Cite as 637 F.3d 1269 (Fed. Cir. 2011)

here involves a crime similar in risk and similar in kind to the enumerated crimes. It involves either an escape from jail or an escape from the immediate custody of an officer transporting the person to or from jail. Escapes from custody, like burglary, will almost always involve the police attempting to apprehend the escapee and are likely to cause "an eruption of violence" upon discovery. Furqueron, 605 F.3d at 615. Such an eruption clearly presents a serious potential risk of physical injury. Also like burglary, escape from custody is a stealth crime that involves a high degree of recklessness.4 Like burglary, arson, and the use of explosives, escape from custody is purposeful, violent and aggressive because it involves a choice that will almost certainly be responded to with force, and potentially violent force, by the police. We conclude, therefore, that a felon who risks escape from custody is likely to use an illegally possessed firearm in a violent way and that escape from custody is therefore a violent felony under the ACCA.5

Having determined that escape from custody under Fla. Stat. § 944.40 is a vio-

Sanchez's purposeful behavior in planning the escape. *Id.* at 932 n. 33.

4. Our decision in Harrison, 558 F.3d 1280, is readily distinguishable. There, the Florida statute distinguished between three categories: (1) willful failure to stop a vehicle or willful fleeing after being ordered by an officer to stop; (2) willful fleeing after the police vehicle has activated its lights and siren; and (3) the conduct in category two, aggravated by either the addition of a high speed chase or wanton disregard for the safety of persons or property. Id. at 1291. Thus, the conduct at issue in Harrison, category two, expressly excluded recklessness. Id. at 1293. Indeed, we concluded that the category two crime "suggest[ed] an unwillingness to engage in violent conduct." Id. at 1296. Unlike the conduct at issue in Harrison, escaping from the custody of a penal institution or from the immediate custody of an officer while being transported to or from a penal institution will ordinarily

lent felony under the ACCA, we affirm the district court's application of the § 924(e) enhancement to Proch's sentence.

AFFIRMED.



SIEMENS MEDICAL SOLUTIONS USA, INC., Plaintiff-Cross Appellant,

v.

SAINT-GOBAIN CERAMICS & PLASTICS, INC., Defendant-Appellant.

Nos. 2010-1145, 2010-1177.

United States Court of Appeals, Federal Circuit.

Feb. 24, 2011.

Background: Exclusive licensee filed action against competitor alleging in-

involve a high degree of recklessness, and a virtual invitation to violence.

5. Our decision today is also readily distinguishable from United States v. Lee, 586 F.3d 859 (11th Cir.2009). There, we held that "a non-violent walkaway escape from unsecured custody [a halfway house] is not sufficiently similar in kind or degree of risk posed to the ACCA's enumerated crimes." Id. at 874. We expressly distinguished the category of crimes at issue in this case: "'the circumstances apparent in a walkaway escape are of an entirely different order of magnitude than escapes from jails and prisons. Residents of halfway houses have certain privileges of ingress and egress, do not live behind concrete walls and barbed wire, and are not under constant surveillance by armed guards." Id. at 873 (quoting approvingly United States v. Piccolo, 441 F.3d 1084, 1088 (9th Cir.2006)).

fringement of patent on gamma or x-ray detector that incorporated particular scintillator. The United States District Court for the District of Delaware, Sue L. Robinson, J., 615 F.Supp.2d 304, denied in part competitor's motion for judgment as matter of law or for new trial and remittitur, and then denied competitor's motion for modification, 2009 WL 4891774. Competitor appealed.

Holdings: The Court of Appeals, Lourie, Circuit Judge, held that:

- separate patentability did not merit proof beyond that of preponderance of evidence;
- (2) equivalence was not tantamount to obviousness;
- (3) district court did not abuse its discretion in not separately instructing jury that presumption of validity applied to subsequent patent;
- (4) district court did not abuse its discretion by excluding subsequently abandoned patent from evidence;
- (5) competitor's expert could not testify on matters not disclosed in his expert report or deposition and he could not rely on testing that was not disclosed;
- (6) substantial evidence existed for award of lost profits based on existence of two-supplier, high-end market;
- (7) district court did not abuse its discretion in reducing jury's damages award regarding lost profits; and
- (8) district court abused its discretion in not determining reasonable royalty.

Affirmed in part, vacated in part, and remanded.

Prost, Circuit Judge, filed dissenting opinion.

1. Patents \$\sim 312(4)\$

Separate patentability, while potentially relevant to equivalence issue and deserving of due weight in infringement analysis, did not merit proof beyond that of preponderance of evidence. 35 U.S.C.A. § 282.

2. Courts \$\sim 96(7)\$

In a patent case, the denial of a motion for judgment as a matter of law (JMOL) or for a new trial is reviewed under the law of the pertinent regional circuit.

3. Federal Courts ☞ 765

The Third Circuit exercises plenary review of a denial of judgment as a matter of law (JMOL), applying the same standard as the district court.

4. Federal Courts € 763.1, 825.1

In the Third Circuit, the standard of review on a motion for a new trial is abuse of discretion unless the court's denial of the motion is based on application of a legal precept, in which case review is plenary.

Federal Civil Procedure 2184.1

Whether a jury instruction is legally erroneous is a question of law.

6. Patents \$\sim 324.5\$

The legal sufficiency of jury instructions on an issue of patent law is reviewed without deference to the district court; a new trial is ordered only when errors in the instructions as a whole clearly mislead the jury.

7. Federal Courts \$\sim 908.1\$

A jury verdict will be set aside, based on erroneous jury instructions, if the movant can establish that those instructions were legally erroneous and that the errors had prejudicial effect.

8. Patents \$\sim 237\$

The equivalents doctrine prohibits one from avoiding infringement liability by making only insubstantial changes and substitutions which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law.

9. Patents \$\infty\$230, 237

The essential inquiry in any determination under the equivalents doctrine is whether the accused product or process contains elements identical or equivalent to each claimed element of the patented invention.

10. Patents \$\sim 237\$

Under the equivalents doctrine, equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum.

11. Patents \$\infty\$ 312(4), 314(5)

Patent infringement, whether literal or by equivalence, is an issue of fact, which the patentee must prove by a preponderance of the evidence.

12. Patents €=112.5

Overcoming the statutory presumption of validity afforded to patents requires proof by clear and convincing evidence. 35 U.S.C.A. § 282.

13. Patents \$\sim 312(4)\$

Jury's finding of infringement under equivalence doctrine by only preponderance of evidence could not invalidate competitor's separate related patent, constructively or otherwise. 35 U.S.C.A. § 282.

14. Patents \$\infty\$16(1), 237

In action to determine whether prior patent had been infringed by subsequently patented product, equivalence was not tantamount to obviousness, since those two legal principles required different analytical frameworks; doctrine of equivalents typically involved application of insubstantial differences test, usually via function-way-result test, and obviousness inquiry could center on objective evidence of commercial success or on level of predictability in the art, and time frames of two inquiries differed. 35 U.S.C.A. § 103(a).

15. Patents ⋐ 16(2)

A patent invalidity analysis requires a comparison between the prior art and the claimed subject matter as a whole, not separate pieces of the claim. 35 U.S.C.A. § 103.

16. Patents \$\sim 314(1)\$

District court did not abuse its discretion in not separately instructing jury that presumption of validity applied to subsequent patent licensed by defendant competitor on scintillator crystals when instructing jury under equivalents doctrine on how to determine whether competitor had infringed prior patent on chemically-similar scintillator crystals that was held by plaintiff exclusive licensee. 35 U.S.C.A. § 282.

17. Courts \$\sim 96(7)\$

In a patent case, a district court's decision to exclude evidence is reviewed under the law of the regional circuit.

18. Federal Courts ⋘823

The Third Circuit reviews a district court's decision to exclude evidence for abuse of discretion.

19. Federal Courts ⋘823

A ruling excluding evidence is accorded particular deference; it may not be reversed unless the determination is arbitrary and irrational. Fed.Rules Evid.Rule 403, 28 U.S.C.A.

20. Federal Courts €=895.5

An erroneous evidentiary ruling is harmless only if it is highly probable that the error did not affect the outcome of the case.

21. Patents \$\sim 312(2)\$

District court did not abuse its discretion by excluding subsequently abandoned patent from evidence, in infringement action regarding patent on scintillator crystals, where competitor had sought to introduce patent only in connection with its license defense to claim of willful infringement by exclusive licensee, district court did admit testimony regarding competitor's license of patent and license itself, and competitor did not make equivalence argument until after trial that patent should have been admitted for its relevance to patentability of those crystals.

22. Patents \$\sim 324.56\$

District court's alleged error in excluding subsequently abandoned patent from evidence was harmless, in infringement action regarding patent on scintillator crystals, where patent, which was abandoned following interference with another patent, was not, and could not have been, asserted in instant case because patent would largely have been cumulative of evidence already of record, including other patent, in that abandoned patent and other patent disclosed and claim substantially same invention, and jury had been informed of existence and content of aban-

doned patent, including competitor's efforts to obtain license.

