

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

LIFESCAN SCOTLAND, LTD. AND LIFESCAN, INC.,
Plaintiffs-Appellees,

v.

**SHASTA TECHNOLOGIES, LLC AND CONDUCTIVE
TECHNOLOGIES, INC.,**
Defendants-Appellants,

AND

**INSTACARE CORP. AND PHARMATECH
SOLUTIONS, INC.,**
Defendants-Appellants.

2013-1271

Appeal from the United States District Court for the
Northern District of California in No. 11-CV-4494, Judge
Edward J. Davila.

Decided: November 4, 2013

GREGORY L. DISKANT, Patterson Belknap Webb & Ty-
ler LLP, of New York, New York, argued for plaintiffs-
appellees. With him on the brief were EUGENE M.
GELERNTER and KATHLEEN M. CROTTY. Of counsel on the

brief were CHARLES HOFFMANN and SEAN MARSHALL, Hoffmann Marshall Strong LLP, of New York, New York.

JOHN J. SHAEFFER, Lathrop & Gage LLP, of Los Angeles, California, argued for defendants-appellants. With him on the brief were ROBERT P. ANDRIS and LAEL D. ANDARA, Roper, Majeski, Kohn & Bentley, of Redwood City, California; and WILLIAM A. RUDY, Lathrop & Gage LLP, of Kansas City, Missouri. Of counsel was CAROLE E. HANDLER, Lathrop Gage LLP, of Los Angeles, California.

Before DYK, PROST, and REYNA, *Circuit Judges*.

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

Dissenting opinion filed by *Circuit Judge* REYNA.

DYK, *Circuit Judge*.

Defendants Shasta Technologies, LLC; Conductive Technologies, Inc.; Instacare Corp.; and Pharmatech Solutions, Inc. (collectively, “Shasta”) appeal from a decision of the United States District Court for the Northern District of California granting a preliminary injunction in favor of Plaintiffs LifeScan Scotland, Ltd. and LifeScan, Inc. (“LifeScan”). The injunction prohibited Shasta from making, using, or selling its blood glucose test strips. The district court found that the making, using, or selling of Shasta’s strips likely indirectly infringes LifeScan’s U.S. Patent No. 7,250,105 (“the ’105 patent”). Because we agree that Shasta has established that it has a patent exhaustion defense, we reverse.

BACKGROUND

I

This case concerns blood glucose monitoring systems, which are used by individuals with diabetes to assist them in maintaining healthy blood glucose levels. Such

systems typically consist of an electrochemical meter and disposable test strips. To use the system, the user first inserts a test strip into the meter, then uses a lancet to draw a small drop of blood and places the drop on the test strip. The strip contains one or more electrodes, which may be “working electrodes” or “reference electrodes,” and which connect to the meter during operation. Each working electrode is coated with an enzyme, such as glucose oxidase, and a mediator, such as ferricyanide. The enzyme reacts with glucose in the blood sample, releasing electrons. The mediator then transfers those electrons to the working electrode. The working electrode is connected to the meter, which measures the resulting electric current. Because this current correlates with the concentration of glucose in the sample, the meter is thus able to measure the user’s blood glucose level. The reaction occurring at the working electrode does not occur at the reference electrode because the reference electrode is not coated with glucose oxidase. Thus, by comparing the current at the reference electrode to the current at the working electrode, the meter can verify that the current produced at the working electrode is solely due to the reaction of the enzyme and mediator with blood glucose in the sample.

Blood glucose meters and disposable test strips of this general design first became available in the 1980s. The ’105 patent claims to improve upon earlier systems. It claims a method of comparing the measurements taken by two separate working electrodes. If the readings of the two working electrodes differ significantly, this indicates problems such as inadequate sample volume or manufacturing defects, and the readings are to be discarded. A reference electrode on the strip serves as a common reference for both working electrodes.

LifeScan manufactures such a system, which it calls the “OneTouch Ultra” blood glucose monitoring system. According to LifeScan, its OneTouch Ultra system uses

the technology described in the '105 patent. Claim 1, the only independent claim in the '105 patent, reads:

1. A method of measuring the concentration of a substance in a sample liquid comprising the steps of:

providing a measuring device[,] said device comprising:

a first working sensor part for generating charge carriers in proportion to the concentration of said substance in the sample liquid;

a second working sensor part downstream from said first working sensor part also for generating charge carriers in proportion to the concentration of said substance in the sample liquid wherein said first and second working sensor parts are arranged such that, in the absence of an error condition, the quantity of said charge carriers generated by said first working sensor[] part [is] substantially identical to the quantity of said charge carriers generated by said second working sensor part; and

a reference sensor part upstream from said first and second working sensor parts which reference sensor part is a common reference for both the first and second working sensor parts, said reference sensor part and said first and second working sensor parts being arranged such that the sample liquid is constrained to flow substantially unidirectionally across said reference sensor

part and said first and second working sensor parts; wherein said first and second working sensor parts and said reference sensor part are provided on a disposable test strip;

applying the sample liquid to said measuring device;

measuring an electric current at each working sensor part proportional to the concentration of said substance in the sample liquid;

comparing the electric current from each of the working sensor parts to establish a difference parameter; and

giving an indication of an error if said difference parameter is greater than a predetermined threshold.

'105 patent col. 6 l. 52 to col 8 l. 4. In LifeScan's OneTouch Ultra system, the "sensor parts" refer to the electrodes located on the strips. The "measuring an electric current . . .," "comparing the electric current . . .," and "giving an indication of an error . . ." steps are performed by the meter.

LifeScan sells 40% of its meters at below cost prices. It distributes the remaining 60% of its OneTouch meters through health care providers, who in turn give the meters to diabetic individuals for free. LifeScan distributes its meters in this way "in the expectation and intent that customers will use its OneTouch Ultra meters with [its] OneTouch Ultra test strips, from which [it] derive[s] a profit." JA 319. Shasta does not sell blood glucose meters, but competes with LifeScan in the market for test strips. Shasta's "GenStrip" test strips are designed to work with LifeScan's meters.

