United States Court of Appeals for the Federal Circuit

2007-1428

PROVERIS SCIENTIFIC CORPORATION
(formerly known as Image Therm Engineering, Inc.),

Plaintiff-Appellee,

v.

INNOVASYSTEMS, INC.,

Defendant-Appellant.

Susan H. Farina, Proveris Scientific Corporation, of Marlborough, Massachusetts, argued for plaintiff-appellee. With her on the brief were Gary R. Greenberg and Louis J. Scerra, Jr., Greenberg Traurig LLP, of Boston, Massachusetts.

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Jeffrey Light, Patients Not Patents, Inc., of Washington, DC, for amicus curiae, Patients Not Patents,Inc.

Appealed from: United States District Court for the District of Massachusetts

Judge William G. Young

United States Court of Appeals for the Federal Circuit

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PROVERIS SCIENTIFIC CORPORATION
(formerly known as Image Therm Engineering, Inc.),

Plaintiff-Appellee,

v.

INNOVASYSTEMS, INC.,

Defendant-Appellant.

Appeal from the United States District Court for the District of Massachusetts in case no. 05-CV-12424, Judge William G. Young.

DECIDED: August 5, 2008

Before SCHALL, BRYSON, and GAJARSA, Circuit Judges.

SCHALL, Circuit Judge.

This is a patent infringement case. Innovasystems, Inc. ("Innova") appeals from the final judgment of the United States District Court for the District of Massachusetts that it infringed claims 3-10 and 13 of United States Patent No. 6,785,400 (the "'400 patent") owned by Proveris Scientific Corporation ("Proveris"). Proveris Scientific Corp. v. Innovasystems, Inc., No. 05-12424 (D. Mass. May 11, 2007). On appeal, Innova argues that the district court erred in ruling that the so-called "safe harbor" provision of

the Drug Price Competition and Patent Term Restoration Act of 1984, known as the "Hatch-Waxman Act," Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. §§ 355, 360cc (2000), and 35 U.S.C. §§ 156, 271, 282 (2000), does not immunize its accused activity from infringement of the '400 patent. Innova also argues that the district court erred in entering judgment as a matter of law ("JMOL") (i) that it infringed claims 3-10 and 13 of the '400 patent and (ii) in favor of Proveris on Innova's affirmative defenses that claims 1, 2, and 9 are invalid by reason of obviousness and that claims 3-8 and 10 and 13 are invalid as anticipated by a single prior art reference. Because we conclude that Innova is not entitled to the protection of the Hatch-Waxman Act safe harbor provision, and that the district court did not err in granting JMOL in favor of Proveris on infringement and on Innova's affirmative defenses, we affirm.