23. Patents ≈292.4

District court did not abuse its discretion by ruling that defendant competitor's expert could not testify on matters not disclosed in his expert report or deposition, and that he could not rely on testing that was not disclosed to exclusive patent licensee during discovery; although expert was unable to use work-related materials in litigation or produce any documents during discovery because his research involved national security matters, fundamental principle of fairness supported court's sensible limitations on expert's testimony because plaintiff did not have any principled way to test expert's recollection and opinion. Fed.Rules Evid.Rule 702, 28 U.S.C.A.; Fed.Rules Civ.Proc.Rules 26(a)(2)(B)(i, ii), 37(c)(1), 28 U.S.C.A.

24. Federal Civil Procedure \$\infty\$1274

Fundamental fairness requires disclosure of all information supplied to a testifying expert in connection with his testimony. Fed.Rules Civ.Proc.Rule 26, 28 U.S.C.A.

25. Patents \$\sim 324.5\$

De novo review applies in a patent case to the question of law of whether lost profits are legally compensable in a particular situation.

26. Patents \$\infty\$ 318(1)

To recover lost profits, the patent owner must show causation in fact, establishing that but for the infringement, he would have made additional profits.

27. Patents @318(1)

In general, to recover lost profits, the patent owner must prove (1) a demand for

the patented product, (2) an absence of acceptable noninfringing substitutes, (3) the manufacturing and marketing capability to exploit the demand, and (4) the amount of profit the patent owner would have made.

28. Patents \$\iiins 312(10)

Substantial evidence existed for award of lost profits based on existence of two-supplier, high-end market for products that used patented scintillator crystals, even though plaintiff lost some sales to third supplier during relevant time period, where there was ample evidence that third supplier had produced product that generally was inferior with respect to important scintillator properties, including light output and decay time.

29. Patents \$\sim 318(1)\$

Accurately identifying a two-supplier market on a claim to recover lost profits requires an analysis that excludes alternatives to the patented product with disparately different prices or significantly different characteristics.

30. Patents \$\sim 318(1)\$

Scanners containing lanthanum bromide (LaBr₃) scintillator crystals were not available, noninfringing substitute for scanners consisting of patented cerium-doped lutetium oxyorthosilicate (LSO) crystals, where there were no commercial PET scanners sold on market using LaBr₃ scintillation crystal and LaBr₃ was at least one and one-half years behind in development of accused crystals that consisted of cerium-doped lutetium-yttrium orthosilicate (LYSO).

31. Patents \$\infty\$ 318(1)

On a claim to recover lost profits, to be "available" an acceptable noninfringing substitute must have been available or on the market at the time of patent infringement; a substitute need not be on sale at the time of infringement, but if the substitute cannot be commercialized "readily," then it is not available for purposes of a lost profits determination.

32. Patents \$\sim 318(3)\$

District court did not abuse its discretion in reducing jury's damages award regarding lost profits as to scanners that used accused scintillator crystals but had not been sold prior to expiration of patent.

33. Courts \$\sim 96(7)\$

In a patent case, the decision of a district court to reduce a jury's damages award is reviewed under the law of the regional circuit.

34. Federal Courts €=827

The Third Circuit reviews a discretionary reduction in a jury award for abuse of discretion since the trial judge is in the best position to evaluate the evidence and assess whether the jury's verdict is rationally based.

35. Patents \$\infty\$ 318(4.1)

To recover lost profits damages, the patentee must show a reasonable probability that, "but for" the infringement, it would have made the sales that were made by the infringer.

36. Patents \$\sim 319(1)\$

District court abused its discretion in not determining reasonable royalty for scanners that used accused scintillator crystals supplied to manufacturer by defendant competitor but that had not been sold by manufacturer prior to expiration of patent, where manufacturer had made those additional scanners. 35 U.S.C.A. §§ 271, 284.

37. Federal Courts €=813

A district court abuses its discretion when it commits legal error in its award of damages.

38. Patents \$\infty\$ 318(2), 319(1)

In a patent case, the floor for a damage award is no less than a reasonable royalty; the award may be split between lost profits as actual damages to the extent they are proven and a reasonable royalty for the remainder. 35 U.S.C.A. § 284.

39. Patents €=319(1)

If a district court eliminates a lost profits award with regard to a portion of infringing devices, the court must then determine an appropriate measure of damages for that portion. 35 U.S.C.A. § 284.

40. Patents \$\sim 314(6)\$

Exclusive licensee did not waive its right to reasonable royalty damages with regard to scanners that used accused scintillator crystals supplied to manufacturer by defendant competitor but that had not been sold by manufacturer prior to expiration of patent, where jury had heard testimony from both parties' damages experts on subject of reasonable royalties, jury had been instructed on reasonable royalty damages, and licensee had pointed out that patent was infringed by making, using, and selling invention, and that jury's award likely was combination of both lost profits and reasonable royalty.

Patents \$\sim 328(2)\$

4,958,080. Infringed.

Patents \$\sim 328(2)\$

6,323,489, 6,624,420. Cited.

Gregg F. LoCascio, Kirkland & Ellis, LLP, of Washington, DC, argued for plaintiff-cross appellant. With him on the brief were John C. O'Quinn, William H. Burgess, Michael A. Pearson, Jr.; and Robert G. Krupka, of Los Angeles, CA.

Carter G. Phillips, Sidley Austin LLP, of Washington, DC, argued for defendant-appellant. With him on the brief were Virginia A. Seitz and James C. Owens. Of counsel on the brief was Arthur I. Neustadt, Oblon Spivak McClelland Maier & Neustadt, L.L.P., of Alexandria, VA.

Before LOURIE, LINN, and PROST, Circuit Judges.

Opinion for the court filed by Circuit Judge LOURIE. Dissenting opinion filed by Circuit Judge PROST.

LOURIE, Circuit Judge.

Saint-Gobain Ceramics & Plastics, Inc. ("Saint-Gobain") appeals from the decision of the United States District Court for the District of Delaware denying Saint-Gobain's motion for judgment as a matter of law ("JMOL") or for a new trial following the jury's finding that Saint-Gobain infringed U.S. Patent 4,958,080 (the "'080 patent") under the doctrine of equivalents. Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc., 615 F.Supp.2d 304 (D.Del.2009) ("JMOL Opinion"). Siemens Medical Solutions USA, Inc. ("Siemens") cross-appeals from the district court's grant of Saint-Gobain's motion for JMOL reducing the jury's award of damages. Id.

Because we discern no legal error in the court's jury instructions and no abuse of discretion in the court's evidentiary rulings, we affirm the decision of the district court denying Saint-Gobain's motion for JMOL or a new trial. However, for the reasons stated below, we vacate the dis-

trict court's damages award and remand for a determination of additional damages.

Background

Positron emission tomography ("PET") is a nuclear medical imaging technique that provides images and information about the chemical structure and function of a patient's organ systems. Opinion at 307. To obtain a PET scan, a patient is administered a radioactive isotope and enters the PET scanner. As the isotope decays in the patient's body, it emits positrons. When a positron collides with an electron in the patient's body, two gamma-ray photons are produced, which exit the patient's body. The photons are detected by the PET scanner's radiation detector, which contains thousands of scintillator crystals arranged in a ring around the patient's body. As the district court found, "[a] scintillator, generally, is a substance that absorbs high energy radiation and, in response, fluoresces photons at a specific, longer wavelength, releasing the previously absorbed energy." Id. at 307 n. The scintillator crystals convert the emitted gamma rays into visible light, which is then detected to produce a threedimensional image of the radioactivity in the patient. This image provides useful diagnostic information about the patient's organ systems. Id. at 307.

Siemens develops, manufactures, and sells PET scanners. The scintillator crystals in Siemens' PET scanners consist of cerium-doped lutetium oxyorthosilicate ("LSO"). *JMOL Opinion* at 307. Saint-Gobain manufactures and sells scintillator crystals for use in PET scanners. Saint-Gobain's crystals consist of cerium-doped lutetium-yttrium orthosilicate ("LYSO"), which differs chemically from LSO in that some of the lutetium is substituted for by

yttrium. *Id.* Specifically, Saint–Gobain's crystals are 10% Y LYSO, meaning that 10% of the lutetium atoms are substituted for by yttrium atoms. Saint–Gobain sells its scintillator crystals to Philips Medical Systems ("Philips"), which manufactures and sells PET scanners that compete with those sold by Siemens. *Id.* at 308.

Siemens owns the '080 patent, which relates to radiation detectors comprising an LSO scintillator crystal and a photodetector. *JMOL Opinion* at 307; J.A. 1210–11. The '080 patent was filed on August 4, 1989 and expired on October 6, 2008. *JMOL Opinion* at 307. Claim 1 of the '080 patent reads as follows:

1. A gamma ray or x-ray detector, comprising: a scintillator composed of a transparent single crystal of cerium-activated lutetium oxyorthosilicate having the general formulation $\text{Ce}_{2x}\text{Lu}_{2(1-x)}\text{SiO}_5$, where x is within the range of from approximately 2×10^{-4} to approximately 3×10^{-2} , and

a photodetector optically coupled to the scintillator for producing an electrical signal in response to the emission of a light pulse by the scintillator.