II

On September 9, 2011, LifeScan filed suit against Shasta. In its amended complaint, it alleged that Shasta's manufacture and distribution of GenStrips would indirectly infringe the '105 patent.¹ It alleged that the users of Shasta's GenStrips would be direct infringers. LifeScan also sought a preliminary injunction barring Shasta "from contributing to and inducing the infringement of [the '105 patent] by selling or offering to sell [its] GenStrip product in the United States." JA 62. Shasta argued that a preliminary injunction should not issue, *inter alia*, because Shasta had a substantial defense based on the doctrine of patent exhaustion under *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008). The sale and distribution of LifeScan's meters, according to Shasta, exhausted LifeScan's rights under its method patent because the meters substantially embody the invention.

The district court granted LifeScan's motion for a preliminary injunction. With respect to LifeScan's likelihood of success on the merits, the court first addressed the issue of patent exhaustion. It began by concluding that LifeScan was likely to establish that its patent was not exhausted with respect to the 60% of meters that it distributes for free. It reasoned that patent exhaustion applies only to a "sale" where the patentee has received

¹ LifeScan's complaint also asserted infringement of two other patents. The District Court subsequently granted Shasta's motion to stay the action as to those other patents pending the outcome of *ex parte* reexamination proceedings at the U.S. Patent and Trademark Office. Order Granting in Part and Den. in Part Defs.' Mot. to Stay, *LifeScan*, No. 11-cv-4494, 2013 WL 1149827, ECF No. 245 (Mar. 19, 2013). These other patents are not pertinent to the preliminary injunction or this appeal.

“consideration” in exchange for the patented product. It concluded that because LifeScan “receive[s] no remuneration at the moment [it] part[s] with [its] patented invention,” LifeScan could likely show that patent exhaustion is inapplicable to the meters distributed for free. JA 9. The court also concluded that patent exhaustion would not apply to LifeScan’s sale of the remaining meters because “the ’105 patent is a method patent that requires both a meter and a test strip for an individual to practice it.” JA 10. Although the court acknowledged that, under *Quanta*, a method claim is exhausted by the sale of a product that “substantially embodies” the invention, JA 11 (quoting *Quanta*, 553 U.S. at 633), it concluded that LifeScan’s meters “likely do not embody the inventive feature of the ’105 patent.” JA 14. The district court also rejected Shasta’s other noninfringement and invalidity arguments. Finally, the district court concluded that the remaining preliminary injunction factors favored LifeScan.

Shasta appeals. We have jurisdiction pursuant to 28 U.S.C. § 1292(c)(1). “[T]o the extent that a district court’s decision to grant a preliminary injunction hinges on questions of law, our review is de novo.” *Nat’l Steel Car, Ltd. v. Can. Pac. Ry., Ltd.*, 357 F.3d 1319, 1325 (Fed. Cir. 2004) (quotation marks and alteration omitted). On April 29, 2013, we granted Shasta’s motion for stay, staying the injunction “pending further order of the court.” *LifeScan Scot., Ltd. v. Shasta Techs., LLC*, No. 2013-1271 (Fed. Cir. Apr. 29, 2013).

DISCUSSION

A preliminary injunction is “an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.” *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (citing *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam)). “A plaintiff seeking a preliminary injunction must establish

that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” *Id.* at 20; *see also Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375–76 (Fed. Cir. 2009). If the accused infringer “raises a substantial question concerning either infringement or validity,” then the patentee has not established that it is likely to succeed on the merits, and a preliminary injunction is not appropriate. *See Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350–51 (Fed. Cir. 2001); *Oakley, Inc. v. Sunglass Hut Int’l*, 316 F.3d 1331, 1340 (Fed. Cir. 2003). Because we conclude that Shasta has established a patent exhaustion defense as a matter of law, we reverse the grant of a preliminary injunction without reaching other issues in this case.

I

LifeScan’s primary argument is that the distribution of its meters, whether by sale or gift, does not trigger exhaustion because its meters do not substantially embody the claims of the ’105 patent. Because the ’105 patent is a method patent, the parties agree that this issue is governed by the Supreme Court’s decision in *Quanta*.

Before *Quanta*, the Supreme Court had repeatedly held, in addressing device patents, that the sale of a patented device exhausted the patent-holder’s right to exclude, and that an infringement suit would not lie with respect to the subsequent sale or use of the device. In *Adams v. Burke*, for example, the accused infringer argued that the sale of patented coffin lids exhausted the patentee’s rights in the lids throughout the United States even though the assignee from whom the accused infringer purchased the lids was only authorized to sell the lids in a limited geographical area. 84 U.S. (17 Wall.) 453 (1873). The Court explained that “the sale by a person

who has the full right to make, sell, and use such a machine carries with it the right to the use of that machine to the full extent to which it can be used.” *Id.* at 455. The Supreme Court applied the patent exhaustion doctrine in many other cases involving product patents. *See, e.g., Keeler v. Standard Folding Bed Co.*, 157 U.S. 659 (1895); *Bloomer v. Millinger*, 68 U.S. (1 Wall.) 340 (1864).

The Court applied the exhaustion doctrine to method as well as product patents in *United States v. Univis Lens Co.*, an antitrust case. 316 U.S. 241 (1942). The patent-holder operated an eyeglass lens business. *Id.* at 243–45. The patent-holder’s licensee sold “lens blanks” to wholesalers and finishing retailers, who then ground and polished the lens blanks into finished lenses that could be used in eyeglasses. *Id.* at 244. The patent-holder owned numerous patents related to eyeglass lenses. *See id.* at 246–47; *United States v. Univis Lens Co.*, 41 F. Supp. 258, 262–63 (S.D.N.Y. 1941) (listing and describing many of the patents-in-suit), *aff’d in part and rev’d in part*, 316 U.S. 241 (1942). Of the patents at issue in the case, eight were product patents describing the “shape, size, composition and disposition of . . . pieces of glass of different refractive power in [lens] blanks.” *Univis*, 316 U.S. at 247. The other relevant patents were method patents. *See id.* at 246–47. The Supreme Court “assume[d] . . . that sale of the [lens] blanks by an unlicensed manufacturer to an unlicensed finisher” to be ground and polished into finished lenses “would constitute contributory infringement by the seller.” *Univis*, 316 U.S. at 248–49.