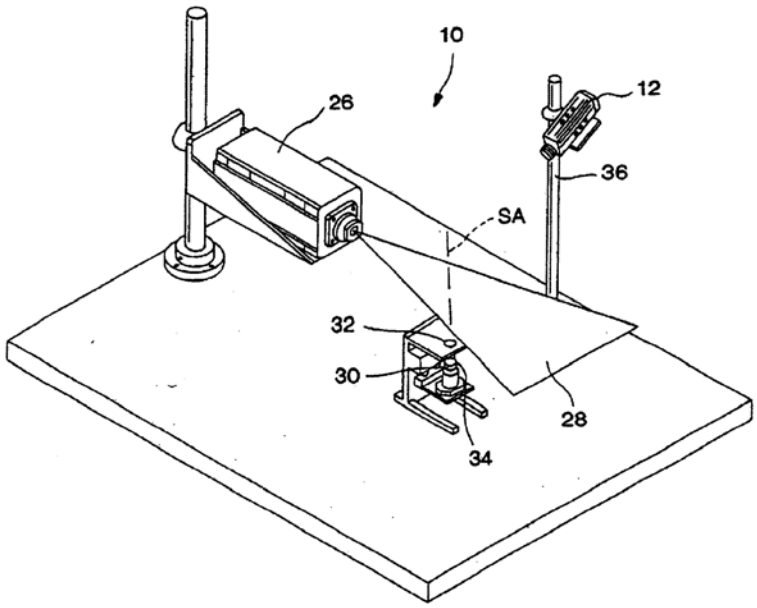
BACKGROUND

I

The '400 patent is directed to a system and apparatus for characterizing aerosol sprays commonly used in various drug delivery devices, such as nasal spray pumps and inhalers. '400 patent, col.1 ll.27-35. During drug research and development, spray characterization measurements are frequently used to calibrate drug delivery devices in accordance with the exact physical properties of a particular drug, in order to maximize the efficiency and effectiveness of drug delivery. '400 patent, col.1 ll.55-59. According to the '400 patent, spray characterization also plays an important role in the regulatory approval process of the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, ch. 675, 52 Stat. 1040 (1938) (codified at scattered sections of title 21 of the United States Code). Under the FDCA,

FDA approval is required for inhaler-based drug delivery devices. ’400 patent, col.1 ll.41-45. The system and apparatus claimed in the ’400 patent are not themselves subject to FDA approval, however.

Figure 2 of the ’400 patent depicts an embodiment of the claimed invention. Figure 2 shows a spray data acquisition system (10) which allows researchers to study and optimize the delivery of various aerosol-based drugs. The system operates through the action of a pumping device (30) which generates an aerosol spray plume (with a spray axis (SA)) whose spray characteristic data is collected by an illumination device (26) and imaging device (12).



The ’400 patent has thirteen claims. Claims 1 and 3 are independent claims. Claims 1, 2, and 13 are system claims, while claims 3-12 are apparatus claims. Claim 1 is representative. It provides as follows:

> A spray data acquisition system comprising:
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> a housing for supporting a pumping device whereby the pumping device is responsive to an applied force to generate an aerosol spray plume through an exit port thereon along a spray axis;
>
> a spray pump actuator, wherein the spray pump actuator is capable of controlling a pumping force and a duration of the aerosol spray plume of the pumping device;
>
> an illumination device for illuminating the aerosol spray plume along at least one geometric plane that intersects the aerosol spray plume; and,
>
> an imaging device for acquiring data representative of a first interaction between the illumination and the aerosol spray plume along the at least one geometric plane.

II

Innova makes and sells a device known as the Optical Spray Analyzer ("OSA"). The OSA itself is not subject to FDA approval. It is, however, used in connection with FDA regulatory submissions. In that setting, the device measures the physical parameters of aerosol sprays used in nasal spray drug delivery devices.

In December of 2005, Proveris filed suit against Innova in the District of Massachusetts, alleging infringement of claims 1-10 and 13 of the '400 patent. As part of its defense, Innova invoked the safe harbor provision of the Hatch-Waxman Act. The safe harbor provision is codified at 35 U.S.C. § 271(e)(1), which states in relevant part:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Innova argued that its allegedly infringing activities are immunized by this provision because its OSA devices are used by third parties solely for the development and submission of information to the FDA.

In due course, both parties moved for summary judgment on the section 271(e)(1) issue. After initially denying both motions, the district court asked the parties to brief further the question of what standard should be applied when considering Innova's safe harbor defense. After reviewing these submissions, and shortly before trial, the court ruled as a matter of law that section 271(e)(1) does not immunize Innova's OSA devices from infringement of the '400 patent. The court stated from the bench, "Also I've reflected at some length on this 271 Safe Harbor. As a matter of law, that's out."