'080 patent col.12 ll.7-15.

Although the '080 patent is the only asserted patent in this case, the parties' arguments on appeal involve two additional patents. U.S. Patent 6,624,420 (the "'420 patent"), which is licensed to Saint–Gobain, discloses radiation detectors comprising LYSO scintillator crystals. *JMOL Opinion* at 307–08. Claim 1 of the '420 patent recites:

1. A scintillator detector for high energy radiation comprising: a monocrystalline structure of cerium doped lutetium yttrium orthosilicate, Ce_{2x} , $(Lu_{1-y}Y_y)_{2(1-x)}SiO_5$ where x=approximately 0.0001

to approximately 0.05 and y=approximately 0.0001 to approximately 0.9999.

'420 patent col.7 ll.39–43. As the formula in claim 1 indicates, the LYSO crystals disclosed in the '420 patent range from 0.01% Y to 99.99% Y. The specification of the '420 patent states that LYSO crystals comprising 30% Y, 50% Y, 70% Y, and 85% Y were prepared. *Id.* col.4 ll.51–58. The '420 patent was filed on February 17, 2000, and its front page lists the '080 patent among the "References Cited."

The parties also reference U.S. Patent 6,323,489 (the "'489 patent"), another patent disclosing LYSO scintillator crystals. The '489 patent was the subject of an interference action with the patent application that issued as the '420 patent. Claim 1 of the '489 patent recites:

1. A crystal scintillator comprising a transparent single crystal of cerium-activated lutetium yttrium oxyorthosilicate having the general formula $\text{Lu}_{(2-x-z)}\text{Y}_x\text{Ce}_z$ SiO_5 , wherein $0.05 \leq x \leq 1.95$ and $0.001 \leq z \leq 0.02$.

'489 patent col.5 ll.2–5. Unlike the '420 patent, the specification of the '489 patent discloses the preparation of a crystal consisting of 10% Y LYSO. *Id.* col.3 l.64–col.4 l.1. The '489 patent was surrendered following an adverse decision in the interference proceeding. *JMOL Opinion* at 307 n. 3.

In April 2007, Siemens sued Saint-Gobain for infringement, including willful infringement, of claims 1 and 2 of the '080 patent. *JMOL Opinion* at 307. Siemens' infringement theory relied on the doctrine of equivalents. Siemens alleged that Saint-Gobain was liable for contributory

 The parties did not dispute that, aside from the scintillator crystals, the PET scanners at issue literally satisfied all other limitations of and induced infringement under 35 U.S.C. § 271(b) and (c) by selling 10% Y LYSO crystals to Philips for use in its PET scanners. Id. at 308-09. Saint-Gobain argued in response that PET scanners comprising its 10% Y LYSO crystals did not infringe the '080 patent under the doctrine of equivalents. Saint-Gobain argued, in particular, that its LYSO crystals are not equivalent to those claimed in the '080 patent, because its crystals are separately claimed in the '420 patent. Id. at 308. In defense to Siemens' allegation of willfulness, Saint-Gobain pointed out that it obtained a license to the '489 patent and then, after the interference, to the '420 patent. Id. at 311-12.

A jury trial was held from September 17 to 25, 2008. *Id.* Despite Saint–Gobain's request for a higher evidentiary standard to prove equivalence (an issue we discuss further below), the court instructed the jury that Siemens must prove contributory and induced infringement under the doctrine of equivalents by a preponderance of the evidence. *Id.* at 309. Regarding the '420 patent, the court instructed the jury as follows:

[Y]ou have heard evidence that Saint–Gobain has a license under the ['420] patent to produce its 10% Y LYSO crystal. In connection with this evidence, I instruct you that a product that is covered by a subsequent patent may still infringe an earlier patent. Nonetheless, in considering the issue of infringement under the doctrine of equivalents, you may consider that Saint–Gobain obtained the license under the ['420] patent, which may be some evidence that the differences between the 10% Y

claims 1 and 2 of the '080 patent. *JMOL Opinion* at 308.

LYSO crystal and the claimed LSO crystal are substantial. Such evidence may be considered along with other evidence of the similarities and differences between the claimed LSO crystal and Saint–Gobain's 10% Y LYSO crystal. It is for you to decide the issue of whether Saint–Gobain's 10% Y LYSO crystal constitutes an equivalent to the claimed LSO crystal of the '080 patent.

Id.; J.A. 451. The court also instructed the jury that, in the event it found infringement, it could consider a reasonable royalty and lost profits as damages. *JMOL Opinion* at 309; J.A. 467–70.

The jury found in favor of Siemens on infringement and awarded total damages of \$52.3 million.² Id. The jury also found that Saint-Gobain's infringement was not willful. Id. Saint-Gobain filed a post-trial motion for JMOL or a new trial, in which Saint-Gobain challenged the following decisions of the district court: (1) a decision not to instruct the jury that infringement by equivalence must be proved in this case by clear and convincing evidence; (2) a decision not to instruct the jury that the '420 patent is presumed valid; (3) a decision not to admit into evidence the '489 patent and certain expert testimony; and (4) a decision to permit the jury to consider lost profits damages. Saint-Gobain further argued that the court should remit the jury's damages award.

In its opinion and order dated May 15, 2009, the district court denied Saint–Gobain's post-trial motion for JMOL or for a new trial. *JMOL Opinion* at 320. How-

2. The verdict form did not ask the jury to specify whether its award resulted from a calculation of reasonable royalty, lost profits, or a combination of the two. J.A. 476–77.

ever, the court granted Saint-Gobain's request to reduce the jury's damages award, finding that evidence supported the jury verdict only up to \$44,937,545. *Id.* at 319. In particular, the court found substantial evidence that Saint-Gobain sold 79 PET scanners' worth of crystals to Philips and that Philips sold 61 scanners prior to the expiration of the '080 patent, but that Philips' sale of the additional 18 scanners was "wholly speculative." Id. at 318–19. The court therefore awarded lost profits damages corresponding to 61 scanners based on the per scanner profit estimate of Siemens' damages expert.3 Id. at 319. The court entered final judgment on December 16, 2009.

The parties timely appealed and cross-appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

[1] Saint-Gobain appeals the district court's denial of its motion for JMOL or for a new trial. In particular, Saint-Gobain challenges the district court's jury instructions with regard to the doctrine of equivalents and the presumption of validity, the decision of the district court to exclude certain evidence, and the district court's decision to permit the jury to consider lost profits damages. Siemens crossappeals the district court's reduction of the jury's damages award.

- [2-4] We review the denial of a motion for JMOL or for a new trial under the law of the pertinent regional circuit. Seachange Int'l, Inc. v. C-COR Inc., 413 F.3d
- 3. The court also awarded lost profits damages for service contracts on PET scanners sold in the United States; these damages are included in the total of \$44,937,545. *JMOL Opinion* at 319.

1361, 1367–68 (Fed.Cir.2005). The Third Circuit exercises plenary review of a denial of JMOL, applying the same standard as the district court. *Curley v. Klem*, 499 F.3d 199, 205–06 (3d Cir.2007); *Rinehimer v. Cemcolift, Inc.*, 292 F.3d 375, 383 (3d Cir.2002). In the Third Circuit, "[t]he standard of review on a motion for a new trial is abuse of discretion unless the court's denial of the motion is based on application of a legal precept, in which case our review is plenary." *Curley*, 499 F.3d at 206 (internal quotation marks omitted); *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1167 (3d Cir.1993).

A. Jury Instructions

[5–7] Whether a jury instruction is legally erroneous is a question of law. Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed.Cir.2000). "This court reviews the legal sufficiency of jury instructions on an issue of patent law without deference to the district court.... and only orders a new trial when errors in the instructions as a whole clearly mislead the jury." DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1304 (Fed.Cir.2006) (en banc in relevant part) (internal quotation marks omitted). Moreover, a jury verdict will be set aside, based on erroneous jury instructions, if the movant can establish that "those instructions were legally erroneous" and that "the errors had prejudicial effect." Advanced Display, 212 F.3d at 1281.

Burden of Proof for Infringement under the Doctrine of Equivalents

Saint-Gobain argues that the district court legally erred in its jury instructions regarding proof of infringement under the doctrine of equivalents. Saint-Gobain asserts that, in cases where an alleged equivalent is separately patented, a heightened evidentiary burden is required. In particular, Saint–Gobain argues that, because its 10% Y LYSO crystals are covered by the '420 patent, the district court erred by not instructing the jury that a finding of equivalence between the 10% Y LYSO crystals and the LSO crystals of the '080 patent necessitates proof beyond that of a preponderance of the evidence.