The Court held that once the lens blanks were sold by a licensed manufacturer, the patent-holder’s rights in them were exhausted. *Id.* at 249–52. The Court reasoned that “[a]n incident to the purchase of any article, whether patented or unpatented, is the right to use and sell it,” and that “the authorized sale of an article which is capable of use only in practicing the patent is a relinquishment of the patent monopoly with respect to the article

sold.” *Id.* at 249. Thus, the Court held that the sale of an article which “embodies essential features” of a patented invention exhausted the patent-holder’s rights in that article. *Id.* at 250–52. The patent-holder conceded that “each [lens] blank . . . embodies essential features of the patented” invention. *Id.* at 249. The Court viewed the method patents as presenting the same question as the device patents, holding that the sale of the blanks exhausted the method patents as well. *See id.* at 246–49; *see also Quanta*, 553 U.S. at 629 (“*Univis* held that the sale of optical lens blanks that partially practiced a patent exhausted the method patents that were not completely practiced until the blanks were ground into lenses.”).

Quanta confirmed that the exhaustion doctrine applies to method patents and clarified the applicable test. 553 U.S. at 628–35. *Quanta* involved several patents containing method claims directed to functions performed by computer processors and chipsets in conjunction with other computer components, such as memory and buses. *Id.* at 621–23. LGE, the patent-holder, licensed Intel to manufacture and sell processors and chipsets embodying the patented technology. *Id.* at 623, 631. Intel, in turn, sold its processors and chipsets to computer manufacturers such as Quanta Computer, who combined the processors and chipsets with unpatented components to create finished computer systems that practiced the method patents. *Id.* at 624. A separate agreement between LGE and Intel required Intel to instruct purchasers of those processors and chipsets that Intel’s license to make and sell the processors and chipsets “d[id] not extend . . . to any product [the purchasers] ma[d]e by combining an Intel product with any non-Intel product.” *Id.* at 623–24 (quotation marks omitted). Nevertheless, Quanta Computer manufactured computers in which Intel processors and chipsets were combined with non-Intel parts. *Id.* at 624. LGE contended that Quanta’s combination of the

Intel processors and chipsets with non-Intel memory and buses infringed the method claims of LGE's patents. *Id.*

The Supreme Court held that LGE's suit was barred by patent exhaustion. The Court first rejected LGE's argument that patent exhaustion did not apply to method patents. The Court stated that it had "repeatedly held that method patents were exhausted by the sale of an item that embodied the method," and pointed to *Univis* as an example of such a prior holding. *Id.* at 629.²

The Court next addressed "the extent to which a product must embody a patent in order to trigger exhaustion." *Id.* at 630. It concluded that the issue was governed by *Univis*. *Id.* at 631. As discussed above, the Supreme Court's finding of exhaustion in *Univis* was based on the patentee's concession that its lens blanks "embodie[d] essential features" of the patented invention. *Univis*, 316 U.S. at 250–51. The Court in *Quanta* thus held that the critical issue, whether a method or product patent is involved, is whether the product "substantially

² The Court in *Quanta* also cited *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436 (1940) as a case where it had applied patent exhaustion to method patents. *Quanta*, 553 U.S. at 629, 629 n.4. *Ethyl Gasoline* was an antitrust suit by the government against a patentee that owned both product and method patents relating to tetraethyl lead for use in motor fuel. *Ethyl Gasoline*, 309 U.S. at 445–46. The patentee argued that its allegedly anticompetitive licensing agreements were within the scope of its patent monopoly. *Id.* at 456–57. The Court held that "by the authorized sales of the fuel by refiners to jobbers the patent monopoly over it is exhausted, and after the sale neither appellant nor the refiners may longer rely on the patents to exercise any control over the price at which the fuel may be resold." *Id.* at 457.

embodies the patent”—i.e., whether the additional steps needed to complete the invention from the product are themselves “inventive” or “noninventive.” 553 U.S. at 633–34. Applying that test to the case before it, the Supreme Court found that the authorized sale of Intel’s processors and chipsets exhausted LGE’s patent rights. *Id.* at 631–34. It explained that the processors and chipsets had no reasonable noninfringing use because they “cannot function until . . . connected to buses and memory” and because “the only apparent object of Intel’s sales to Quanta was to permit Quanta to incorporate the Intel [processors and chipsets] into computers that would practice the patents.” *Id.* at 632. The Court further held that Intel’s products substantially embodied the patents because “[e]verything inventive about each patent [was] embodied in the Intel [processors and chipsets]” and “because the only additional step necessary to practice the patent[s] was] the application of common processes or the addition of standard parts.” *Id.* at 633.

A

The facts relevant to the patent exhaustion issue here are undisputed. Shasta argues that under *Quanta* and other Supreme Court cases, the transfer of the meters to health care providers and users exhausts LifeScan’s patent rights. LifeScan disagrees. It first contends that *Quanta* is inapplicable because its meters have reasonable noninfringing uses. Relying on language from *Quanta* noting that the Intel processors and chipsets “had no reasonable noninfringing use,” 553 U.S. at 638, LifeScan argues that the sale of a component does not result in exhaustion where the component has reasonable noninfringing uses. LifeScan’s theory appears to be that if the meters had a reasonable noninfringing use, then the transfer of the meters would not necessarily imply that the recipient was authorized to practice the claimed invention as opposed to the noninfringing alternative. We have recently rejected the contention that a potential non-

infringing use prevents exhaustion where the use in question is the very use contemplated by the patented invention itself. *Keurig, Inc., v. Sturm Foods, Inc.*, No. 13-1072, slip op. at 7 (Fed. Cir. Oct. 17, 2013).

