claims relating to the apparatus comprising a solid tissue dilator; B) claims relating to the apparatus comprising a hollow dilator and guidewire; and C) claims relating to the apparatus comprising a guidewire and no dilator.[1]

On October 5, 1994, the Janzen applicants filed a divisional application from the '183 application, which later issued as U.S. Patent No. 5,830,130 ("the '130 patent"). On July 3, 1995, the PTO entered restriction requirements in the '130 application. These restriction requirements were identical to the earlier restriction requirements for the '183 patent. In the '130 application, the

[1]The restriction requirement also required the applicants to elect one of eight identified sub-species, which correspond to the various types of plugs disclosed in the application, and one of five sub-sub-species, corresponding to the appartus used.

Janzen applicants elected to prosecute device claims (Group I) involving an "apparatus comprising a hollow dilator and guidewire" (Species B).

2. Prosecution of the '439 and '498 patents

The Janzen applicants followed the '130 application with two continuation applications. One of these continuation applications eventually issued as the '439 patent, which is the patent that the jury found to be invalid for double patenting. The other continuation application eventually issued as the '498 patent.

The Janzen applicants used the '439 patent to provoke an interference with another patent to determine who was entitled to claim priority to the invention. A series of delays that seem to be on the part of the PTO resulted in the '439 application languishing in the PTO for an uncommonly long time. An interference was eventually declared, and the PTO Board of Patent Appeals and Interferences issued a judgment in the Janzen applicants' favor as the first to invent the claimed subject matter. On March 7, 2006–eleven years after filing–the application finally issued as the '439 patent. In contrast, the PTO took less than two years to examine the other continuation, and the '498 patent was issued on March 10, 1998, which was eight years earlier than the issuance of the '439 patent, even though the '439 patent application was filed eighteen months before the '498 patent application.

B. The Safe Harbor Provision of 35 U.S.C. §121

In the present case, the jury found that the '439 patent is invalid for double patenting over the '498 patent. However, St. Jude claims that the safe harbor provision of 35 U.S.C. § 121 protects the '439 Patent from any double patenting challenge based on the '498 Patent. Section 121 provides in pertinent part:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions .... *A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them*, if the divisional application is filed before the issuance of the patent on the other application.

35 U.S.C. § 121. The emphasized sentence of § 121 is referred to as the safe harbor provision.

In other words, when the PTO determines that a single patent application contains claims directed to two or more separate and distinct inventions, it issues a "restriction requirement." *See* Manual of Patent Examining Procedures 800. This restriction requirement compels an applicant to elect a single invention for prosecution in the pending application and to file additional applications to pursue the unelected inventions. *Id*. The safe harbor provision applies to protect the claims of the divisional application from being invalidated under double patenting by the claims of the original parent application or patent issuing therefrom. *See* 35 U.S.C. § 121. In enacting § 121, Congress recognized that patentees should not be punished for complying with PTO restriction requirements. *Boehringer Ingleheim Int'l v. Barr Labs, Inc.*, 592 F.3d 1340, 1350 (Fed Cir. 2010).

1. Both the '439 and 498 patents were filed as a result of restriction requirements

A patent is filed "as a result of" a restriction requirement if the patent subject to a double-patenting challenge and the application in which the restriction requirement was entered "share a common lineage" and claims subject matter the applicants were not permitted to pursue in an earlier patent. *Id*. The "as a result of" requirement applies to the challenged patent as well as the reference patent. *Id*. at 1352.

Here, both the ‘498 and the ‘439 patents descend from the ‘183 patent application via the divisional application that issued as the ‘130 patent. In other words, the ‘498 and the ‘439 patents are continuation applications deriving from the same divisional application (the ‘130 patent application). The ‘130 patent application is a divisional of the ‘183 patent application. Thus, the ‘498 patent and the ‘439 patent share a common lineage. Both of these patents trace their lineage to a patent in which a restriction requirement was imposed. Thus, both of these patents were filed as a result of a restriction requirement.

ACI argues that the ‘439 patent was not filed as a result of a restriction requirement because its claims were copied from what was known as the Lee patent for the purpose of provoking an interference. The Court disagrees. Any motivation to provoke an interference is irrelevant to whether an application was filed as a result of a restriction requirement. *See id*. at 1353.

ACI asserts that the ‘498 patent was not filed as a result of a restriction requirement because the claims were new claims and were never entered in an earlier Janzen application. However, the Federal Circuit has stated that "new or amended claims in a divisional application are entitled to the benefit of § 121." *Symbol Technologies*, 935 F.2d 1569, 1579 (Fed. Cir. 1991). Claims may be amended, but "they must not be so amended as to bring them back over the line imposed in the restriction requirement." *Gerber Garment Tech., Inc. v. Lectra Sys.*, 916 F.2d 683, 688 (Fed Cir. 1990). Here, what is important to consider is whether the amended claims remain consonant with the restriction requirements, and the Court will take up the consonance issue later in this order.

The Federal Circuit has applied the safe harbor provision where the claims of neither the reference patent nor the challenged patent are identical to claims withdrawn from the application in which the restriction requirement was imposed. In the *Boehringer* case, the Federal Circuit found

that the safe harbor provision applied where the reference patent contained all new claims and the challenged patent also included new claims. *Boehringer*, 592 F.3d at 1344. Thus, the Court rejects ACI's argument that the '498 patent was not filed as a result of a restriction requirement because the claims were new and had never been entered in a earlier Janzen patent.

