

**United States Court of Appeals  
for the Federal Circuit**

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**ST. JUDE MEDICAL, INC., AND ST. JUDE MEDICAL  
PUERTO RICO, LLC,**  
*Plaintiffs-Appellees,*

**v.**

**ACCESS CLOSURE, INC.,**  
*Defendant-Appellant.*

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2012-1452

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Appeal from the United States District Court for the  
Western District of Arkansas in No. 08-CV-4101, Senior  
Judge Harry F. Barnes.

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Decided: September 11, 2013

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ANDREI IANCU, Irell & Manella, LLP, of Los Angeles,  
California, argued for plaintiffs-appellees. With him on  
the brief were MORGAN CHU, ALAN J. HEINRICH, KEITH A.  
ORSO, C. MACLAIN WELLS, ERIC B. HANSON and LAURA  
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JOSEPH R. RE, Knobbe, Martens Olson & Bear, LLP, of  
Irvine, California, argued for defendant-appellant. With  
him on the brief was TANYA MAZUR. Of counsel on the  
brief were CHARLES K. VERHOEVEN, DAVID EISEMAN and

MATTHEW D. CANNON, Quinn Emanuel Urquhart & Sullivan, LLP, of San Francisco, California.

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Before LOURIE, PLAGER, and WALLACH, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* PLAGER.

Concurring opinion filed by *Circuit Judge* LOURIE.

PLAGER, *Circuit Judge*.

This is a patent case. Access Closure, Inc. (ACI), the defendant at trial, appeals from several rulings made by the United States District Court for the Western District of Arkansas in favor of St. Jude Medical, Inc. and St. Jude Medical Puerto Rico, LLC (collectively “St. Jude”), plaintiffs patentees. The rulings relate to three patents that St. Jude asserted against ACI: U.S. Patent No. 7,008,439 to Janzen et al. (the Janzen patent or ’439 patent); and U.S. Patent No. 5,275,616 to Fowler (the ’616 patent) and U.S. Patent No. 5,716,375 to Fowler (the ’375 patent)—we refer to the ’616 and ’375 patents collectively as the “Fowler patents.”

ACI appeals three of the district court’s rulings: (1) that the safe-harbor provision of 35 U.S.C. § 121 protects the Janzen patent from invalidity due to double-patenting; (2) the construction of key terms in the Janzen patent; and (3) that ACI was not entitled to JMOL that the Fowler patents are invalid for obviousness. For the reasons that follow, we (1) *reverse* the district court’s safe harbor ruling regarding the Janzen patent; (2) in light of our safe harbor ruling, determine that the district court’s rulings regarding the claim constructions in the Janzen patent are moot; and (3) *affirm* the district court’s ruling that the Fowler patents are nonobvious and not shown to be invalid.

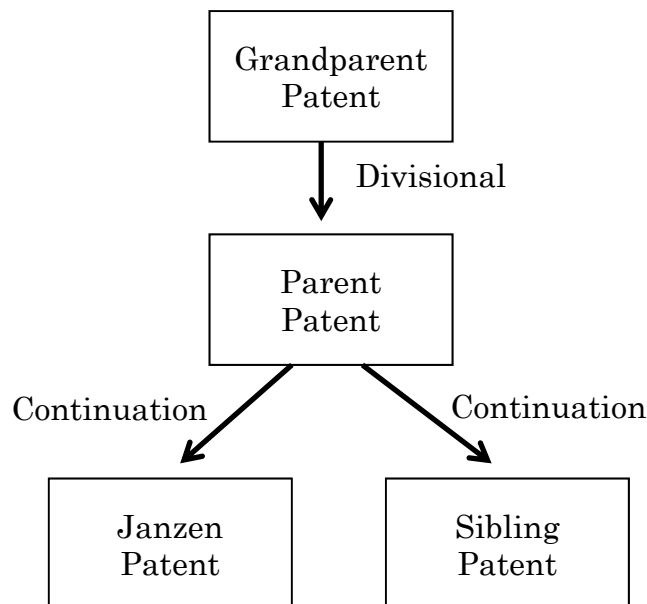
## I. BACKGROUND

The patents in this appeal relate to methods and devices for sealing a ‘vascular puncture.’ A vascular puncture occurs when a medical procedure requires a medical professional to puncture through the skin and into a vein or artery to insert a medical device, such as a catheter, into a patient’s vasculature. After such a procedure concludes, the medical professional typically removes the medical device from the vasculature.