At trial, the district court granted JMOL in favor of Proveris with respect to infringement of claims 3-10 and 13 of the '400 patent. Thus, as to claims 3-10 and 13, the court informed the jury that there was "[n]o dispute about infringement as to those claims." At trial, the district court also excluded certain expert testimony proffered by Innova relating to its affirmative defenses that claims 1, 2, and 9 of the '400 patent are invalid by reason of obviousness and that claims 3-8 and 10 and 13 of the patent are invalid as anticipated by a single prior art reference. As a result, the court granted JMOL in favor of Proveris on Innova's invalidity defenses. Following trial, the jury found claims 1 and 2 of the '400 patent not infringed, and awarded no damages for infringement of claims 3-10 and 13. Thereafter, the district court entered final judgment of infringement and issued a permanent injunction barring Innova from infringement of

the ’400 patent. Innova then filed this timely appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

On appeal, Innova contends that the district court erred (1) in ruling as a matter of law that section 271(e)(1) does not immunize it from infringement of the ’400 patent, (2) in granting JMOL of infringement of claims 3-10 and 13, and (3) in granting JMOL in favor of Proveris on its affirmative defenses that the asserted claims of the ’400 patent were invalid by reason of anticipation and obviousness. We address Innova’s contentions in turn.

I

Innova’s first argument on appeal is that the district court erred in ruling as a matter of law that its manufacture and sale of the OSA device are not immunized by the safe harbor provision of 35 U.S.C. § 271(e)(1). Since the pertinent facts are not in dispute, this argument presents a question of statutory interpretation, an issue of law that we review de novo. Romero v. United States, 38 F.3d 1204, 1207 (Fed. Cir. 1994).

A

Congress enacted the Hatch-Waxman Act in order to eliminate two unintended distortions of the effective patent term resulting from the premarket approval required for certain products by the FDCA.[1]

The first distortion was the reduction of effective patent life caused by FDA premarket approval. Because patent applications were filed early in the regulatory

[1] Under the FDCA, various products are subject to FDA regulatory review prior to market entry. See, e.g., 21 U.S.C. § 360e (medical devices); § 348 (food additives); § 376 (color additives); and § 355 (new drugs).

process, but market entry was delayed pending regulatory review, the early years of the patent term were spent obtaining premarket approval for the patented invention rather than generating profits. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 669 (1990).

The second distortion was the de facto extension of effective patent life at the end of the patent term, which also resulted from FDA premarket approval requirements. Prior to the Hatch-Waxman Act, competitors' activities involving a patented invention during the patent term constituted an act of infringement, even if undertaken for the sole purpose of obtaining FDA regulatory approval. See Roche Prods., Inc. v. Bolar Pharms. Co., 733 F.2d 858 (Fed. Cir. 1984), cert. denied, 469 U.S. 856 (1984). Because such activities could not begin until patent expiration, patent owners enjoyed a de facto patent term extension while competitors spent time following patent expiration obtaining FDA premarket approval necessary for market entry. Eli Lilly, 496 U.S. at 670.

The Hatch-Waxman Act sought to eliminate these distortions via two key provisions, now codified at 35 U.S.C. §§ 156 and 271(e)(1). The first provision, section 156, sought to eliminate de facto patent term reduction by providing patent term extension for those patents claiming a "product" subject to regulatory delays caused by the FDA premarket approval process.[2] For purposes of section 156, the term "product"

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[2] In relevant part, section 156 provides:

> The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent . . . if –
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> ***
>
> (4) the product has been subject to a regulatory review period before its commercial marketing or use . . . .

35 U.S.C. § 156(a).

means a "drug product" and "[a]ny medical device, food additive, or color additive subject to regulation under the [FDCA.]" 35 U.S.C. § 156(f).

The second provision, section 271(e)(1), sought to eliminate de facto patent term extension. It sought to do so by providing a safe harbor that immunized competitors from infringement on account of making, using, offering to sell, or selling within the United States or importing into the United States a "patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). The basic idea behind this provision was to allow competitors to begin the regulatory approval process while the patent was still in force, followed by market entry immediately upon patent expiration. Thus, in Telectronics Pacing Systems v. Ventritex, Inc., 982 F.2d 1520 (Fed. Cir. 1992), we pointed out that, as a result of section 271(e)(1), "a competitor who anticipates coming into the marketplace with a product that utilizes a currently patented invention may make, use, and sell that product so long as it is 'solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.'" Id. at 1525.