Saint-Gobain's rationale for this heightened burden is the following: The jury's finding of equivalence "constructively invalidated" the '420 patent, because "a legal conclusion of invalidity for obviousness was ... the clearly implied result of the jury's verdict." Opening Br. of Def.-Appellant Saint-Gobain at 21. Thus, due to this implied result, the district court legally erred by failing to instruct the jury that equivalence must be found by clear and convincing evidence—i.e., the evidentiary burden required to overcome the statutory presumption of validity under 35 U.S.C. § 282. In support of its argument, Saint-Gobain relies on Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., in which we stated, "when a device that incorporates the purported equivalent is in fact the subject of a separate patent, a finding of equivalency, while perhaps not necessarily legally foreclosed, is at least considerably more difficult to make out." 493 F.3d 1368, 1379-80 (Fed.Cir.2007) (internal footnote omitted). On account of the allegedly erroneous jury instruction, Saint-Gobain asks us to set aside the jury verdict of infringement and order a new trial.

In response, Siemens argues that, even in cases of separate patentability, infringement by equivalence is proved by a preponderance of the evidence. According to Siemens, our cases consistently hold that although the fact of separate patentability may be considered by the jury along with other relevant evidence of noninfringement, this fact does not alter the required burden of proof. Siemens argues that the statement in *Festo* is dictum and points instead to cases including *Hoechst Celanese Corp v. BP Chems. Ltd.*, 78 F.3d 1575, 1582 (Fed.Cir.1996), in which we explained that "[t]he fact of separate patentability presents no legal or evidentiary presumption of noninfringement." Because the jury was correctly instructed,

Siemens argues, the verdict of infringe-

ment should be affirmed.

[8–10] The doctrine of equivalents prohibits one from avoiding infringement liability by making only "insubstantial changes and substitutions ... which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law." Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607, 70 S.Ct. 854, 94 L.Ed. 1097 (1950). The "essential inquiry" in any determination under the equivalents doctrine is whether "the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention." Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 40, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997). We have assessed the insubstantiality of an alleged equivalent by applying the function-way-result test as set forth in Union Paper-Bag Mach. Co. v. Murphy, 97 U.S. 120, 125, 24 L.Ed. 935 (1877), which asks whether an element of an accused product "performs substantially the same function in substantially the same way to obtain the same result" as an element of the patented invention. See, e.g., TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc., 529 F.3d 1364, 1376 (Fed.Cir.2008); Abraxis Biosci., Inc. v. Mayne Pharma (USA) Inc., 467 F.3d 1370, 1379 (Fed.Cir.2006); see also Graver Tank, 339 U.S. at 608, 70 S.Ct. 854. We remain mindful, however, that "'[e]quivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum.'" Warner-Jenkinson, 520 U.S. at 24–25, 117 S.Ct. 1040 (quoting Graver Tank, 339 U.S. at 609, 70 S.Ct. 854).

[11] Saint-Gobain makes an interesting argument, not illogical, (and ably articulated by the dissent) regarding a correspondence between the nonobviousness of an accused product, as shown by its separate patentability, and its infringement of another patent under the doctrine of equivalents. However, we agree with Siemens that the district court did not legally err by instructing the jury that infringement in this case may be proved by a preponderance of the evidence. Patent infringement, whether literal or by equivalence, is an issue of fact, which the patentee must prove by a preponderance of the evidence. Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1310 (Fed.Cir.2005) ("To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device literally or under the doctrine of equivalents."); see also Morton Int'l, Inc. v. Cardinal Chem. Co., 5 F.3d 1464, 1468 (Fed.Cir.1993); SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1123 (Fed.Cir.1985) (en banc) ("The patentee bears the burden of proving infringement by a preponderance of the evidence."). Saint-Gobain nonetheless insists that in one particular situation—where the purported equivalent is claimed in a separately issued United States patent-proof of infringement by equivalence requires clear and convincing evidence. As we shall explain, however, we decline to inject Saint-Gobain's proposed rule into the interstices of our longstanding equivalence doctrine jurisprudence.

Saint–Gobain argues that *Festo* mandates an increased burden of proof in cases of separate patentability, but *Festo* did not involve this issue. In *Festo*, in the context of prosecution history estoppel as a legal limitation on the doctrine of equivalents, our sole consideration was whether an equivalent was unforeseeable as of the patent application's filing date. *Festo*, 493 F.3d at 1377. Nonetheless, Saint–Gobain points out that, in rejecting one party's proposed legal standard for foreseeability, we stated:

We have not directly decided whether a device—novel and separately patentable because of the incorporation of an equivalent feature—may be captured by the doctrine of equivalents, although we have held that when a device that incorporates the purported equivalent is in fact the subject of a separate patent, a finding of equivalency, while perhaps not necessarily legally foreclosed, is at least considerably more difficult to make out. But there is a strong argument that an equivalent cannot be both non-obvious and insubstantial.

Id. at 1379–80 (internal footnotes omitted). Saint–Gobain also relies upon the concurring opinion in Roton Barrier, Inc. v. Stanley Works, in which Judge Nies wrote that "a second patent, depending on its subject matter, may be relevant to the issue of whether the changes [in an accused device] are substantial," and that "[a] substitution in a patented invention cannot be both nonobvious and insubstantial." 79 F.3d 1112, 1128 (Fed.Cir.1996) (Nies, J., additional views).

These passages, however, cannot reasonably be read to require proof of equivalency by clear and convincing evidence in cases of separate patentability. Rather, these statements indicate that where, as here, the alleged equivalent is claimed in a separate patent, this fact, when weighed by the fact-finder together with all other relevant evidence, may make equivalency "considerably more difficult to make out" by a preponderance of the evidence.

The issue of infringement by a separately patented equivalent was addressed in the Supreme Court decision of Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 50 S.Ct. 9, 74 L.Ed. 147 (1929). In that case, the patent in suit, filed by Winters and Crampton, claimed an improved refrigerator door latch that automatically locked as the door closed. Id. at 36-37, 50 The allegedly infringing door latch was covered by a later-issued U.S. patent to Schrader. In its opinion, the Court first acknowledged that the accused device did not literally infringe the narrow claims of the Winters and Crampton patent. Id. at 41, 50 S.Ct. 9. The Court then proceeded to apply the function-way-result test to the accused device and found infringement by equivalence. Id. at 41–42. The Court held that infringement cannot be avoided in a device that has "no substantial departure" from the claimed invention. Id. at 42, 50 S.Ct. 9. The Court further noted: "Nor is the infringement avoided ... by any presumptive validity that may attach to the Schrader patent by reason of its issuance after the Winters and Crampton patent." Id. at 43, 50 S.Ct. 9. The Court thus found equivalence in the face of separate patentability without imposing a heightened evidentiary burden.

The passage in *Festo* relied on by Saint–Gobain includes citations of numerous

cases in which we, like the Court in Sanitary Refrigerator, rejected arguments that separate patentability warrants anything more than consideration of this fact together with all others weighing for and against equivalency. Festo, 493 F.3d at 1379 n. 8 (citing Glaxo Wellcome, Inc. v. Andrx Pharms., Inc., 344 F.3d 1226 (Fed. Cir.2003); Hoechst Celanese, 78 F.3d 1575; Nat'l Presto Indus. v. W. Bend Co., 76 F.3d 1185 (Fed.Cir.1996); Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569 (Fed.Cir.1984)).

In Hoechst Celanese, for example, the accused infringer argued that the fact that it "is practicing a process that is separately patentable ... is presumptive evidence of non-infringement," both literally and by equivalence. 78 F.3d at 1582. We disagreed, noting that "[t]he fact of separate patentability presents no legal or evidentiary presumption of noninfringement." In Glaxo Wellcome, we vacated a district court's grant of summary judgment of noninfringement, both literally and under the doctrine of equivalents. F.3d at 1233. In doing so, we rejected the accused infringer's argument that it did not infringe because its accused pharmaceutical formulation was separately patented. We explained that, "[a]lthough this fact may be weighed by the district court, particularly if there is an issue of 'insubstantial' change with respect to equivalency, separate patentability does not automatically negate infringement." Id.

Moreover, in *National Presto*, we confirmed that "[t]he fact of separate patentability is relevant, and is entitled to due weight," but does not confer any presumption of noninfringement; rather, "[s]uch evidence when present warrants consideration by the trier of fact, along with the other evidence of the differences and simi-

larities of the patented and accused devices." 76 F.3d at 1192. In *Atlas Powder*, we rejected the argument that the grant of a patent to an accused infringer constitutes a *prima facie* determination of nonequivalence. 750 F.2d at 1580. Instead, we endorsed the view that "'[p]atentable difference does not of itself tend to negative infringement.'" *Id.* at 1581 (quoting *Herman v. Youngstown Car Mfg. Co.*, 191 F. 579, 585 (6th Cir.1911)).