Prior to the development of the technology at issue in this case, the medical professional was then required to apply external pressure to the puncture site until clotting occurred. Due to a variety of factors, the medical professional often had to apply pressure to the puncture site for an extended period of time. This caused discomfort to the patient and increased the recovery time. The Janzen and Fowler patents disclose a variety of methods and devices for sealing a vascular puncture with the objective of improving patient recovery.

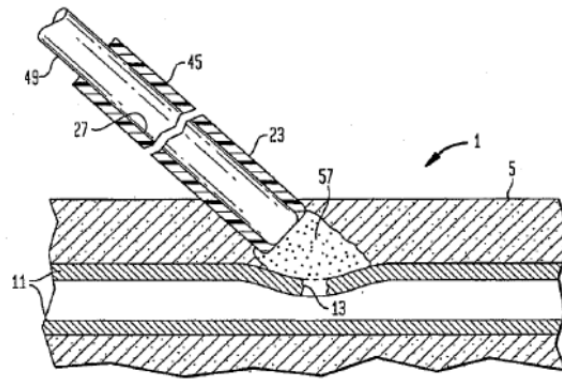
### A. The Janzen Patent

There are four patents of importance in the Janzen family. The following chart illustrates the relationship between these patents.



The Janzen patent discloses a medical device that inserts a plug into a vascular puncture to seal the puncture and prevent bleeding. Janzen patent, col.2 ll.29–33. The disclosed device has a sheath and a piston or plug pusher that pushes a plug through the sheath and ejects it into the skin at the puncture site. *Id.* col.5 ll.31–42. The plug may be composed of collagen or some other material that can be absorbed by the body. *Id.* col.2 ll.22–24. Figure 10 of the Janzen patent, reproduced below, depicts a representative embodiment of the Janzen device.

FIG. 10



The Janzen patent has three claims at issue in this appeal, dependent claim 7, independent claim 8, and independent claim 9. Independent claim 8, which is generally representative, includes “an elongated member,” “[a] plug member . . . disposed in said elongated member,” and “an ejecting mechanism for ejecting said plug member from [a] distal end of said elongated member so as to place said plug member in blocking relation with said puncture, so as to seal said puncture.” *Id.* col.10 l.56 – col.11 l.2.

The Janzen patent is a descendant from U.S. Patent Application No. 07/746,339, filed on August 16, 1991 (the grandparent application). In response to the grandparent application, the examiner issued an Examiner’s Action

that stated that the claims in the application included at least two patentably distinct inventions, one drawn to a device, the other drawn to a method, denominated here as Groups I and II:

[Group] I. Claims . . . drawn to a device for use in sealing a puncture in a wall of a blood vessel.

[Group] II. Claims . . . drawn to a method of sealing a puncture in a wall of a blood vessel.

J.A. 18,557. The Examiner's Action required restriction of the application under 35 U.S.C. § 121 to one of the two inventions/groups. *Id.*

In addition to the device/method restriction, the examiner stated that the claims included patentably distinct Species A, B, and C (as described below), and the Examiner's Action required that the applicant elect one of these Species in addition to electing Group I or Group II.<sup>1</sup>

Species A: Claims relating to the apparatus comprising a solid tissue dilator;

Species B: Claims relating to the apparatus comprising a hollow dilator and guidewire;

Species C: Claims relating to the apparatus comprising a guidewire and no dilator.

J.A. 18,558. The applicant responded to the restriction and elected Group I, Species B, that is, the application would now include only claims relating to a device/apparatus comprising a dilator and guidewire. The

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<sup>1</sup> The examiner also required election of subspecies not at issue in this appeal.

grandparent application as thus restricted ultimately issued as U.S. Patent No. 5,391,183, the grandparent patent.

On October 5, 1994, the applicant filed U.S. Patent Application No. 08/318,380 (the parent application) as a “divisional” of the grandparent application. During examination of the parent application, the examiner again imposed a restriction requirement and an election of species that were substantially identical to the restrictions imposed on the grandparent application. In response, the applicant again elected the same group and species, Group I, Species B.<sup>2</sup> The parent application ultimately issued as U.S. Patent No. 5,830,130, the parent patent.

Before the parent patent issued, the applicant filed U.S. Patent Application No. 08/399,535, the Janzen application, as a continuation of the parent application. However, in the Janzen application, the applicant canceled the original claims and copied both device and method claims from a different patent to provoke an interference proceeding. The Janzen application ultimately prevailed in the interference, and issued with both device and method claims as the '439 patent, i.e., the Janzen patent.