Even if a showing of reasonable noninfringing uses of a product could alone be sufficient to avoid exhaustion here, we would find no merit in LifeScan's argument. LifeScan bases this argument on expert testimony that Shasta could have designed new strips that would work with LifeScan's meter in a noninfringing way. But the question is not whether Shasta could design a noninfringing use for LifeScan's meters, it is whether the individual users (the alleged direct infringers) have a noninfringing use for the meters. Here, there is no suggestion that the users can put LifeScan's meters to noninfringing uses.

In any event, alternative uses are relevant to the exhaustion inquiry under *Quanta* only if they are both "reasonable *and intended*" by the patentee or its authorized licensee. *Quanta*, 553 U.S. at 631 (emphasis added); *see also Univis*, 316 U.S. at 249 (noting that "the only *object of the sale* is to enable [purchasers] to grind and polish [the lens blanks] for use as a lens by the prospective wearer" (emphasis added)). LifeScan admits that it distributes its meters "in the expectation *and intent* that customers will use its OneTouch Ultra meters with [its] OneTouch Ultra test strips," JA 319 (emphasis added), and that such use practices the '105 patent. Thus, even if LifeScan's proposed alternative uses for its meters were reasonably available to users, they were plainly not intended, and are therefore not relevant to the issue of patent exhaustion.

B

LifeScan next argues that exhaustion is inapplicable because the meters do not embody the essential features of the '105 patent. In *Quanta*, the Supreme Court emphasized that "[e]verything inventive about each patent [was]

embodied in the Intel [processors and chipsets]” because they “control[led]” and “carr[ie]d out” the functions described in the patents. *Quanta*, 553 U.S. at 633–34. Similarly, the question here is whether the meters “control” and “carry out” the inventive functions described in the method claims of the ’105 patent. *See id.*

As originally filed, the application that led to the ’105 patent claimed two separate inventions—the comparing method performed by the meter and the configuration of electrodes on the test strips. Thus, the specification describes a “method” in which “the measuring device compares the current generated by two working sensor parts and gives an error indication if they are too dissimilar,” ’105 patent col. 2 ll. 27–31, 33, and separately describes the originally-claimed arrangement of electrodes on the test strip so that the “two working sensor parts are arranged one downstream of the other,” *see id.* col. 3 ll. 43–44. However, while the claims directed to the comparing method were allowed, the claims directed to the test strips themselves were rejected. The question is what the inventive features of the method claims were. What is “inventive” about patent claims in the patent exhaustion context is what distinguishes them from the prior art. *See Univis*, 316 U.S. at 248–49.

Contrary to the dissent, a biosensor with multiple electrodes was known in the prior art, as LifeScan’s own expert admitted. JA 1459. *See also* U.S. Patent No. 5,120,420, col. 3, ll. 19–30. Here, the undisputed facts, the specification of the patent, and the prosecution history all suggest that the claimed inventive concept of the method claims of the ’105 patent lies in the meter, rather than the strips, because the meters “control” and “carry out” the inventive functions of the method claims in

comparing the readings of the two working electrodes.³ The text of the '105 patent itself strongly supports the conclusion that the meter's error-detecting functions are its inventive concept. Its abstract describes the invention by stating that "[i]n accordance with the present invention *a measuring device compares the current generated by two working sensor parts and gives an error indication if they are too dissimilar.*" '105 patent, at [57] (emphasis added). The abstract makes no mention of the configuration of the test strips. *See id.* The specification likewise emphasizes error detection by the meter, stating that inaccuracies can arise from "insufficient sample liquid" or "defects in the production of test strips," *id.* col. 1 ll. 39–64, and that the invention can detect both types of errors by "compar[ing] the current generated by two working sensor parts," *id.* col. 2 ll. 27–39. Indeed, discussion of this comparison function performed by the meter and its error-detecting benefits is found throughout the specification. *See, e.g., id.* col. 3 ll. 3–17; *id.* col. 3 l. 59 to col. 4 l. 6; *id.* col. 5 ll. 26–63. LifeScan itself argued to the district court that "the idea of comparing the currents from the two working sensors and seeing if they're in substantial agreement or not . . . is the crux of the invention." JA 2108–09. The district court, too, found that the invention of the '105 patent was directed to addressing the problem of inaccurate readings by comparing the results from two working sensors and displaying an error message if necessary. The prosecution history in particular confirms that the meter's comparing function is the key to the invention reflected in the method claims. During prosecution of the application that led to the '105 patent, LifeScan attempted to obtain apparatus claims directed to

³ Shasta argues that the claims of the '105 patent are invalid as obvious. Because we conclude that LifeScan is not likely to prevail on the patent exhaustion issue, we do not reach Shasta's validity arguments.

the disposable test strip with two working electrodes. In response to a final rejection of its apparatus claims on the strips as anticipated, LifeScan amended its claims to the strips by adding the limitation that the second working electrode is “downstream from [the] first working [electrode].” However, the examiner once again rejected those claims as anticipated, and LifeScan abandoned them.⁴ Despite finding LifeScan’s test strips unpatentable, the examiner allowed the method claims of the ’105 patent to issue, explaining that the method claims were distinguishable from the prior art because they

require[] the steps of “measuring an electric current at each working sensor part proportional to the concentration of said substance in the sample liquid; comparing the electric current from each of the working sensor parts to establish a difference parameter; and giving an indication of an error if said difference parameter is greater than a predetermined threshold.”