None of these cases cited in Festo supports a requirement of proof of equivalency by clear and convincing evidence in cases involving separate patentability. Indeed, in other cases we have likewise indicated that separate patentability, while potentially relevant to the equivalence issue and deserving of due weight in the infringement analysis, does not merit a heightened evidentiary burden. See, e.g., Abraxis Biosci., 467 F.3d 1370, 1382 (Fed. Cir.2006) (affirming the district court's finding of infringement by equivalence and stating that separate patentability of the accused pharmaceutical formulation did not outweigh substantial evidence of its equivalence); Fiskars, Inc. v. Hunt Mfg. Co., 221 F.3d 1318, 1324 (Fed.Cir.2000) (holding that the trial court judge did not err by withholding evidence of separate patentability from the jury, because "it is well established that separate patentability does not avoid equivalency as a matter of law"); Zugo Corp. v. Wyko Corp., 79 F.3d 1563, 1570 (Fed.Cir.1996) ("The nonobviousness of the accused device, evidenced by the grant of a United States patent, is relevant to the issue of whether the change therein is substantial.").

[12, 13] Saint-Gobain argues that proof by clear and convincing evidence is required on the facts of this case, because the jury's finding of equivalence "construc-

tively invalidates" the '420 patent. We disagree with Saint-Gobain's reasoning in several respects. First, patents are afforded a statutory presumption of validity under 35 U.S.C. § 282, and overcoming this presumption requires proof by clear and convincing evidence. See, e.g., Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1359-60 (Fed.Cir.2007); Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1375 (Fed.Cir.1986). Even if equivalence were relevant to obviousness, a point on which we need not and do not express an opinion, the jury properly found infringement under the equivalence doctrine by only a preponderance of the evidence. Thus, ipso facto, the jury's finding could not invalidate the '420 patent, constructively or otherwise.

[14] Moreover, with regard to Saint-Gobain's contention that equivalence is tantamount to obviousness, we disagree. The two legal principles require different analytical frameworks. The doctrine of equivalents, although "not the prisoner of a formula," Graver Tank, 339 U.S. at 609, 70 S.Ct. 854, typically involves application of the insubstantial differences test, usually via the function-way-result test. Obviousness, by contrast, requires analysis under the four Graham factors. Graham v. John Deere Co., 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966); accord KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406-07, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007). Unlike equivalence, an obviousness inquiry may center on, for example, objective evidence of commercial success, e.g., Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569, 1579 (Fed.Cir.1991), or on the level of predictability in the art, e.g., Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1089 (Fed.Cir.2008). Indeed, although we express no view regarding the validity of the

'420 patent, we note that Saint–Gobain's "constructive invalidity" argument fails to account for the commercial success of its own 10% Y LYSO crystals or the unpredictability in the field of crystallization. See, e.g., id. (noting experts' agreement regarding the unpredictability of crystallization).

Furthermore, the time frames of the two inquiries differ. Under the doctrine of equivalents, "the proper time for evaluating equivalency ... is at the time of infringement, not at the time the patent was issued," Warner-Jenkinson, 520 U.S. at 37, 117 S.Ct. 1040, yet obviousness asks whether a claimed invention "would have been obvious at the time the invention was made," 35 U.S.C. § 103(a). These and other differences between equivalence and obviousness undermine Saint-Gobain's theory of "constructive invalidation."

[15] Saint-Gobain's professed justification for a clear and convincing standard also overlooks an important distinction regarding claim scope. The jury's infringement verdict indicates only that Saint-Gobain's marketed 10% Y LYSO crystals are equivalent to the LSO crystals of claim 1 or 2 of the '080 patent. JMOL Opinion at 308-09. Importantly, the verdict does not imply equivalence between the '080 patent and the full claim scope of the '420 patent—which, as noted above, covers LYSO crystals ranging from 0.01% Y to 99.99% Y. An invalidity analysis under § 103 requires a comparison between the prior art and the claimed "subject matter as a whole, not separate pieces of the claim." Sanofi-Synthelabo, 550 F.3d at 1086. The jury made no such comparison under the doctrine of equivalents, further highlighting the fallacy of Saint-Gobain's premise that the '420 patent was "constructively invalidated."

In summary, we agree with neither the proposed rule nor the rationale proffered by Saint-Gobain. We, like the district court, "decline[] to be the first (and only) court to depart from an extended history of patent infringement jurisprudence applying the preponderance of the evidence standard." *JMOL Opinion* at 310. We therefore hold that, even though the alleged equivalent in this case was separately patented, the district court did not legally err by instructing the jury that infringement under the doctrine of equivalents may be proved by a preponderance of the evidence.⁴

2. Presumption of Validity of the '420 Patent

[16] Saint-Gobain also argues that, because the validity of the '420 patent was at issue in this case, the district court erroneously denied its proposed jury instruction that the '420 patent was entitled to a presumption of validity. Saint-Gobain reasons that because the '420 patent issued after the patent examiner considered the '080 patent as prior art, 10% Y LYSO crystals are necessarily nonobvious and patentable over LSO crystals. Saint-Gobain equates the issuance of the '420 patent to a determination by the Patent and Trademark Office ("PTO") that 10% Y LYSO and LSO crystals are not substantially equivalent. Thus, Saint-Gobain argues, instructing the jury that the '420 patent is presumed valid "would have made proof of equivalence more difficult, as Festo requires." Opening Br. of Def.-Appellant Saint-Gobain at 35. Saint-Gobain further argues that at trial Siemens challenged the validity and enforceability

 Because Saint-Gobain does not appeal the jury's finding by a preponderance of the evidence that Saint-Gobain infringed the '080 of the '420 patent, thus heightening the need for its proposed jury instruction.

Siemens responds that the validity of the '420 patent was not at issue in this case and therefore that the presumption of validity was not applicable to the case. Siemens also stresses that the '420 patent was admitted into evidence, that the jury was informed during the trial that all patents are presumed valid, and that the district court permitted Saint-Gobain to reiterate this point during its closing arguments. Siemens argues that, in connection with Saint-Gobain's defense to willfulness and the intent prong to inducement, Siemens was justified in probing the circumstances under which Saint-Gobain itself believed the '420 patent might be invalid. Accordingly, Siemens asserts that the district court properly exercised its discretion by declining to instruct the jury regarding the presumption of validity of the '420 patent.

We conclude that the district court's decision not to provide separate instructions to the jury about the presumption of validity did not "clearly mislead the jury." DSU Med., 471 F.3d at 1304 (internal quotation marks omitted). Patent validity was not an issue before the jury: the validity of the '080 patent was not challenged at trial, and, as we explained above, the verdict of infringement by equivalence in no way affected the validity of the '420 patent. As the district court correctly noted, Siemens probed aspects of the '420 patent in connection with Saint-Gobain's license defense to willfulness, but "appropriately stopped short of directly challenging the validity of the '420 patent." JMOL Opinion at 313. Thus, the requested instruc-

patent under the doctrine of equivalents, we do not address that issue in our opinion.

tion was not directly relevant to the issues before the jury.

To the extent that the presumed validity of the '420 patent made a finding of infringement by equivalence more difficult, as Saint-Gobain argues, the jury had notice of the presumption. During the trial, the jury viewed a video providing an overview of the patent system, which stated in part that "[t]o prove that a patent is invalid, the law requires a higher standard of proof, since the PTO is presumed to have done its job correctly." Id.; J.A. 652. In its closing arguments, Saint-Gobain affirmatively stated at least three times on the record that the '420 patent is presumed valid. JMOL Opinion at 312; J.A. 1763-88. In its final instructions, the district court invited the jury as part of its equivalence analysis to "consider that [Saint-Gobain] obtained the license under the ['420] patent, which may be some evidence that the differences between the 10% Y LYSO crystal[s] and the claimed LSO crystal[s] are substantial." JMOL Opinion at 309. We therefore agree with the district court that the jury was not clearly misled by the court's ruling excluding a specific jury instruction on the validity of the '420 patent.

B. Exclusion of Evidence

[17–20] We review a district court's decision to exclude evidence under the law of the regional circuit. Del. Valley Floral Grp., Inc. v. Shaw Rose Nets, LLC, 597 F.3d 1374, 1379 (Fed.Cir.2010). The Third Circuit reviews a district court's decision to exclude evidence for abuse of discretion. Glass v. Phila. Elec. Co., 34 F.3d 188, 191 (3d Cir.1994); see also Rhodia Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1376–77 (Fed.Cir.2005). "A ruling excluding evidence under Rule 403 is ac-

corded particular deference, and ... it may not be reversed unless the determination is arbitrary and irrational." *In re Paoli R.R. Yard PCB Litig.*, 113 F.3d 444, 453 (3d Cir.1997) (internal quotation marks omitted). An erroneous evidentiary ruling "is harmless only if it is highly probable that the error did not affect the outcome of the case." *Glass*, 34 F.3d at 191 (internal quotation marks omitted).

1. The '489 Patent

[21] Saint-Gobain argues that the district court erred by excluding the '489 patent from evidence. Saint-Gobain contends that the '489 patent demonstrates the patentability, and therefore the nonequivalence, of 10% Y LYSO. Saint-Gobain further contends that the '489 patent served to rebut Siemens' attack on the validity of the '420 patent.