The applicant also pursued another continuation based on the parent application. This sibling to the Jan-

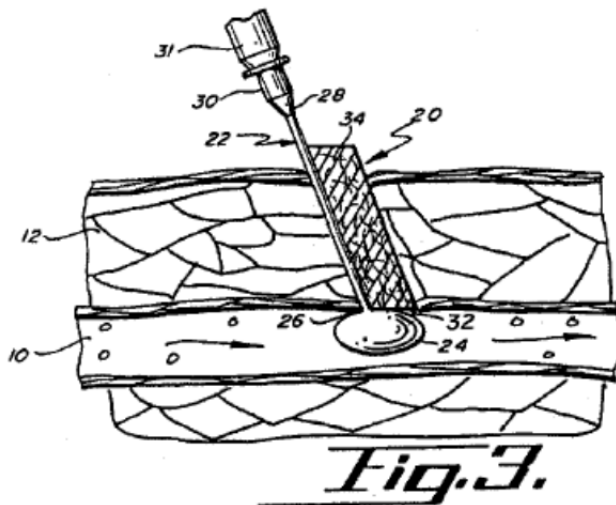
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<sup>2</sup> ACI contends that the parent application was not a true divisional since it elected the same invention as the grandparent. ACI relied on this fact to support one of its arguments that the Janzen patent does not qualify for safe harbor protection. Since we hold that the Janzen patent does not qualify for safe harbor protection on other grounds (*see infra*), we need not address this issue.

zen application ultimately issued as U.S. Patent 5,725,498, the sibling patent or '498 patent. The sibling patent issued earlier than the Janzen patent due to the Janzen patent's interference proceeding.

### B. The Fowler Patents

Like the Janzen patent, the Fowler patents disclose devices and methods for closing a vascular puncture with a plug, but the Fowler patents also disclose a balloon catheter with a balloon configured to position the plug. '616 patent, col.4 l.46 – col.5 l.6.<sup>3</sup> A user inserts the balloon catheter in the puncture tract until the balloon is positioned in the vessel, and the user inflates the balloon. *Id.* The user then inserts a plug such that the plug contacts the inflated balloon; the inflated balloon prevents the plug from extending into the vessel. *Id.* After the plug is positioned, the user removes the balloon catheter, leaving the plug in the puncture to promote healing. *Id.* col.5 ll.6–9. This arrangement is seen in Figure 3 of the Fowler patents, reproduced below.



<sup>3</sup> The Fowler patents share a common written description; therefore, we only refer to the written description of the '616 patent.

Two claims from the Fowler patents, dependent claim 14 of the '616 patent and independent claim 21 of the '375 patent, are involved in this appeal. Claim 21 is generally representative and recites, “a vessel plug” and “at least a portion of [a] positioning member [that] is expandable . . . to position said vessel plug in the incision proximally of the blood vessel such that said vessel plug obstructs the flow of blood through the incision without extending into the blood vessel.” '375 patent, col.10 ll.12–22.

### C. Procedural History

St. Jude filed its complaint in the United States District Court for the Western District of Arkansas on October 22, 2008, alleging that ACI infringed several of its patents, including the Janzen patent and the Fowler patents. During the litigation, the district court issued a *Markman* order in which it construed various claim terms found in the Janzen patent, including “means for ejecting” and “ejecting mechanism.” See *St. Jude Med., Inc. v. Access Closure, Inc.*, 4:08-CV-04101-HFB, 2010 WL 2868507 (W.D. Ark. July 19, 2010). The parties proceeded to trial before a jury.

The jury rendered a verdict that ACI had infringed claims 7 and 8 of the Janzen patent, but that claims 7, 8, and 9 of the Janzen patent were invalid for double patenting in light of the sibling '498 patent. Implicit in the jury's double patenting finding was the jury's conclusion that claims 7, 8, and 9 of the Janzen patent were not patentably distinct from claim 7 of the sibling patent.

The district court termed the jury's double patenting finding an “advisory opinion” since the court had withheld from the jury the question of whether the safe harbor provision in 35 U.S.C. § 121 prevented the claims from being invalidated. *St. Jude Med., Inc. v. Access Closure, Inc.*, 08-CV-4101, 2011 WL 5374424, at \*1 (W.D. Ark. Nov. 8, 2011). The district court then held a bench trial to determine whether the safe harbor provision applied to



the Janzen claims. The court concluded that the safe harbor did apply, thus overturning the jury's invalidity finding, and upholding the validity of the claims. *Id.*

With regard to the Fowler patents, the jury found that ACI had infringed claim 14 of the Fowler '616 patent, and claim 21 of the Fowler '375 patent. The jury also found that ACI willfully infringed the Fowler claims. Regarding validity, the jury found that the Fowler claims were not obvious and thus valid.