For purposes of this case, the critical terms in 35 U.S.C. § 271(e)(1) are "patented invention" and "reasonably related." In Eli Lilly, the Supreme Court addressed the issue of whether a patented cardiac defibrillator fell within the section 271(e)(1) safe harbor. 496 U.S. at 664. In that case, Eli Lilly & Co. ("Lilly") filed an action against Medtronic, Inc. ("Medtronic") in federal district court in Pennsylvania, seeking to enjoin Medtronic from testing and marketing an implantable cardiac defibrillator. Lilly claimed

that Medtronic's actions infringed two of its patents. Medtronic defended against the suit on the ground that its activities were reasonably related to the development and submission of information under the FDCA, and thus exempt from a finding of infringement under section 271(e)(1). Id. at 664. The district court rejected Medtronic's argument, concluding that the exemption did not apply to the development and submission of information relating to medical devices. Following a jury trial, the jury returned a verdict for Lilly on infringement of the first patent. After the district court directed a verdict for Lilly on infringement of the second patent, it entered judgment for Lilly and issued a permanent injunction against infringement of both patents. Id. On appeal, this court reversed, holding that by virtue of section 271(e)(1), Medtronic's activities could not constitute infringement if they were undertaken to develop information reasonably related to the development and submission of information necessary to obtain regulatory approval under the FDCA. The court remanded to the district court for a determination of whether that condition had been met. Id.

The Supreme Court granted certiorari. The question before the Court was whether the scope of the section 271(e)(1) safe harbor was limited to drugs, or also extended to medical devices, such as Medtronic's defibrillator. The Court held that medical devices were covered. It thus affirmed the decision of the Federal Circuit. After analyzing the language of section 271(e)(1), the Court "confirmed" the Federal Circuit's interpretation of the statute based upon "the structure of the [Hatch-Waxman] Act taken as a whole." 496 U.S. at 669. After reviewing the dual distortions noted above that led to the Hatch-Waxman Act, the Court stated:

> It seems most implausible to us that Congress, being demonstrably aware of the dual distorting effects of

> regulatory approval requirements in this entire area – dual distorting effects that were roughly offsetting, the disadvantage at the beginning of the term producing a more or less corresponding advantage at the end of the term – should choose to address both those distortions only for drug products; and for other products named in [35 U.S.C. § 156(f)[3]] should enact provisions which not only leave in place an anticompetitive restriction at the end of the monopoly term but simultaneously expand the monopoly term itself, thereby not only failing to eliminate but positively aggravating distortion of the 17-year patent protection. It would take strong evidence to persuade us that this is what Congress wrought, and there is no such evidence here.

Id. at 672-73. Continuing, the Court stated that, "[a]part from the reason of the matter," there were "textual indications" that sections 156 and 271(e)(1) were "meant generally to be complementary." Id. at 673.

The Court noted that interpreting the phrase "patented invention" in section 271(e)(1) to include all products listed in section 156(f) produced a "perfect 'product' fit" between the two provisions. Id. at 672. The Court pointed out that all of the products eligible for patent term extension under section 156 – including drugs, medical devices, food additives, and color additives – were subject to FDA premarket approval. Id. Conversely, all products subject to premarket approval that were not eligible for patent term extension under section 156(f) – such as new animal drugs and veterinary biological products – were excluded from the section 271(e)(1) safe harbor provision as well.[4] Id. at 674. Because of this nearly perfect product correlation between sections

[3] At the time Eli Lilly was decided, the products named in section 156(f) were "[a] human drug product" and "[a]ny medical device, food additive, or color additive subject to regulation under the [FDCA]." Id. at 671.

[4] It is to be noted that the versions of sections 271(e)(1) and 156(f) which were before the Supreme Court in Eli Lilly in 1990 differed slightly from the current versions of both provisions. As the Court noted in Eli Lilly, at that time, new animal

156 and 271(e)(1), and the roughly offsetting patent term distortions those two provisions were designed to address, the Court essentially interpreted section 271(e)(1) to include at least "all inventions" within the ambit of section 156. See id. at 673-74.