In response, Siemens argues that, because Saint-Gobain failed to raise its relevance argument regarding the '489 patent at the district court, this argument is now waived. Siemens also contends that the district court properly excluded the '489 patent, because its potential to confuse the jury outweighed its potential relevance. Finally, Siemens argues that any error associated with the court's ruling is harmless, because the jury was informed of the existence and content of the '489 patent.

We agree with Siemens that the district court did not abuse its discretion by excluding the '489 patent from evidence. At trial, Saint–Gobain sought to introduce the '489 patent only in connection with its license defense to Siemens' claim of willful infringement. *JMOL Opinion* at 311–12. As the district court noted, Saint–Gobain "did not offer the '489 patent for a disclosure of LYSO crystals." *Id.* at 312. In

response to Saint-Gobain's request, the district court admitted testimony regarding Saint-Gobain's license of the '489 patent and the license itself, but excluded the '489 patent under Rule 403, reasoning that "there is a high likelihood of confusion to the jury" in admitting the abandoned patent. *Id.*

Only after trial did Saint-Gobain argue for the first time that the '489 patent should have been admitted for its relevance to the patentability of LYSO crystals. Id. Because at the time of its evidentiary ruling the district court was not informed of Saint-Gobain's view that the '489 patent was relevant to its equivalence argument, Saint-Gobain cannot now attack the court's evidentiary ruling on this basis. See Old Chief v. United States, 519 U.S. 172, 182 n. 6, 117 S.Ct. 644, 136 L.Ed.2d 574 (1997) ("It is important that a reviewing court evaluate the trial court's decision from its perspective when it had to rule and not indulge in review by hindsight."). Thus, the district court's ruling under Rule 403 was not arbitrary and irrational.

[22] We also agree with Siemens that any error associated with the district court's ruling was harmless. The '489 patent, which was abandoned following the interference with the '420 patent, was not (and could not have been) asserted in this case. Even if Saint-Gobain had presented its relevance arguments prior to the court's evidentiary ruling, the '489 patent would largely have been cumulative of evidence already of record, including the '420 patent. Id. at 312. Both the '420 and '489 patents disclose and claim substantially the same invention—hence the interference proceeding. Id. at 308 n. 3. During the trial, the jury was informed of the existence and content of the '489 patent, including Saint-Gobain's efforts to obtain a

license (*id.* at 312; J.A. 940; J.A. 1244–45; J.A. 1261–62), and Saint–Gobain presented to the jury a timeline that contained both a text reference to the '489 patent's issuance and an image of the patent itself (J.A. 2032). For these reasons we conclude that it is "highly probable" that any error associated with the exclusion of the '489 patent did not affect the outcome of this case, and therefore that any error in the district court's evidentiary ruling was harmless. *Glass*, 34 F.3d at 191.

2. Expert Testimony

[23] Saint-Gobain argues that the district court abused its discretion by granting Siemens' motion to exclude certain testimony of Saint-Gobain's expert, Dr. McClellan, regarding the use of LYSO in applications other than PET. Saint-Gobain argues that the '080 patent claims a scintillator without regard to its particular application, and therefore that it was inappropriate to limit the substantial equivalence inquiry solely to PET scan applications. Saint-Gobain also points out that the importance of different scintillation properties can vary dramatically by application, so the district court could not properly determine substantial equivalence by examining only a single application.

Siemens responds that the district court did not restrict Dr. McClellan from testifying on the scintillation properties Saint—Gobain now complains were excluded; the court only prevented Dr. McClellan from going beyond his expert disclosures or discussing matters not disclosed to Siemens during discovery. Siemens asserts that the court's ruling imposed sensible limitations on expert testimony under the Federal Rules of Civil Procedure. Siemens contends that Dr. McClellan in fact testified at length about many of the scintilla-

tion properties that Saint-Gobain claims were excluded. Siemens further contends that Saint-Gobain waived the arguments it now makes on appeal by failing to make a specific proffer of the testimony that Dr. McClellan would have presented at trial.

The district court did not abuse its discretion in its ruling regarding the expert testimony of Dr. McClellan. We agree that the district court "did not render a specific ruling regarding the substance of Dr. McClellan's testimony," JMOL Opinion at 313, but rather imposed sensible limitations on proposed testimony based upon undisclosed data and information. In its evidentiary ruling, the district court noted that Dr. McClellan's experience with LSO and LYSO resulted from studies he performed as a government contractor at the Los Alamos National Laboratory ("LANL"). Siemens Med. Solutions USA. Inc. v. Saint-Gobain Ceramics & Plastics, Inc., 2008 WL 3862091, at *1 (D.Del. Aug. 20, 2008) ("Evidence Order"). Because his research involved national security matters, Dr. McClellan was unable to use any work-related materials in the litigation or to produce any LANL documents during discovery. Id. The court expressed concern that, without any ability for Siemens to examine the studies that formed the basis of Dr. McClellan's opinions, "there is clearly no principled way to test his recollection and opinion." Id.

The district court further noted in its evidentiary ruling that, although there were documents at LANL relating to the studies referenced in Dr. McClellan's expert report, he did not review these materials to refresh his recollection when preparing his report. *Id.* The court thus identified a "serious question of whether his recollection of data generated several years ago can possibly constitute a suffi-

cient basis for an expert opinion" under Rule 702 of the Federal Rules of Evidence. Id. For these reasons, the court granted Siemens' motion to exclude portions of Dr. McClellan's testimony that were not disclosed in discovery—i.e., it ruled that Dr. McClellan could not testify on matters not disclosed in his expert report or deposition, and he could not rely on testing that was not disclosed to Siemens during discovery. Id.; JMOL Opinion at 314.

The court's evidentiary ruling was justified and well reasoned. The court's judgment comports with Fed.R.Civ.P. 26(a)(2)(B)(i)-(ii), which requires experts to provide a written report containing "a complete statement of all opinions the witness will express and the basis and reasons for them" and "the facts or data considered by the witness in forming them." As the Advisory Committee Note accompanying the 1993 amendments to Rule 26 explains: "Given this obligation of disclosure, litigants should no longer be able to argue that materials furnished to their experts to be used in forming their opinions—whether or not ultimately relied upon by the expert—are privileged or otherwise protected from disclosure when such persons are testifying or being deposed." Fed.R.Civ.P. 26 advisory committee's note.

[24] Rule 26, therefore, "proceeds on the assumption that fundamental fairness requires disclosure of all information supplied to a testifying expert in connection with his testimony." In re Pioneer Hi-Bred Int'l, Inc., 238 F.3d 1370, 1375 (Fed. Cir.2001). We agree with the district court that "the fundamental principle of fairness" supports its sensible limitations on Dr. McClellan's testimony, as Siemens had "no principled way to test his recollection and opinion." Evidence Order at *1.

The court's ruling further complies with Fed.R.Civ.P. 37(c)(1), which states that, if a party fails to comply with Rule 26(a), "the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Saint-Gobain does not argue that its failure to disclose was substantially justified or harmless. Thus, the district court did not abuse its discretion by ruling that Dr. McClellan could not testify on matters not disclosed in his expert report or deposition, and that he could not rely on testing that was not disclosed to Siemens during discovery.

C. Lost Profits Damages

[25-27] Whether lost profits are legally compensable in a particular situation is a question of law that we review de novo. Poly-Am., L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303, 1311 (Fed.Cir.2004) (citing Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1544 (Fed.Cir.1995) (en banc)). "To recover lost profits, the patent owner must show causation in fact, establishing that but for the infringement, he would have made additional profits." Wechsler v. Macke Int'l Trade, Inc., 486 F.3d 1286, 1293 (Fed.Cir.2007) (internal quotation marks omitted). Thus, in general, "the patent owner must prove (1) a demand for the patented product, (2) an absence of acceptable noninfringing substitutes, (3) the manufacturing and marketing capability to exploit the demand, and (4) the amount of profit the patent owner would have made." Cohesive Techs., Inc. v. Waters Corp., 543 F.3d 1351, 1373 (Fed.Cir. 2008) (quoting Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1373 (Fed.Cir.1991)); see also Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir.1978).

[28] Saint-Gobain argues that the court erred by allowing the jury to consider lost profits damages, because Siemens failed to demonstrate that it would have made Saint-Gobain's sales "but for" the infringement. Saint-Gobain does not dispute that Philips' LYSO scanner competed with Siemens' LSO scanner. However, Saint-Gobain cites evidence that General Electric ("GE") sold scanners containing bismuth germinate ("BGO") scintillator crystals, JMOL Opinion at 315, and argues that the market thus consisted of three competing sellers: Siemens, Philips, and GE. Saint-Gobain contends that GE's BGO scanners competed with Siemens' LSO scanners, because Siemens lost PET scanner sales to GE. Saint-Gobain also argues that it could have made and sold scanners containing lanthanum bromide (LaBr₃) scintillator crystals, which were an available, noninfringing substitute for LSO crystals.