After the jury rendered its verdict, ACI filed a renewed JMOL motion on various issues. The district court denied ACI's motion. J.A. 119–20.

ACI now appeals the district court's application of the safe harbor provision to the Janzen patent, the court's construction of the claim terms "means for ejecting" and "ejecting mechanism" from the Janzen patent (*see* Janzen patent col.10 l.21 and col.10 l.66, respectively), and the court's denial of ACI's renewed motion for JMOL that the Fowler claims are invalid for obviousness.<sup>4</sup>

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<sup>4</sup> In the trial court proceedings, ACI raised the question of whether the safe harbor provision in § 121 applied at all since the Janzen patent and the sibling patent are continuation patents, not divisional patents. The trial court rejected that argument, concluding that, though they are continuations, they descended from a divisional application filed as a result of the restriction requirement, citing prior Federal Circuit cases. *St. Jude Med., Inc. v. Access Closure, Inc.*, 08-CV-4101, 2011 WL 5374424, at \*4 (W.D. Ark. Nov. 8, 2011). We agree with the trial court, and with Judge Lourie (*see* Concurrence at 2), that on these facts the safe harbor provision as a general proposition is an available defense to a double-patenting charge; because we hold the defense fails on

We have jurisdiction over this appeal under 28 U.S.C. § 1295(a)(1).

## II. DISCUSSION

### A. The Janzen Patent and The Safe Harbor Provision

#### 1.

We first address the district court's application of the safe harbor provision to the Janzen patent. The safe harbor provision arose from difficulties created by restriction requirements imposed by the U.S. Patent and Trademark Office (PTO) during examination, followed by double patenting challenges in the courts. A restriction requirement arises during examination at the PTO when an applicant pursues what are determined to be *multiple patentably distinct* inventions in the *same application* (see 35 U.S.C. § 121). Subsequently, a double patenting challenge may arise when, in an infringement suit, the patentee is charged with having pursued the *same or obviously similar* inventions in *multiple applications*, one or more of which later issued as the patent in suit (see *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985)). A successful double patenting defense invalidates the offending claims in the patent.

Prior to the 1952 Patent Act, when § 121 was enacted, patentees could be faced with a situation in which the PTO and courts caused these two doctrines to collide. To illustrate, assume the PTO imposes a restriction requirement on a patent application because the PTO concludes that the application claims invention A and invention B which are deemed to be *patentably distinct* inventions. The applicant then removes claims to invention B from

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other grounds, however, we need not further address or decide this aspect of the safe harbor issue.

the restricted application and files those claims in a subsequent application. The restricted application and the subsequent application later issue as patents.

In a later court challenge, a court concludes that invention A and invention B are *not* patentably distinct, and thus the claims in the patent resulting from the subsequent application are invalid for double patenting of the same invention. *See Remington Rand Bus. Serv. v. Acme Card Sys. Co.*, 71 F.2d 628, 633–34 (4th Cir. 1934); *see also In re Kauffman*, 152 F.2d 991, 993 (C.C.P.A. 1946). This conflicting result was recognized as inherently unfair, and the safe harbor was created to preclude it. *Studiengesellschaft Kohle mbH v. N. Petrochemical Co.*, 784 F.2d 351, 358 (Fed. Cir. 1986) (Newman, J., concurring).

The safe harbor provision states:

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 safe harbor provision, not a model of clarity, is at the center of the parties' dispute over the validity of the Janzen patent.

## 2.

ACI contends that the Janzen patent violates consonance. The judicially-created consonance concept derives from the safe harbor's "as a result of" requirement and

specifies that the “line of demarcation between the ‘independent and distinct inventions’ that prompted the restriction requirement be maintained.” *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990). An applicant’s pursuit of two or more non-elected inventions in the same subsequent application does not *by itself* violate the line of demarcation. See *Boehringer Ingelheim Int’l GmbH v. Barr Labs, Inc.*, 592 F.3d 1340, 1350 (Fed. Cir. 2010) (“The safe harbor is provided to protect an applicant from losing rights when an application is *divided*. The safe harbor of § 121 is not lost if an applicant does not file separate divisional applications for every invention or when independent and distinct inventions are prosecuted together.”). However, in *Gerber*, we concluded that “[p]lain common sense dictates that 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.” *Gerber*, 916 F.2d at 687.