JA 1849. The examiner thus found that the “measuring,” “comparing,” and “giving an indication of an error” steps distinguished the method claims from the prior art, not the arrangement of the electrodes. Therefore, those steps, and not the configuration of the electrodes on the strips, were the inventive features of the method claims. Having secured a patent premised on the inventive quality of the comparing function, rather than the particular strip

⁴ LifeScan also attempted to patent its strips in a continuation application, U.S. Patent Application Serial No. 11/772,714. There too, the examiner rejected LifeScan’s attempts to obtain a patent on its test strips, finding that its strips were both anticipated by U.S. Patent No. 6,258,229 and obvious in light of U.S. Patent No. 5,120,420.

configuration, LifeScan cannot now argue the contrary for purposes of exhaustion.

There is also no dispute that in LifeScan's blood glucose testing system, it is the meter, not the strips, which performs the "measuring," "comparing," and "giving an indication of an error" steps. LifeScan concedes in its brief that its meters "determine[] the blood glucose level in the sample by measuring the electrical current produced." Appellee's Br. at 6. Similarly, LifeScan stated to the district court that "[t]he separate electrical currents measured at each working sensor *are compared by the meter.*" JA 69 (emphasis added). Finally, LifeScan's expert testified that it is the meter that "will display an error indicating that the strip is defective." JA 1484. Because it is the meter alone that performs these key inventive steps of the claimed method, the meter substantially embodies the method claims of the '105 patent. *See Quanta*, 553 U.S. at 633–34.

LifeScan also appears to argue that its meter does not embody its patented methods because its strips themselves are inventive and should have been found separately patentable. LifeScan bases this argument on expert testimony asserting that the patent examiners erred in repeatedly rejecting its attempts to patent its strips, and that the strips would indeed have been separately patentable. But the question here is not whether the strips would have been separately patentable or whether the United States Patent and Trademark Office erroneously denied a patent on the strips.⁵ The question is whether the strips embodied the inventive features of the claims that were actually allowed by the examiner. In allowing

⁵ The dissent's statements that the majority's decision "make[s] inventiveness for exhaustion purposes coextensive with patentability," Dissent at 8, are demonstrably inaccurate.

the method claims, the examiner did not attribute an inventive feature to the strips themselves. Having accepted the rejection of its claims drawn to the strips themselves by abandoning those claims in both its original and continuation applications, LifeScan cannot now argue that the strips themselves were the invention. The fact that the specification may have described the strips in considerable detail and as “inventive” is of no consequence in view of the facts that the claims covering the strips were not allowed, and that the meter rather than the strips performs the inventive feature of the patent claims that were actually allowed.

To be sure, if a patent had actually issued on the strips, the patentability of the strips could be relevant to exhaustion. That principle was announced in *Morgan Envelope Co. v. Albany Perforated Wrapping Paper Co.*, 152 U.S. 425 (1894). There, unlike here, a patent had actually issued on a subsidiary element (toilet paper rolls) of a patented combination. *Id.* at 427, 430. The patentee had obtained patents on a particular type of roll of toilet paper and on the combination of those toilet paper rolls with a fixture on which the roll was mounted. *Id.* at 427, 430–31. After concluding that the rolls themselves were not patentable over the prior art, *see id.* at 427–30, the Court considered whether the sale of the fixture exhausted the patent rights in the combination. *See id.* at 431–32. The accused infringer apparently conceded that the fixtures “involve[d] a patentable novelty,” but argued that the mere sale of new rolls of toilet paper to those who had previously purchased fixtures from the patentee did not constitute infringement because of exhaustion by sale of the fixtures. *See id.* at 430–31. The Court agreed, concluding that the sale of the fixtures exhausted the patentee’s rights. *Id.* at 431–35. The Court noted that the sale of one element of a patented combination could in some instances constitute indirect infringement, *id.* at 433, but it found that principle inapplicable

where the element made by the alleged infringer is an article of manufacture perishable in its nature, which it is the object of the mechanism to deliver, and which must be renewed periodically, whenever the device is put to use. Of course, if the product itself is the subject of a valid patent, it would be an infringement of that patent to purchase such product of another than the patentee; *but if the product be unpatentable, it is giving to the patentee of the machine the benefit of a patent upon the product, by requiring such product to be bought of him.*

Id. (emphasis added). The Court explained that, for example,

[i]f a log were an element of a patentable mechanism for sawing such log, it would, upon the construction claimed by the plaintiff, require the purchaser of the sawing device to buy his logs [from] the patentee of the mechanism, or subject himself to a charge of infringement. This exhibits not only the impossibility of this construction of the patent, but the difficulty of treating the paper of an element of the combination at all.

Id. *Morgan Envelope* therefore confirms that if one item in the patented combination is either unpatented or if the patent on it is invalid, and the inventive concept resides in a second item, then the sale of the second item exhausts a product patent in the combination. *See id.* at 432–33, 435. The same principle is equally applicable to method claims, *Quanta*, 553 U.S. at 628–29, as is confirmed by our recent decision in *Keurig*, No. 13-1072, slip op. at 7 (Fed. Cir. Oct. 17, 2013), where we held that a method of using a coffee brewer in combination with disposable cartridges was exhausted by the sale of the brewer.