Siemens argues in response that sufficient evidence supported submitting the question of lost profits to the jury and the jury's award. Siemens argues that, but for the infringement, it would have made the sales made by Saint-Gobain. Siemens further argues that substantial evidence supports a high-end, two-supplier PET market consisting of Siemens' LSO scanners and Saint-Gobain's LYSO scanners. Siemens contends that GE's BGO scanners were cheaper and generally inferior to LSO and LYSO, and therefore were not competitive. In addition, Siemens argues that it is irrelevant whether it lost sales to GE, because the issue is what Philips' customers would have done had Saint-Gobain's infringement not occurred. Lastly, Siemens argues that the jury had ample supporting evidence to believe Siemens' claim that LaBr₃ was not available and was an unacceptable alternative to LSO and 10% Y LYSO.

We perceive no legal error in the district court's decision to permit the jury to award lost profits damages. On appeal, the dispute between Saint–Gobain and Siemens over lost profits centers on (1) whether there existed a two-supplier, highend market for PET scanners, and (2) whether LaBr₃ scanners were available, acceptable noninfringing alternatives to LSO scanners. On both issues, Siemens presented substantial evidence to support a lost profits award.

[29] Accurately identifying a two-supplier market "'requires an analysis which excludes alternatives to the patented product with disparately different prices or significantly different characteristics." Micro Chem., Inc. v. Lextron, Inc., 318 F.3d 1119, 1124 (Fed.Cir.2003) (quoting Crystal Semiconductor Corp. v. TriTech Microelecs. Int'l, Inc., 246 F.3d 1336, 1356 (Fed. Cir.2001)). Here, the parties disputed whether GE's BGO scanner was an alternative to the LSO and LYSO scanners such that a three-supplier market existed. The district court summarized the ample evidence that BGO was generally inferior to LSO with respect to important scintillator properties, including light output and decay time. JMOL Opinion at 315-16. In addition, the district court credited the testimony of Siemens' head of marketing and sales, who testified that BGO-based scanners do not compete with Siemens' LSO-based scanners in the high-end PET scanner market, id. at 316, because BGO scanners, with their relatively poor image quality, were purchased by "customers that are extremely tight in their budgets," whereas the more expensive LSO scanners were purchased by customers seeking the "highest performance and high technology." J.A. 985.

The district court also credited Saint–Gobain's own documents and the testimony

of Saint-Gobain's witnesses, which consistently described a two-supplier "high-end PET scanner market" consisting only of LSO and LYSO scanners. *JMOL Opinion* at 316. Saint-Gobain is correct in arguing that its damages expert provided testimony indicating that Siemens lost some sales to GE's BGO scanners during the relevant time period. However, as the district court correctly noted, there was ample evidence for a reasonable jury to infer the existence of a two-supplier market for high-end PET scanners consisting of Siemens' LSO scanners and Philips' LYSO scanners. *Id*.

[30, 31] The parties also whether LaBr₃-based scanners were available substitutes. To be "available," an acceptable noninfringing substitute must have been "available or on the market" at the time of infringement. Grain Processing Corp. v. Am. Maize-Prods. Co., 185 F.3d 1341, 1349 (Fed.Cir.1999) (emphasis and internal quotation marks omitted). A substitute need not be on sale at the time of infringement, but if the substitute cannot be commercialized "readily," then it is not available for purposes of a lost profits determination. See Micro Chem., 318 F.3d at 1123; cf. Grain Processing, 185 F.3d at 1354. At trial, the parties disputed whether LaBr₃ was an available alternative to LSO, and on appeal Saint-Gobain points to evidence that it asserts supports the availability of LaBr₃. Notwithstanding, the evidence reasonably supported a finding that LaBr₃ was not an available alternative. As the district court noted, evidence showed that LaBr₃ was at least a year and a half behind LYSO in development. JMOL Opinion at 317. In addition, Saint-Gobain stipulated that there were no commercial PET scanners sold on the market using a LaBr₃ scintillation crystal. J.A. 1111. The court also cited evidence demonstrating several disadvantages inherent to LaBr₃, including its inferior density and hygroscopicity. *JMOL Opinion* at 317.

Because of the substantial evidence in the record supporting the elements required for an award of lost profits, we find no legal error in the district court's decision to permit the jury to consider lost profits damages.

D. Cross–Appeal of the Reduction of the Jury's Damage Award

[32–34] Siemens cross-appeals the district court's decision to reduce the jury's damages award. We review the decision of a district court to reduce a jury's damages award under the law of the regional circuit. Minks v. Polaris Indus., Inc., 546 F.3d 1364, 1369-70 (Fed.Cir.2008); Tronzo v. Biomet, Inc., 236 F.3d 1342, 1346 (Fed. Cir.2001). The Third Circuit reviews a discretionary reduction in a jury award for abuse of discretion. Cortez v. Trans Union, LLC, 617 F.3d 688, 716 (3d Cir.2010); see also Spence v. Bd. of Educ. of the Christina Sch. Dist., 806 F.2d 1198, 1201 (3d Cir.1986) ("[A trial judge's determination] that a decision of the jury is clearly unsupported and/or excessive.... falls within the discretion of the trial judge, whose decision cannot be disturbed by this court absent a manifest abuse of discretion."). "The trial judge is in the best position to evaluate the evidence and assess whether the jury's verdict is rationally based." Rivera v. V.I. Housing Auth., 854 F.2d 24, 27 (3d Cir.1988). Accordingly, the scope of review "is exceedingly narrow." Cortez, 617 F.3d at 719.

Siemens argues that substantial evidence supports the jury's full award of

damages. Specifically, Siemens contends that there was sufficient circumstantial evidence that Philips either had arranged to sell or would in fact sell all 79 scanners following their manufacture. Siemens argues in the alternative that the court erred by not awarding at least reasonable royalty damages for the remaining 18 scanners, because evidence showed that these 18 scanners were at least made, if not sold. Siemens thus argues that the district court erred by failing to consider that, under 35 U.S.C. § 271, it is an act of infringement to make, use, or offer to sell a patented invention, even if the product is not actually sold.

Saint-Gobain responds that the court correctly reduced the jury's damages award, because, as the district court determined, the evidence is "wholly speculative" regarding the sale of the additional 18 scanners. In addition, Saint-Gobain argues that Siemens did not assert a right to a reasonable royalty before the district court, so this argument is now waived on appeal. Finally, Saint-Gobain argues that the evidence does not support a finding that the 18 scanners' worth of crystals were actually used to make scanners.

[35] We conclude that the district court did not abuse its discretion in reducing the jury's damages award regarding lost profits on the additional 18 scanners. As discussed above, to recover lost profits damages, "the patentee must show a reasonable probability that, 'but for' the infringement, it would have made the sales that were made by the infringer." Rite-Hite, 56 F.3d at 1545. Here, the parties do not dispute that Saint-Gobain delivered 79 scanners' worth of crystals to Philips, and that Philips made and sold at least 61 scanners. JMOL Opinion at 318. Rather, the dispute on appeal centers on wheth-

er Philips actually manufactured and sold the additional 18 scanners.

As Siemens itself acknowledges, the only "evidence" of infringing sales of the 18 scanners was (1) Saint-Gobain's delivery of 79 scanners' worth of crystals to Philips, and (2) the testimony of Philips' designated corporate representative, who agreed that "it's not in Philips' interest to hold a lot of inventory of crystals" and that "[Philips doesn't] want to buy all of [its] supplies way in advance of when [it] need[s] them." JMOL Opinion at 318; J.A. 1004. As the district court correctly found, this evidence indicates that Philips generally did not stockpile crystals and thus had incorporated them into infringing scanners—i.e., that Philips made the additional 18 scanners—but the evidence does not suggest that Philips sold the additional 18 scanners prior to the expiration of the '080 patent. JMOL Opinion at 319. Thus, with regard to the additional 18 scanners, there is no proof of "sales that were made by the infringer." Rite-Hite, 56 F.3d at 1545. We therefore agree with Saint-Gobain that the district court did not abuse its discretion by reducing the jury's damages award to account for the lack of substantial evidence supporting lost profits damages associated with the additional 18 scanners.

[36–38] However, we agree with Siemens that the court erred by failing to consider any damages on the additional 18 scanners. A district court abuses its discretion when it commits legal error in its award of damages. State Indus., Inc. v. Mor–Flo Indus., Inc., 883 F.2d 1573, 1577 (Fed.Cir.1989). Under 35 U.S.C. § 271, a party infringes a patent by contributing to or inducing another party to make, use, offer to sell, or sell a patented invention in the United States. In addition, under 35

U.S.C. § 284, "the floor for a damage award is no less than a reasonable royalty ... and the award may be split between lost profits as actual damages to the extent they are proven and a reasonable royalty for the remainder." *Id.*; accord Rite–Hite, 56 F.3d at 1545.