In AbTox, Inc. v. Exitron Corp., 122 F.3d 1019 (Fed. Cir. 1997), we applied the reasoning of the Supreme Court in Eli Lilly. After being sued for patent infringement, AbTox, Inc. ("AbTox") alleged in a counterclaim that Exitron Corporation and MDT Corporation ("defendants") infringed its U.S. Patent No. 4,321,232 (the "'232 patent"). The '232 patent claimed a medical device used in sterilizing medical instruments. AbTox, 122 F.3d at 1020-21. Defendants moved for summary judgment of noninfringement, claiming that their use of the invention claimed in the '232 patent in pursuit of FDA approval for a plasma sterilizer was covered by the safe harbor provision of section 271(e)(1). Id. at 1027. After the district court granted the motion, AbTox appealed.

The patented medical device in AbTox presented an issue not confronted in Eli Lilly, due to the varying levels of FDA regulation for different medical devices. We observed that although all three categories of medical devices, Classes I, II, and III, are subject to varying levels of FDA premarket approval, only Class III medical devices are eligible for patent term extension under section 156. Id. at 1028-29. Both AbTox's

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drugs and veterinary biological products were simultaneously excluded from both provisions. 496 U.S. at 674.

In contrast, sections 271(e)(1) and 156(f) now include new animal drugs and veterinary biological products, unless they have been "primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques . . . ."

These slight statutory differences do not undermine the relevance of the Court's Eli Lilly analysis. Instead, we think the persisting symmetry between both provisions over time further confirms the Court's view that sections 271(e)(1) and 156 operate in tandem.

invention and defendants' products were Class II medical devices, ineligible for patent term extension, unlike the eligible Class III medical device in Eli Lilly. Faced with a tension between the Supreme Court's broader holding in Eli Lilly that "patented invention" means "all inventions" within section 156, and the Court's narrower focus on statutory symmetry between the two provisions, we adopted the broader holding that the phrase "patented invention" of section 271(e)(1) includes any medical device, regardless of its eligibility for patent term extension under section 156. Id.

Precedent also has addressed which activities are sufficiently "reasonably related" to FDA approval for purposes of section 271(e)(1). In Telectronics, we held that demonstrating an implantable defibrillator at medical conferences was "reasonably related" to FDA approval because it facilitated the selection of clinical trial investigators. 982 F.2d at 1523. Most recently, in Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005), the Supreme Court interpreted "reasonably related" in determining whether section 271(e)(1) immunizes the use of patented inventions in preclinical research if the experimental results are never submitted to the FDA, id. at 195. In Merck, patented compounds were used in preclinical studies to identify and evaluate drugs useful for inhibiting angiogenesis. Id. at 198-99. The Court held that "reasonably related" activity does not require actual submission of information to the FDA; it also includes those situations in which a party has "a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA . . . ." Id. at 206-07. On remand, we held that the preclinical research in question was "reasonably related" to

FDA approval. Integra Lifesciences I, Ltd. v. Merck KGaA, 496 F.3d 1334, 1348 (Fed. Cir. 2007).

B

We turn now to the parties' contentions on appeal. Innova argues that it is entitled to the benefit of the section 271(e)(1) safe harbor because it is undisputed that it has only offered to sell the OSA to pharmaceutical companies and the FDA. Innova also states that it is undisputed that the OSA is and was used exclusively in applications for regulatory approval in accordance with the requirements of the FDCA. Innova urges that "Congress wrote § 271(e)(1) extremely broadly" when it said that it was not an act of infringement to sell a "patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." According to Innova, Congress intended to include within the safe harbor all "patented inventions" unless specifically excluded. Innova contends that both Lilly and Merck support its position and that the safe harbor provision should not be limited so as to exclude research tools – assuming its OSA device is viewed as such.