The requirement for consonance applies to both the patent challenged for double patenting (the challenged patent) and the patent being used as a reference against the challenged patent (the reference patent). *Boehringer*, 592 F.3d at 1352 (“We have repeatedly held that the ‘as a result of’ requirement applies to the challenged patent as well as the reference patent.”). Consonance in a case like this requires that the challenged patent, the reference patent, *and* the patent in which the restriction requirement was imposed (the restricted patent) do not claim any of the same inventions identified by the examiner.

Looking first at the restricted patent—in this case the grandparent—defendant ACI argues that the Examiner’s Action in the grandparent application defined two inventions: the device of Group I and the method of Group II. And, as earlier noted, the grandparent patent that issued included only claims to the device of Group I. According

to ACI, the restriction requirement into two Groups set the line of demarcation, and the election of species had no effect on that line. Consequently, the Janzen patent crossed the line of demarcation since it contained claims to both a device (Group I) and a method (Group II), and thus violated consonance.

St. Jude argues that the election of species in the grandparent application *did* affect the line of demarcation. According to St. Jude, the Examiner's Action imposed a multi-level restriction: the device/method restriction at a first level and the election of species at a second level. Thus, the Examiner's Action demarcated not two, but six different inventions: Group I, Species A; Group I, Species B; Group I, Species C; Group II, Species A; Group II, Species B; and Group II, Species C. St. Jude asserts that the claims of the Janzen patent maintained consonance since the Janzen patent included claims to Group I, Species C and Group II, Species C, which did not overlap with the inventions, Group I, Species B, pursued in the grandparent patent.

The parties' dispute turns in large measure on the nature and effect of the examiner-imposed election of species. An election of species is similar to a restriction and again is explained best by example. An applicant may file an application containing claims to a generic invention, such as a widget. The application may also include claims to several patentably distinct species of the generic invention, such as the widget + X, the widget + Y, and the widget + Z.

After reviewing the application, the examiner may impose an election of species that requires the applicant to choose one of the species for examination. The election of species, like a typical restriction, helps the examiner to focus the examination process. The applicant typically elects a species (e.g., widget + X), focuses on prosecuting the generic claims to the widget and any claims to the

widget + X species, and withdraws the claims to the non-elected species, widget + Y and widget + Z. If the generic claim to the widget is allowed, the applicant may obtain claim coverage on all of the species. If the generic claim is not allowed, the application is restricted.

The PTO regulation that formally sets forth the framework for an election of species is 37 C.F.R. § 1.146:

In the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable.

Thus, § 1.146 states that if no generic claim is found allowable, then the election of species will create a restriction under 35 U.S.C. § 121. 37 C.F.R. § 1.146 (“his or her claim *will be restricted* if no claim to the genus is found to be allowable”) (emphasis added).<sup>5</sup>

Returning to the parties’ arguments, ACI agrees that the method/device restriction in the grandparent application affected the line of demarcation, but argues that the election of species did not affect the line because an election of species is inherently different from a restriction requirement.

This argument overlooks a critical point in this case: the grandparent application lacked a generic claim. The Examiner’s Action that included the restriction requirement and election of species in the grandparent applica-

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<sup>5</sup> Section 1.146 cites to 35 U.S.C. § 121 as statutory authority.

tion stated that “no claims are generic.” J.A. 18,558. The allowed and issued claims likewise lacked a generic claim. The Examiner’s Action stated the consequences if the claims of the application were held allowable without a generic claim: “Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims *shall be restricted* if no generic claim is finally held allowable.” J.A. 18,558 (emphasis added). Since no generic claim was applied for, and no such claim was finally held allowable, that is what occurred: the election of species in the grandparent created a *restriction*.<sup>6</sup> Thus, there were two restriction requirements imposed on the grandparent application: the original device/method restriction, and the second restriction that resulted from the election of species.