[39] Here, the jury determined that Saint-Gobain infringed the '080 patent by inducing and contributing to Philips' infringement. JMOL Opinion at 309. The district court correctly noted that substantial evidence supported the conclusion that Philips made the additional 18 scanners. Id. at 319. One who "makes" a patented invention without authorization infringes the patent. 35 U.S.C. § 271(a) (2006). Yet, after eliminating the jury's lost profits award on these 18 scanners, the district court failed to consider whether any "damages adequate to compensate for the infringement" were owed to Siemens. 35 U.S.C. § 284 (2006); see also JMOL Opinion at 319. If district court eliminates a lost profits award with regard to a portion of infringing devices, the court must then determine an appropriate measure of damages for that portion. Crystal Semiconductor, 246 F.3d at 1355. Overlooking the requirement of 35 U.S.C. § 284 is legal error. Id.

[40] Here, the court abused its discretion by failing to determine a reasonable royalty for the remaining 18 scanners. We are not persuaded by Saint-Gobain's arguments that Siemens waived its right to reasonable royalty damages. The jury heard testimony from both parties' damages experts on the subject of reasonable royalties. The jury was also instructed on reasonable royalty damages. In opposition to Saint-Gobain's motion for JMOL, Siemens pointed out that a patent is in-

fringed by making, using, and selling the invention, and that the jury's award was likely a combination of both lost profits and a reasonable royalty. Moreover, Saint-Gobain's own damages expert testified that, in the event that Saint-Gobain is found to infringe, at least a reasonable royalty would be owed on all 79 scanners, including the additional 18 scanners that were not sold by Philips. J.A. 1632–33.

We therefore remand to the district court so that the court may determine a reasonable royalty for the additional 18 scanners, to be added to the award of \$44,937,545 in lost profits for 61 scanners that were sold. In determining the reasonable royalty, the district court may rely on the present record if deemed adequate, or may elect to receive additional expert testimony on what royalty would be reasonable under the circumstances. 35 U.S.C. § 284 (2006).

Conclusion

The district court's judgment entered in favor of Siemens is affirmed. However, we vacate the damages award and remand for the court to consider a reasonable royalty for the additional 18 infringing scanners, to be added to the \$44,937,545 in lost profits for the 61 scanners that were sold.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED

Costs

Costs to Siemens.

PROST, Circuit Judge, dissenting.

I respectfully dissent because, in my view, there is a tension between the equivalence and nonobviousness inquiries presented in this appeal.

As it has here, this tension comes to light when a patentee asserts the doctrine of equivalents against some feature that the U.S. Patent and Trademark Office ("PTO") declared to be a point of novelty in a separate patent. To prevail on equivalence, the patentee must prove that the feature is insubstantially different from the limitations of his asserted claim. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 610, 70 S.Ct. 854, 94 L.Ed. 1097 (1950); accord Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1310 (Fed.Cir. 1998). In an ordinary case, we would say that the patentee's efforts to prove infringement will not be hindered by an accused infringer's proof of separate patenting. Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1581 (Fed.Cir.1984). The equivalence analysis, however, presents a unique circumstance.

Where equivalence is used against a feature that is separately patented, the patentee's attempts to show that the feature is insubstantially different from the asserted patent crash into the well-settled presumption that patents are nonobvious over the prior art. See Zygo Corp. v. Wyko Corp., 79 F.3d 1563, 1570 (Fed.Cir.1996). When a fact finder concludes that a feature is "insubstantially different" from a patent, how are we then to view the validity of the patent putatively establishing that same feature as "nonobvious"?

Examining the legal standards underlying obviousness and equivalence only emphasizes the potential for overlap. The Supreme Court has instructed us that four factors should be used in assessing obviousness: (1) the scope and content of the prior art, (2) the differences between the prior art and the claims, (3) the level of ordinary skill in the art, and (4) secondary

considerations such as commercial success, unexpected results, and long-felt need. Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 17–18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966); accord Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1378 (Fed.Cir. 2005). These factors are intended to guide judges and juries in determining whether a hypothetical "skilled artisan" would have viewed the claimed invention as one that was suggested in a straightforward way by the prior art and the general level of knowledge in the field. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417–18, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007). The caselaw is replete with courts elaborating these standards in the hope of making this difficult analysis as fair and straight-forward as possible.

The standard for equivalence—"insubstantial difference"—has also been well-explored. If a skilled artisan, at the time of the accused infringement, viewed a substitution to a patented invention as insubstantially different from the claim, the substitution is equivalent and infringement may arise. Graver Tank, 339 U.S. at 610, 70 S.Ct. 854; Warner—Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997). The doctrine prevents accused infringers from evading liability by making "trivial" changes to the patented invention. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabush-

1. In the past, some litigants attempted to avoid this second step entirely, and prove "anticipation by equivalents." This court rejected that theory, holding that a claim is invalid under § 102 if and only if each and every limitation of the claim is literally present in a single prior art reference. But while it rejected "anticipation by equivalents," this court noted that the doctrine of equivalents was, "if one wished to draw a parallel, ... somewhat akin to obviousness." Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 748 (Fed.Cir.1987); see also Richardson v. Suzuki

iki Co., 535 U.S. 722, 733, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002). That a substitution is "trivial" or "insubstantially different" may be proved by showing that the substitution performs the same function, in the same way, with the same result as the technology of the claim limitation. Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 813 (Fed.Cir. 2002).

The majority reasons that these two tests, obviousness and equivalence, are separate from one another. But while the details differ, I find there is an inevitable area of overlap. Assume a court, applying Graver Tank and its progeny, found that to a person of skill in the art a substitution was insubstantially different from a claim limitation. Having so found, and setting aside (for the moment) consideration of the time frames at which obviousness and equivalence are assessed, the court would need only a further finding that the skilled artisan had some reason to make the substitution to find the limitation obvious under Graham and KSR.¹ This is not a high bar. For a truly insubstantial change, the predictability of outcome when substituting the one for the other suggests that a reason to combine will be easy to prove. Rothman v. Target Corp., 556 F.3d 1310, 1319 (Fed.Cir.2009).

I therefore disagree with the majority in that I do not view it acceptable to leave

Motor Co., 868 F.2d 1226, 1236 (Fed.Cir. 1989) (discussing the doctrine of equivalents as "a legal theory that is pertinent to obviousness under Section 103, not to anticipation under Section 102"). Notably, however, this court has declined to extend the doctrine of equivalents to cover on infringement embodiments that were present in the prior art. Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677, 685 (Fed.Cir.1990), overruled in part on other grounds by Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 99–103, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993).

the fact-finder—here, a jury—without instruction on how it might navigate the

equivalence inquiry without undermining the presumption of nonobviousness that we must accord issued patents.

Judge Nies anticipated the challenge we face when she wrote, "a substitution in a patented invention cannot be both nonobvious and insubstantial." Roton Barrier, Inc. v. Stanley Works, 79 F.3d 1112, 1128 (Fed.Cir.1996) (Nies, J., Additional Views). A similar concern was voiced by Judge Dyk (and quoted by the majority) in this court's Festo decision. Maj. Op. at 1278-79 (quoting Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 493 F.3d 1368, 1379–80 (Fed.Cir.2007)). This appeal now squarely presents the issue.

I believe that the best path through this difficult situation is to expressly incorporate Judges Nies and Dyk's reasoning into the equivalence analysis: a separately-patented (and presumptively nonobvious) substitution cannot be "insubstantial" unless some fact distinguishes the equivalence finding from the PTO's earlier nonobviousness determination.

The passage of time presents one opportunity for such a distinction. The majority is correct that an equivalence analysis differs from an obviousness analysis in the time frame concerned. Obviousness is assessed at the time of the invention, and equivalence at the time of the alleged infringement. A finding that, from the time of the separately-patented invention to the time of accused infringement, the state of the art advanced in such a way as to make a previously non-obvious substitution obvious, would allow an equivalence finding

In this appeal, Saint-Gobain sought a jury instruction emphasizing the '420 patent's presumption of validity. I believe such an instruction should have been given, and so diswithout upsetting the presumption of nonobviousness. In the absence of such a finding, in my view a separately-patented substitution may not be held equivalent.

Returning to the present appeal, I believe the trial court should have given more direct guidance to the jury concerning the effect the '420 patent's separate coverage of Saint-Gobain's 10% Y LYSO crystals had on the jury's duty as fact finder. Specifically, I believe it was reversible error for the court not to inform the jury that it could find equivalence if and only if it also found that the state of the art concerning LSO crystals had advanced from the time of the '420 patent's invention to the alleged infringement so that the 10% Y composition, though previously nonobvious, had become obvious and I therefore respectfully insubstantial.² dissent.



CANCER RESEARCH TECHNOLOGY LIMITED and Schering Corporation, Plaintiffs-Appellants,

v.

BARR LABORATORIES, INC. and Barr Pharmaceuticals, Inc., Defendants-Appellees.

No. 2010-1204.

United States Court of Appeals, Federal Circuit.

Feb. 28, 2011.

Appeal from the United States District Court for the District of Delaware in case

sent. But in my view the additional guidance set forth herein was necessary to give full effect to the instruction Saint-Gobain articulated.