However, LifeScan argues that exhaustion does not apply because the strips here are not “standard” parts. Although the Supreme Court in *Quanta* referred to the other computer components that were combined with Intel’s processors and chipsets as “standard parts,” 553 U.S. at 633, *Quanta* does not suggest that only standard parts can be viewed as noninventive. Rather, the Court focused on the fact that “[e]verything *inventive* about each patent [was] embodied in the Intel [processors and chipsets].” *Id.* (emphasis added). Moreover, the Court’s reference to “standard parts” did not imply that those parts were configured identically in the prior art, but rather refers to the fact that standard parts could be easily adapted to work with the Intel processors and chipsets. Indeed, it was undisputed in *Quanta* that the computer manufacturers specifically designed the remainder of their computer systems for compatibility with Intel’s processors and chipsets according to Intel’s specifications.⁶ Here, strips with two working electrodes were disclosed by the prior art. The fact that the prior art strips might have required some reconfiguration to use with LifeScan’s meters is irrelevant. There is no suggestion that prior art strips with two working electrodes

⁶ See, e.g., Decl. of Raymond Chen in Supp. of Mot. by Asustek and Asus for Partial Summ. J. at 1–2, ¶¶ 10–13, *LG Elecs., Inc. v. Asustek Computer Inc.*, No. 01-cv-326, ECF No. 163 (N.D. Cal. May 3, 2002) (stating that “Asustek specifically designs and makes the Asustek Products to use the functionalities and processes in the Intel chipsets and microprocessors” and that “[d]eviations from [Intel] specifications relating to functions controlled or performed by the [processor] and/or memory would render Asustek Products technically inoperable”).

could not be easily configured to work with meters performing a comparing function.⁷

C

Rejecting a claim of exhaustion in this case would be particularly problematic because LifeScan would be permitted to eliminate competition in the sale of the strips even though the strips do not embody the claimed invention and are themselves not patentable. Allowing LifeScan to control sale of the strips would be akin to allowing a tying arrangement whereby the purchasers of the meters could be barred from using the meters with competing strips. *See Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 517 (1917) (holding unlawful a patentee’s attempt to “under color of its patent . . . derive its profit . . . from the unpatented supplies with which [the patented product] is used”); *Carbice Corp. of Am. v. Am. Patents Dev. Corp.*, 283 U.S. 27, 33 (1931) (“Control over the supply of . . . unpatented material is beyond the scope of the patentee’s monopoly . . .”).

In both the tying and exhaustion cases, the Supreme Court has expressed particular concern with extension of the patent monopoly to items that must be renewed periodically and that are not themselves patentable. *Carbice*, 283 U.S. at 31 (“The limited monopoly to make, use, and vend an article may not be expanded by limitations as to materials and supplies necessary to the operation of it.” (quotation marks omitted)); *Morgan Envelope*,

⁷ The parties have not argued, and therefore we do not decide, whether there would be any impact on exhaustion principles if a strip were “especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use” within the meaning of 35 U.S.C. § 271(c).

152 U.S. at 433 (finding no indirect infringement “where the element made [and sold] by the alleged infringer . . . must be renewed periodically, whenever the device [sold by the patentee] is put to use”).

The basic principle underlying the Supreme Court’s exhaustion cases is that the authorized transfer of ownership in a product embodying a patent carries with it the right to engage in that product’s contemplated use. *See Quanta*, 553 U.S. at 631 (noting that the intended use of the Intel processors and chipsets was to be combined and used with other computer components so as to practice the patent); *Univis*, 316 U.S. at 249 (“[T]he only object of the sale is to enable the [purchaser] to grind and polish [the lens blank] for use as a lens by the prospective wearer.”); *Adams*, 84 U.S. at 455 (“The true ground on which [the Supreme Court’s early exhaustion cases] rest is that the sale by a person who has the full right to make, sell, and use such a machine carries with it the right to the use of that machine to the full extent to which it can be used . . .”). Here, barring the use of the meter with strips manufactured by the accused infringer would bar the use of the meters for their contemplated function and extend the patent monopoly improperly as we recently held in *Keurig*, No. 13-1072, slip op. at 7 (Fed. Cir. Oct. 17, 2013). We hold that the sale of the meter exhausted LifeScan’s patent rights.

II

LifeScan’s final argument is that even if its meters substantially embody the asserted claims, patent exhaustion is nevertheless inapplicable to the 60% of its meters that are not sold but instead distributed for free. LifeScan asserts that it received no “reward” for distributing them (because they were distributed without charge), and that the district court therefore properly found that patent exhaustion did not apply. We are

therefore asked to decide, as a matter of first impression, whether patent exhaustion applies to a product distributed for free. We conclude that, in the case of an authorized and unconditional transfer of title, the absence of consideration is no barrier to the application of patent exhaustion principles.

Although the Supreme Court has often discussed exhaustion in terms of a “sale” and a “purchaser,” *see, e.g., Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1766 (2013); *Adams*, 84 U.S. at 456, the Court has never confined the application of patent exhaustion to that context. The Court explained the rationale underlying the doctrine of patent exhaustion in *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539 (1853). *See also Quanta*, 553 U.S. at 625. *McQuewan* involved the effect of a patent term extension on patent licensees holding licenses to use the patented planing machine during the original patent term. 55 U.S. (14 How.) at 547–48. The Court held that “the purchaser of the . . . machine for the purpose of using it in the ordinary pursuits of life” was entitled to continue using the machine during the extended term. *Id.* at 549. The Court explained that

when the machine *passes to the hands* of the purchaser, it is no longer within the limits of the [patent] monopoly. It passes outside of it, and is no longer under the protection of the act of Congress. . . . The implement or machine *becomes [the purchaser’s] private, individual property*, not protected by the laws of the United States, but by the laws of the State in which it is situated.

Id. at 549–50 (emphases added). In other words, the patentee’s transfer of the right to use the machines “exhaust[ed]” his rights as to those machines. *See Univis*, 316 U.S. at 250 (citing *McQuewan*, 55 U.S. (14 How.) at 549–50).