Proveris responds that "[t]he patented inventions that fall within the scope of § 271(e)(1) do not include patents on equipment that may be used in a pharmaceutical laboratory, such as microscopes, analytical balances, computers, and Proveris's Spray VIEW equipment." Proveris states that Congress created the patent term extension for "products" in 35 U.S.C. § 156(a) when it created the safe harbor in section 271(e)(1), doing so within the context of providing generic drug developers with the means to compete commercially immediately upon the expiration of a drug's patent. Under these

circumstances, Proveris reasons, section 271(e)(1) extends only to the infringement of patents that claim "products" as that term is defined in section 156(f) and to other patented inventions that are inherent to the development of "products." Thus, in Proveris's view, the patents which may be infringed with immunity, if the infringement is solely for uses reasonably related to the development and submission of information to the FDA, include patents on drug products, medical devices, food additives, and color additives. According to Proveris, section 271(e)(1) does not immunize infringement of patents on laboratory or manufacturing equipment. Proveris also argues that Innova's OSA device is not "reasonably related" to FDA submissions because Innova's infringement is not for purposes of its own FDA-related research, but rather for commercial sale to third parties engaged in such research.

C

The district court's ruling and the parties' contentions clearly frame the question before us: whether section 271(e)(1) immunizes the manufacture, marketing, or sale of Innova's OSA, which is used in the development of FDA regulatory submissions, but is not itself subject to the FDA premarket approval process. For the reasons set forth below, we hold that the section 271(e)(1) safe harbor does not immunize the OSA from infringement.

We think the Supreme Court's approach in Eli Lilly is instructive. In Eli Lilly, the Court examined the language of section 271(e)(1) in light of the overall statutory structure and underlying policy considerations leading to the enactment of the Hatch-Waxman Act. In that regard, as seen, sections 156 and 271(e)(1) were enacted in order to eliminate two unintended distortions of the effective patent term resulting from

premarket approval required of certain products pursuant to the FDCA. In Eli Lilly, the Supreme Court explained that the first distortion was the reduction of effective patent life caused by the FDA premarket approval process, while the second distortion was the de facto extension of effective patent life at the end of the patent term – also caused by the FDA premarket approval process. 496 U.S. at 669-70. The first distortion adversely affected patentees; the second distortion adversely affected those seeking FDA approval in order to enter the market to compete with patentees. It is the second distortion that is relevant to this case.

As far as the second distortion is concerned, Innova's OSA device is not subject to FDA premarket approval. Rather, FDA premarket approval is required only in the case of the aerosol drug delivery product whose spray plume characteristics the OSA measures. In short, Innova is not a party seeking FDA approval for a product in order to enter the market to compete with patentees. Because the OSA device is not subject to FDA premarket approval, and therefore faces no regulatory barriers to market entry upon patent expiration, Innova is not a party who, prior to enactment of the Hatch-Waxman Act, could be said to have been adversely affected by the second distortion. For this reason, we do not think Congress could have intended that the safe harbor of section 271(e)(1) apply to it. Put another way, insofar as its OSA device is concerned, Innova is not within the category of entities for whom the safe harbor provision was designed to provide relief. We thus agree with the district court that Innova is not entitled to the benefit of the section 271(e)(1) safe harbor.

At the same time, just as Innova is not a party who, prior to enactment of the Hatch-Waxman Act, could be said to have been adversely affected by the second

distortion discussed by the Supreme Court in Eli Lilly, so too Proveris is not a party who, prior to enactment of the Act, could be said to have been adversely affected by the first distortion. That is because Proveris is not a patentee who would have been faced with a reduction of effective patent life caused by the FDA approval process, the reason being that the invention claimed in the '400 patent is not subject to the premarket approval required by the FDCA. We think this is significant because, as noted above, in Eli Lilly the Court spoke of its interpreting the phrase "patented invention" in section 271(e)(1) to include all products listed in section 156(f) as producing a "perfect 'product' fit" between the two provisions. 496 U.S. at 672. The result we reach today achieves the same kind of fit, or symmetry. Because Proveris's patented product is not subject to a required FDCA approval process, it is not eligible for the benefit of the patent term extension afforded by 35 U.S.C. § 156(f). At the same time, because Innova's OSA device also is not subject to a required FDCA approval process, it does not need the safe harbor protection afforded by 35 U.S.C. § 271(e)(1).