2. The safe harbor provision applies to continuation patents

ACI argues that the '498 and '439 patents are not subject to the safe harbor provision in § 121 because they are continuation patents, not divisional patents. However, the Federal Circuit has held that § 121 applies specifically to continuing applications deriving from a divisional application filed as a result of a restriction requirement." *Boehringer*, 592 F.3d at 1352. In *Amgen, Inc. v. F. Hoffman-La Roche Ltd.*, the Federal Circuit held that "intervening continuation applications do not render a patent ineligible for § 121 protection so long as they descended from a divisional application filed as a result of a restriction requirement." 580 F.3d 1340, 1354 (Fed Cir. 2009). Both the '498 and the '439 patents are continuation patents of the '130 patent application (a divisional application), which was filed as a result of the restriction requirement imposed during prosecution of the '183 patent. Accordingly, the Court rejects ACI's argument that the safe harbor provision does not apply to the '439 and '498 patents because they are continuation patents.

3. The '439 and '498 patents remain consonant with the restriction requirements

A party invoking the safe harbor provision must ensure that the applications filed after the restriction requirement remain consonant with the lines of demarcation between claimed inventions. In other words, an applicant cannot elect to pursue claims from one group of a restriction requirement and then subsequently pursue claims from that same group in a later application. "'[A]

divisional application filed as a result of a restriction requirement may not contain claims drawn to the invention set forth in the claims elected and prosecuted to patent in the parent application.'" *Boehringer*, 592 F.3d at 1354 (quoting *Gerber Garment Tech.*, 916 F.2d at 688 (Fed. Cir. 1990)). Rather, the claims prosecuted in two or more applications having common lineage in a divisional chain must honor, as between applications, the lines of demarcation drawn by the examiner to what he or she considered independent and distinct inventions in the restriction requirement. *Boehringer*, 592 F.3d at 1354. The Court finds the consonance requirement the most challenging issue in analyzing this particular case.

ACI argues that claim 7 of the '498 patent and the asserted claims of the '439 patent claim the same invention and are not consonant with the restriction requirement. Specifically, ACI asserts that both patents claim the same subject matter: an apparatus comprising a guidewire and no dilator (Species C). There is no dispute that the '439 patent claims are within Species C. The dispute centers on claim 7 of the '498 patent. ACI argues that claim 7 of the '498 patent does not describe a dilator and therefore is also directed to Species C (guidewire and no dilator). St. Jude disagrees and asserts that claim 7 of the '498 patent does describe a dilator and thus is directed to Species B (hollow dilator and a guide wire).

Claim 7 of the '498 patent describes a "hollow sheath having a cross-section which is larger than the cross-section of said puncture." The "said puncture" refers to the puncture in the artery. The dispute boils down to whether the hollow sheath described in claim 7 is a dilator. If so, the claim is directed to Species B; if not, the claim is directed to Species C. Claim 7 does not mention the word "dilator" and does not specifically say that the sheath must dilate. Instead, it describes a hollow sheath having a cross-section larger than the cross-section of the puncture in the artery.

There is no doubt that an oversized sheath can be used to dilate the tissue channel; the dispute is whether that oversized sheath is necessarily classified as a dilator in these particular circumstances. Dr. Sandor Kovacs testified that, when a sheath having a cross-section larger than the cross-section of the artery puncture is inserted into the tissue, it widens the channel and is thus a dilator. On the other hand, Dr. Charles Brown testified that just because an instrument dilates does not mean it is a dilator. As an interventional cardiologist, he thinks of other specific tools as dilators and would not consider the hollow sheath in claim 7 to be a dilator. However, the issue here is how the PTO uses the term "dilator" in the restriction requirement, not how Dr. Brown uses the term in his medical practice as a cardiologist.

During the prosecution of the '183 patent, the applicants pursued an original claim that described a sheath like the one recited in claim 7 of the '498 patent and likewise did not use the term "dilator." The '183 claim recited a "hollow sheath ... having a cross sectional profile larger than said puncture." (Application No. 07/746,339 (8/16/91) at claim 1). In response to the restriction requirement imposed during the prosecution of the '183 patent, the applicants ultimately identified that claim as directed to Species B (hollow dilator and guidewire). At the trial in this case, Judge Stoner testified that the PTO agreed with the applicants' classification of the claim. For classification purposes, it seems that the PTO was not concerned with the fact that the word "dilator" was not used in the claim language as long as the sheath functioned as a tissue dilator. In fact, the PTO accepted the applicants' classification of a claim describing the same oversize sheath as having a dilator. Like the original claim pursued by the applicants in the '183 patent, the Court is convinced that claim 7 of the '498 patent is directed to Species B (hollow dilator and guidewire), not Species C (guidewire and no dilator).

Because the Court finds that the oversized, hollow sheath of claim 7 is a dilator, as understood by the PTO, it falls into Species B. In contrast, the asserted claims of the '439 patent fall into Species C. Accordingly, the Court finds that the applicants respected the PTO's directives and that the '498 and '439 patents remain consonant with the lines of demarcation between the claimed inventions. Accordingly, the consonance requirement is satisfied.

C. Conclusion

For the foregoing reasons, the Court finds that the safe harbor provision applies here. Thus, the safe harbor provision of 35 U.S.C. § 121 protects the '439 patent from any double patenting challenge based on the '498 patent.

IT IS SO ORDERED, this 8th day of November, 2011.

/s/ Harry F. Barnes
Hon. Harry F. Barnes
United States District Judge