Thus, despite frequent references to “sales” and “purchasers,” the Court has more fundamentally described exhaustion as occurring when the patented product “passes to the hands” of a transferee and when he “legally acquires a title” to it. *Millinger*, 68 U.S. (1 Wall.) at 351 (“legally acquires a title”); *Chaffee v. Boston Belting Co.*, 63 U.S. (22 How.) 217, 223 (1859) (“passes to the hands,” “legally acquires a title”); *McQuewan*, 55 U.S. (14 How.) at 549–50 (“passes to the hands”). Similarly, the Court has stated that exhaustion can occur by a transfer “from any other person . . . authorized [by the patentee] to convey it.” *Millinger*, 68 U.S. (1 Wall.) at 351 (emphasis added); *Chaffee*, 63 U.S. (22 How.) at 223 (same); see *Black’s Law Dictionary* 273 (1st ed. 1891) (defining “convey” to mean “[t]o pass or transmit the title to property from one to another”). So too, in *Univis*, the Court stated that the patentee’s “monopoly remains so long as he retains the ownership of the patented article.” 316 U.S. at 250 (emphasis added). Each of these formulations is broad enough to include a transfer of title that does not amount to a sale. A “sale” limitation would indeed be inconsistent with the Supreme Court’s decision in *McQuewan*, where the particular machines at issue had never been sold, but had instead been manufactured by the accused infringer with the permission of the patentee. See 55 U.S. (14 How.) at 548. Yet that lack of a “sale” was no barrier to the application of patent exhaustion. See *id.* at 549–50. Because the machines had been constructed with the patentee’s authorization and were the “private, individual property” of the accused infringer, they were “no longer under the protection of” the Patent Act. *Id.* The narrow application of patent exhaustion urged by LifeScan would be inconsistent with the doctrine’s underlying rationale—to permit the owner of an item who received it in an authorized transfer to use it.

LifeScan relies on language in Supreme Court exhaustion decisions mentioning the receipt of “considera-

tion” or “reward” by the patentee as supporting exhaustion. See, e.g., *Univis*, 316 U.S. at 251 (“[T]he patentee has received his reward for the use of the invention by the sale of the article . . .”); *Adams*, 84 U.S. (17 Wall.) at 456 (“[W]hen the patentee . . . sells a machine . . . whose sole value is in its use, he receives the consideration for its use and he parts with the right to control that use.”). But none of the cases cited by LifeScan involved any suggestion that exhaustion could be avoided by showing the absence or inadequacy of the patentee’s reward in a transfer by gift.

At bottom, a patentee has a choice as to how to secure its reward. A patentee may “demand[]” a particular price in exchange for an “article and the invention which it embodies.” See *Univis*, 316 U.S. at 251; see also *McQueenan*, 55 U.S. (14 How.) at 552. Alternately, a patentee may choose to give that article away for free in the hope of obtaining a future benefit, as LifeScan did here. But a patentee cannot evade patent exhaustion principles by choosing to give the article away rather than charging a particular price for it. Where a patentee unconditionally parts with ownership of an article, it cannot later complain that the approach that it chose results in an inadequate reward and that therefore ordinary principles of patent exhaustion should not apply.⁸

⁸ To be sure, the amount of compensation received by the patentee may in some instances be relevant to the question of whether a particular transaction is indeed an unconditional transfer of ownership as opposed to a conditional sale or license. See *Princo Corp. v. Int’l Trade Comm’n*, 616 F.3d 1318, 1328 (Fed. Cir. 2010) (en banc). No such inquiry is necessary here. Although LifeScan points to a notice on its meters’ packaging that purportedly requires customers to use LifeScan’s test strips and appears to argue that it has provided users with “only a

Additionally, while not “controlling” regarding issues of patent law, *see Bobbs-Merill Co. v. Straus*, 210 U.S. 339, 346 (1908) (quotation marks omitted), copyright cases further reinforce our conclusion that patent exhaustion applies to gifts.⁹ In the Supreme Court’s recent decision in *Kirtsaeng v. John Wiley & Sons, Inc.*, the Court held that the first sale doctrine in copyright law (comparable to the patent exhaustion doctrine) applies equally whether the copyrighted work is manufactured in the United States or abroad. 133 S. Ct. 1351, 1355–56 (2013). Although copyright’s first sale doctrine, unlike patent exhaustion, has been codified by statute, *see* 17

conditional grant of use rights,” Appellee’s Br. at 11, 36, our cases make clear that such notices are relevant only if they are “in the form of a contractual agreement,” *Jazz Photo Corp. v. Int’l Trade Comm’n*, 264 F.3d 1094, 1108 (Fed. Cir. 2001). Unless the purchaser has made an “express contractual undertaking,” the transfer is an unconditional sale, not a conditional sale or license. *Id.* at 1107–08; *Hewlett-Packard v. Repeat-O-Type Stencil*, 123 F.3d 1445, 1453 (Fed. Cir. 1997) (“[A] seller’s intent, unless embodied in an enforceable contract, does not create a limitation on the right of a purchaser to use, sell, or modify a patented product.”). Here, LifeScan expressly states that it “does not contend that the notice forms a binding contract.” Appellee’s Br. at 45. Accordingly, LifeScan’s contention that its transfer of the meters to health care providers and patients was “conditional” or a mere “license” is meritless.

⁹ The Supreme Court has frequently explained that copyright cases inform similar cases under patent law. *See, e.g., Bauer v. O’Donnell*, 229 U.S. 1, 13–14 (1913) (“In providing for grants of exclusive rights and privileges to inventors and authors we think Congress had no intention to use the term ‘vend’ in one sense in the patent act and ‘vending’ in another in the copyright law.”).

U.S.C. § 109(a), the Supreme Court looked to the doctrine’s common law roots to interpret that provision. *Kirtsaeng*, 133 S. Ct. at 1363 (“The ‘first sale’ doctrine is a common-law doctrine with an impeccable historic pedigree.”). The Court explained that the first sale doctrine was traceable to “the common law’s refusal to permit restraints on the alienation of chattels.” *Id.* To elaborate on that common-law policy, the Court quoted at length from Lord Coke’s *Institutes of the Laws of England*, stating:

[If] a man be possessed of . . . a horse, or of any other chattell . . . and *give or sell* his whole interest . . . therein upon condition that the *Donee or Vendee* shall not alien[ate] the same, the [condition] is voi[d], because his whole interest . . . is out of him, so as he hath no possibilit[y] of a Reverter, and it is against Trade and Traffi[c], and bargaining and contracting betwee[n] man and man: and it is within the reason of our Author that it should ouster him of all power given to him.