It makes logical sense that the election of species affected the line of demarcation when no claim was generic. If the election of species did not affect the line, double patenting would have prevented the Janzen applicant from obtaining valid claims directed to non-elected species. This result would be unfair since it was the examiner, not the applicant, who created the further division of the application with the election of species, and the exam-

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<sup>6</sup> We note that § 1.146 contemplates imposing an election of species in an application *having a generic claim*. 37 C.F.R. § 1.146 (“In the first action on an application *containing a generic claim* to a generic invention . . . .”) (emphasis added). Since the parties do not concern themselves with the issue of whether an examiner can impose an election of species *when no generic claim is in the application*, we assume for purposes of this case that the Examiner had authority to do so. *See* 35 U.S.C § 121.

iner already stated on the record that the non-elected species were patentably distinct from the elected species. The unfairness of the result would violate the purpose of the safe harbor.

For these reasons, we hold that the restriction resulting from the election of species affected the line of demarcation. In particular, the first restriction separated Group I from Group II, and the second restriction operated on top of the first restriction to separate the Species.

3.

With the line of demarcation settled, we must determine whether that line was honored—that is, whether any of the same restricted inventions are claimed in the challenged patent (the Janzen patent), the reference patent (the sibling patent), or the restricted patent (the grandparent patent). We review whether the requirements of § 121 have been satisfied as a question of law and without deference. *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, n.1 (Fed. Cir. 2004).

As noted above, the two restrictions placed upon the grandparent application together carved out Species A, B, and C. The Janzen application pursued Group I, Species C and Group II, Species C, which were different than the invention pursued in the grandparent application, Group I, Species B. Therefore, the line of demarcation was maintained in this respect.

However, turning to the sibling patent, we conclude that consonance was not maintained. The sibling patent's independent claim 1 is drawn to a method of sealing a puncture in a wall of a blood vessel involving neither a guidewire nor a dilator (i.e., a claim directed to Group II, but not limited to any of Species A, B, or C). Thus the sibling application was not filed “as a result” of the restriction since it pursued a claim generic to all of the



Species in Group II, and therefore overlapped Group II, Species C found in the Janzen patent.

The jury found that claims 7, 8, and 9 of the Janzen patent are not patentably distinct from claims of the sibling patent. The trial court saved invalidity under this finding based on double patenting rules by applying the safe harbor provision. Since we conclude that the Janzen patent and the sibling patent did not maintain consonance, and therefore the safe harbor provision cannot apply, we hold that claims 7, 8, and 9 of the Janzen patent are invalid. The trial court's ruling to the contrary is reversed.

#### B. The Janzen Patent and Claim Construction

ACI also appeals the district court's construction of "means for ejecting" and "ejecting mechanism" from claims 7 and 8 of the Janzen patent. Because we hold that these claims are invalid for double patenting, the claim construction issue is now moot.

#### C. The Fowler Patents and Obviousness

We last turn to ACI's argument that the Fowler patents are invalid for obviousness. To argue obviousness, ACI relies on a 1988 article by Kenichi Takayasu, M.D., et al., that describes a method and device for sealing a puncture in a liver vein with a compressed "gelfoam stick." Takayasu et al., "A New Hemostatic Procedure for Percutaneous Transhepatic Portal Vein Catheterization," *Jpn. J. Clin. Oncol.* 18:227-30 (1988) ("Takayasu"). ACI also argues obviousness based on a 1971 article by Karl Smiley that describes a technique for blocking bleeding from a vessel using a balloon catheter. Smiley and Perry, "Balloon Catheter Tamponade of Major Vascular Wounds," *Am. J. of Surgery*, 326-27 (1971) ("Smiley").

According to ACI, Takayasu and Smiley establish that there was a known problem in the art—achieving hemostasis in punctured or damaged blood vessels—and the

prior art references both disclosed methods of solving that problem. ACI argues that a person of ordinary skill in the art would have reasonably expected to permanently stop bleeding in blood vessels by combining the techniques described in Takayasu and Smiley in the manner claimed by the Fowler patents. For these reasons, ACI argues that claim 14 of the Fowler '616 patent, and claim 21 of the Fowler '375 patent are invalid for obviousness under 35 U.S.C. § 103.

In response, St. Jude contends that both prior art references fail to disclose the Fowler patent's claimed feature of a balloon configured to operate as a positioning device to prevent a plug from entering a blood vessel. In particular, St. Jude argues that the references lack "an elongate positioning member . . . to position said vessel plug . . . without extending into the blood vessel" from claim 21 of the '375 patent and "inflating a member on an insertion member to identify the location of the blood vessel adjacent to the incision" and "positioning the vessel plug in the incision such that the distal end of the vessel plug is located proximally of the blood vessel" from the combination of independent claim 9 and its dependent claim 14 of the '616 patent.