As seen, Innova argues that it is entitled to the protection of section 271(e)(1)'s safe harbor because it is offering for sale and selling a "patented invention" (the invention claimed in the '400 patent) "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." Innova's position is that its offering for sale and its sale of the OSA device fit squarely within the statutory language because, like the product claimed in the '400 patent, the OSA is used in a way which is "reasonably related" to the "development and submission of information" pertinent to the FDA premarket approval required for inhaler-based drug delivery

devices. The problem with that argument is that it is premised on the proposition that the device claimed in the '400 patent is, for purposes of section 271(e)(1), a "patented invention." As we have just seen, it is not. We therefore reject the argument.

For the foregoing reasons, we see no error in the ruling of the district court that Innova's marketing and sale of its OSA device are not exempted from infringement by the safe harbor provision of 35 U.S.C. § 271(e)(1).

II

Innova's second contention on appeal is that the district court erred in granting JMOL of infringement of claims 3-10 and 13 of the '400 patent. The district court employed a special verdict form allowing the jury to consider the infringement of only claims 1 and 2 of the '400 patent. The record indicates the court took this action in response to what it viewed as Innova's admissions during and prior to trial that it did not have a defense to Proveris's claims of infringement of claims 3-10 and 13 of the '400 patent. Innova argues that the court's JMOL ruling was in error because a patentee bears the burden of proof with respect to infringement of every claim. Innova contends that Proveris failed to meet its burden with respect to claims 3-10 and 13. Proveris responds that Innova's counsel conceded infringement of claims 3-10 and 13 during a pre-trial conference with the district court judge, leaving the jury to consider only claims 1 and 2 at trial. As evidence of this concession, Proveris points to portions of the record in which Innova purportedly agreed with, or failed to object to, statements that claims 3-10 and 13 were admittedly infringed.[5]

[5] For example, during cross-examination, in response to questioning by Proveris's counsel that "there's no issue with respect to infringement as to claims 3 through 10 and 13 of the asserted patent," Innova's witness, Mr. Quinn, agreed. Trial

We review a district court's grant or denial of JMOL under the law of the regional circuit to which an appeal from the district court would normally lie. Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 425 F.3d 1366, 1372 (Fed. Cir. 2005). The regional circuit in this case is the First Circuit, which reviews de novo an order granting or denying JMOL. See Hochen v. Bobst Group, Inc., 290 F.3d 446, 453 (1st Cir. 2002); Larch v. Mansfield Mun. Elec. Dep't, 272 F.3d 63, 67 (1st Cir. 2001). JMOL is appropriate when "a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. P. 50(a)(1). We have reviewed the portions of the record cited by Proveris, and agree that the only reasonable conclusion is that Innova did indeed concede infringement with respect to claims 3-10 and 13, leaving a dispute only as to claims 1 and 2 for the jury to consider. Accordingly, we find no error by the district court in its grant of JMOL of infringement of claims 3-10 and 13.

III

Innova's final argument on appeal is that the district court erred in excluding or limiting the testimony of its invalidity experts, and consequently ruling in favor of Proveris on the issue of validity as a matter of law. In support of its claim that claims 1, 2, and 9 were invalid by reason of obviousness and that claims 3-8 and 10 and 13 were invalid as anticipated by a single prior art reference, Innova asserted a number of prior art references. In that connection, it sought to introduce supporting testimony from John

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Tr. at 241, Proveris Scientific Corp. v. Innovasystems, Inc., No. 05-12424 (D. Mass. May 11, 2007). Likewise, during trial the court stated that there was "no real dispute but what claims 3 through 10 and 13 do infringe the patent," to which Innova did not object. Id. at 168. In addition, the court also stated that "as [to] the other claims it's not disputed, but it is disputed as to claims 1 and 2, those were infringed," to which Innova again did not object. Id. at 286.