We review the jury's conclusions on obviousness without deference and the underlying findings of fact for substantial evidence. *The Johns Hopkins Univ. v. Data-scope Corp.*, 543 F.3d 1342, 1345 (Fed. Cir. 2008). We see no error in the district court's legal conclusion of non-obviousness. Neither Takayasu nor Smiley discloses a balloon configured to operate as a positioning device to prevent a plug from entering a blood vessel as claimed in the Fowler patents. Takayasu discloses no balloon at all, and Smiley discloses a balloon that is used to control the bleeding of a gunshot wound or an abdominal aneurism.

Moreover, we are not persuaded by ACI's arguments to combine the teachings of Takayasu and Smiley. ACI

points to Takayasu and Smiley, arguing that achieving hemostasis in blood vessels was a known problem in the art. But we note that Takayasu and Smiley both teach the same thing to overcome this problem: inserting an object into a wound to help achieve hemostasis. Takayasu teaches inserting a gelfoam stick, and Smiley teaches inserting a balloon. One of ordinary skill in the art at the time of the invention would have viewed the balloon and the gelfoam stick as substitutes to achieve the same hemostasis objective, not as complementary devices to achieve the positioning benefit of St. Jude's claimed invention.

ACI also notes that Takayasu discloses visualizing the placement of the gelfoam stick with x-ray and ultrasound imaging. Presumably, ACI is suggesting that since x-ray and ultrasound were used to place a gelfoam stick, it would have been obvious to one of skill in the art at the time of the invention to use a balloon to prevent a plug from entering a blood vessel. But ACI fails to explain why it would have been obvious to do so. Certainly the balloon in Smiley is not used to position a plug as claimed, and ACI provides no evidence that a balloon had ever been so used. Nor does ACI explain why common sense would lead one of ordinary skill in the art to abandon the non-invasive x-ray and ultrasound technology in favor of an invasive, inflatable balloon.

Therefore, while Takayasu does disclose using x-ray and ultrasound to help place a gelfoam stick, between this disclosure and the claimed invention lies a logical chasm—a chasm not bridged by the prior art, common sense, or ACI's statements that the claimed invention was obvious. Even under our “expansive and flexible” obviousness analysis (*see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415, (2007)), we must guard against “hindsight bias” and “*ex post* reasoning” (*id.* at 421). Doing so here compels us to reject ACI's argument.

ACI further contends that, because St. Jude’s expert Dr. Kovacs allegedly provided only conclusory testimony, the district court erred by rejecting ACI’s proposed combination. Dr. Kovacs testified that the proposed combination of Takayasu and Smiley was “very, very far out and it makes no sense to me whatsoever” and “[c]ombining two references which are independently farfetched is farfetched times farfetched, it’s farfetched squared.” J.A. 10634–35.

Even if Dr. Kovacs provided conclusory testimony, ACI did not carry its burden of proving invalidity. We have held that “[s]ince we must presume a patent valid, the patent challenger bears the burden of proving the factual elements of invalidity by clear and convincing evidence.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 (Fed. Cir. 2007). This burden of proof never shifts to the patentee. *Id.* ACI failed to carry its burden of proof. Therefore, ACI’s arguments about Dr. Kovacs are immaterial.

We find each of ACI’s obviousness arguments without merit and affirm the district court’s refusal to grant ACI’s renewed motion for JMOL.

### III. CONCLUSION

For the foregoing reasons, we conclude that the district court should be *affirmed-in-part* and *reversed-in-part*.<sup>7</sup>

### **AFFIRMED-IN-PART; REVERSED-IN-PART**

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<sup>7</sup> We do not rule on any decision issued by the district court to enhance damages relating to the jury’s finding of willfulness.

# United States Court of Appeals for the Federal Circuit

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ST. JUDE MEDICAL, INC., AND ST. JUDE MEDICAL  
PUERTO RICO, LLC,  
*Plaintiffs-Appellees,*

v.

ACCESS CLOSURE, INC.,  
*Defendant-Appellant.*

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2012-1452

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Appeal from the United States District Court for the  
Western District of Arkansas in No. 08-CV-4101 Senior  
Judge Harry F. Barnes.

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LOURIE, *Circuit Judge*, concurring.

I agree with the results of the majority opinion in all respects, but I would arrive at the conclusion of invalidity of the '439 Janzen patent by a different route.

In a nutshell, this case is resolved by the failure of the granted Janzen and '498 (sibling) patents to maintain consonance with the original restriction requirement. The accompanying requirement for election of species, which perhaps raises an issue of first impression, is a complication that should not come into play in deciding the appeal. That is where I differ with the majority opinion and the district court.

Under § 121, “[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 . . . 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.

First, it is worthy of note that this provision contemplates that it is divisional applications that are filed pursuant to a restriction, and the Janzen patent issued on a continuation, not a divisional application. The very title of § 121 is “Divisional applications.” It refers to divisional applications three times, twice in relation to the immunity from double patenting issue. However, we have held that the protections of § 121 are not vitiated by the presence of a continuation application in a chain of applications, even though the statute refers only to divisionals. *Amgen Inc. v. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1354 (Fed. Cir. 2009). Thus, I agree that the ’498 sibling patent would fall within the § 121 safe harbor, as it issued on a continuation application and, being limited to methods, maintains consonance with the original restriction requirement between devices and methods.

However, regarding the Janzen patent, our case law has held that a subsequent divisional application claiming immunity under §121 must claim subject matter “consonant” with the restriction requirement. *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1381 (Fed. Cir. 2003); *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990). That did not occur here with Janzen. The restriction requirement required dividing claims to devices from claims to methods, and the Janzen patent contains both device and method claims. It is the opposite of consonant. The district court referred to the consonance issue as the “most challenging issue” in

the case, and I believe it is dispositive of the result, although not as the district court decided it.

The application that led to the '183 (grandparent) patent was subjected to a restriction requirement, distinguishing between claims 1-38, drawn to devices, and claims 39-94, drawn to methods. While the applicants elected to prosecute the claims to devices, they then acted contrary to that election, filing another divisional application, still containing claims to both devices and methods. They received the same restriction requirement. They then filed continuation applications that issued as the Janzen patent and the '498 sibling patent. The Janzen patent thus claimed both devices and methods, contrary to the applicants' previous elections and not consonant with their election to prosecute the device claims in the earlier application and hence the method claims elsewhere.

In the parent application that preceded both the Janzen patent and the '498 sibling patent, the patent examiner, beyond making a restriction requirement, also required an election of species from what were referred to as patentably distinct species A, B, and C, stating "the claims shall be restricted if no generic claim is finally held to be allowable. Currently no claims are generic." Such a requirement for election of species is not the same as a restriction requirement. It is tentative and its consequences are avoidable by the applicant obtaining the allowability of a generic claim encompassing the various species or by filing separate applications to pursue the nonelected subject matter. In my view, the district court and the majority err in even considering the effect of the requirement for election of species in this case.

The district court analyzed claim 7 of the '498 sibling patent and concluded that the consonance issue was contingent upon whether claim 7 describes a dilator and guidewire—species B—whereas the claims of the Janzen

patent elected species C, limited to a guidewire alone. The court concluded that claim 7 of the '498 sibling patent was directed to species B, and the claims of the Janzen patent to species C, so, in its view, there was no consonance problem.

I agree with the majority that the district court erred in failing to recognize that the Janzen patent contains *both* claims to methods (9-10) and claims to devices (1-8). Thus, the Janzen claims are not consonant with the restriction requirement in the grandparent and parent patents. As such, whether filed as a divisional or a continuation, the Janzen patent does not receive the benefit of § 121's immunity from double patenting. As indicated, and contrary to the reasoning of the majority, it is not the distinction between species that is the issue, because they arose from a requirement to elect species pending the allowability of a generic claim, but to the distinction between the method and device inventions that were actually the subject of the original restriction requirement.

Thus, I disagree with the majority's commingling of the restriction requirement and requirement for an election of species. The election of species requirement was not a restriction requirement. It was not final, but was contingent on the absence of an allowable generic claim. If there was no generic claim, as appears to be the case, then the applicant could have argued that the species were not independent and distinct inventions. Alternatively, a separate application could have been filed on non-elected species.

It is true that 37 C.F.R. § 1.146, dealing with election of species, states that the "claim will be restricted if no claim to the genus is found to be allowable." But the appearance of the word "restriction" in the rule relating to election of species does not make it another requirement



for restriction piled onto the § 121 requirement for restriction.

The *Boehringer* case, cited in the majority opinion only for a lesser point, does not change this analysis. It does not deal with an election of species, just a requirement for restriction.

I therefore believe that the majority opinion overcomplicates the analysis of this appeal and improperly commingles restriction practice with election of species practice. But I nonetheless agree with its conclusions.