Waters, the president of Innova, as well as Charles Quinn, a patent attorney. The district court excluded the testimony of Mr. Waters on the ground that he had not prepared or submitted an expert report. At the same time, the court limited Mr. Quinn's testimony to a discussion of the contents of the prosecution history and a discussion of spray plumes. The court determined this was the correct approach because Mr. Quinn was a patent attorney with past experience using plumes to maneuver satellites while employed as an engineer in General Electric's missile and space division. However, he had no other relevant experience qualifying him to testify about the devices in question. Because these evidentiary rulings left Innova without expert testimony to substantiate its invalidity defenses, the district court entered JMOL in favor of Proveris.

Innova appeals the district court's evidentiary rulings that resulted in the entry of JMOL in favor of Proveris on the validity issue. First, it argues that the '400 patent was so simple and easily understood that the district court erred in requiring expert testimony to establish invalidity. Second, it urges that because Mr. Waters and Mr. Quinn were both persons of ordinary skill in the art, the district court improperly excluded or limited their testimony. We review a district court's evidentiary rulings under the law of the regional circuit. Sulzer Textil A.G. v. Picanol N.V., 358 F.3d 1356, 1363 (Fed. Cir. 2004). The First Circuit reviews evidentiary rulings for an abuse of discretion. Cavallaro v. United States, 284 F.3d 236, 245 (1st Cir. 2002).

We see no abuse of discretion in the district court's rulings with respect to the testimony of Mr. Waters and Mr. Quinn. First, the '400 patent teaches a device used for calibrating drug delivery devices; this subject matter is sufficiently complex to fall beyond the grasp of an ordinary layperson. We thus are not prepared to say the district

court abused its discretion in requiring Innova to present expert testimony in order to establish invalidity. Neither do we see an abuse of discretion in the court's evidentiary rulings involving Innova's proffered expert testimony. Mr. Waters's testimony was properly excluded because he did not submit a written expert report in compliance with Federal Rule of Civil Procedure 26(a)(2)(B). See Pena-Crespo v. Puerto Rico, 408 F.3d 10, 13-14 (1st Cir. 2005) ("In this case, Plaintiff's expert witness . . . did not prepare or submit a written report meeting the requirements of Rule 26(a)(2)(B). . . . Accordingly, the district court did not abuse its discretion in excluding [the witness] from testifying as an expert witness at trial."). We come to the same conclusion with respect to the court's ruling limiting the scope of Mr. Quinn's testimony to the prosecution history and the topic of plumes, because they were the only matters within his relevant expertise. Although a mechanical engineer by training, his technical experience was limited to satellite design while employed as an engineer at General Electric. Accordingly, we cannot say the district court did not act within its discretion in finding Mr. Quinn unqualified to testify about laboratory equipment used in the development of drug delivery devices. See, e.g., Malave-Felix v. Volvo Car Corp., 946 F.2d 967, 973 (1st Cir. 1991) (holding that the trial court acted within its discretion in determining that the expertise of an automobile systems expert did not extend to the mental processes and human factors which may have caused an automobile accident).

In sum, we see no abuse of discretion in the district court's decision to exclude and limit, respectively, the testimony of Mr. Waters and Mr. Quinn. Accordingly, we will

not disturb the district court's grant of JMOL in favor of Proveris on the issue of Innova's affirmative defense of invalidity.[6]

CONCLUSION

For the foregoing reasons, we affirm the final judgment of the district court.

AFFIRMED.

[6] On appeal, Innova has presented no meaningful argument as to why, if the district court's evidentiary rulings stand, the grant of JMOL was improper.