Id. (quoting 1 E. Coke, *Institutes of the Laws of England* § 360, p. 223 (1628)) (omissions and alterations in original) (emphases added). Thus, the policy underlying the first sale doctrine draws no distinction between gifts and sales. The same policy undergirds the doctrine of patent exhaustion. See *Straus v. Victor Talking Mach. Co.*, 243 U.S. 490, 500–01 (1917) (explaining that a patentee’s attempt “to place restraints upon [a patented product’s] further alienation [was] such as have been hateful to the law from Lord Coke’s day to ours”).

The Ninth Circuit specifically addressed the application of copyright’s first sale doctrine to gifts in *UMG Recordings, Inc. v. Augusto*, 628 F.3d 1175 (9th Cir. 2011). In that case, UMG owned a copyright in the content of promotional CDs. *Id.* at 1177. It distributed these promotional CDs for free to individuals such as music critics

and radio programmers. *Id.* When Augusto obtained and sold the CDs, UMG brought suit against him for copyright infringement, arguing that his sales constituted a violation of its exclusive rights to the content of the CDs. *See id.* at 1178; *see also* 17 U.S.C. § 106(3). The Ninth Circuit disagreed. It held that UMG’s free distribution of the CDs exhausted its rights under copyright law. *Augusto*, 628 F.3d at 1183. The court reasoned that “[n]otwithstanding its distinctive name, the [first sale] doctrine applies not only when a copy is first sold, but when a copy is given away or title is otherwise transferred without the accouterments of a sale.” *Id.* at 1179. The court explained that “[o]nce the copyright owner places a copyrighted item in the stream of commerce . . . , he has exhausted his exclusive statutory right to control its distribution.” *Id.* (quotation marks omitted).

The common policies underlying patent exhaustion and the first sale doctrine would be significantly undermined by the rule LifeScan advocates in this case. Absent a valid contractual restriction, restraints upon the downstream use or sale of a patented product “offend against the ordinary and usual freedom of traffic in chattels,” *see John D. Park & Sons Co. v. Hartman*, 153 F. 24, 39 (6th Cir. 1907), and that is so regardless of the amount of consideration demanded by the patentee when it originally parted with the product. Indeed, conditioning patent exhaustion on the adequacy of the patentee’s reward “would cast a cloud of uncertainty” over every transaction and every patented product. *Tessera, Inc. v. Int’l Trade Comm’n*, 646 F.3d 1357, 1370 (Fed. Cir. 2011) (holding that patent exhaustion applied even though the seller failed to pay promised royalties to the patentee). That result would be “wholly inconsistent with the fundamental purpose of patent exhaustion—to prohibit post[-]sale restrictions on the use of a patented article.” *Id.* (citing *McQuewan*, 55 U.S. (14 How.) at 549). If patentees could evade exhaustion merely by giving away one component

of an apparatus or method claim and tying the recipient's ability to use that component to the subsequent purchase of another component, then patent exhaustion would be a dead letter and consumers' reasonable expectations regarding their private property would be significantly eroded. See *Quanta*, 553 U.S. at 630–31; *United States v. Masonite Corp.*, 316 U.S. 265, 280 (1942) (“Since patents are privileges restrictive of a free economy, the rights which Congress has attached to them must be strictly construed so as not to derogate from the general law beyond the necessary requirements of the patent statute.”). We therefore conclude that patentees cannot circumvent the application of patent exhaustion principles by distributing a product embodying the patent for free.

CONCLUSION

In summary, we hold that patent exhaustion principles apply equally to all authorized transfers of title in property, regardless of whether the particular transfer at issue constituted a gift or a sale. We further conclude that LifeScan's OneTouch Ultra meters substantially embody the methods claimed in the '105 patent and that their distribution therefore exhausts LifeScan's patent rights. We therefore reverse the district court's grant of a preliminary injunction and remand for further proceedings consistent with this opinion.

REVERSED AND REMANDED

COSTS

Costs to Shasta.

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

LIFESCAN SCOTLAND, LTD. AND LIFESCAN, INC.,
Plaintiffs-Appellees,

v.

**SHASTA TECHNOLOGIES, LLC AND CONDUCTIVE
TECHNOLOGIES, INC.,**
Defendants-Appellants,

AND

**INSTACARE CORP. AND PHARMATECH
SOLUTIONS, INC.,**
Defendants-Appellants.

2013-1271

Appeal from the United States District Court for the Northern District of California in No. 11-CV-4494, Judge Edward J. Davila.

REYNA, *Circuit Judge*, dissenting.

The majority holds that LifeScan's sale (or promotional giveaway) of its unpatented blood glucose meter¹

¹ On its packaging and promotional materials, LifeScan's OneTouch® Ultra® blood glucose meters and test strips list a number of patents embodied in the com-

exhausts its rights in a patented method, which requires a specialized test strip that is consumed in practicing the method, because the meter “controls and carries out” the functions described in the patent and LifeScan failed to obtain a patent for the test strip. The majority reaches its result by conflating the patentability of a product with the product’s ability to substantially embody the essential features of a patented method. The majority reasons that because LifeScan did not obtain a patent on its test strips, those strips could not substantially embody the essential features of its method patent. Yet, the Supreme Court has recognized that it makes “no difference as to the infringement or non-infringement of a combination that one of its elements or all of its elements are unpatented.” *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 375 (1961) (Harlan, J., dissenting) (quoting *Leeds & Catlin Co. v. Victor Talking Machine Co.*, 213 U.S. 325, 333 (1909)). The Court’s recent pronouncement in the context of method patent exhaustion makes Justice Harlan’s observation in *Aro* no less applicable today. See *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 632 (2008). I disagree with the patentability gloss that the majority casts on the otherwise straightforward exhaustion standard expressed in *Quanta*. Accordingly, I respectfully *dissent*.

I.

The Supreme Court has held that the sale of a product triggers exhaustion when its only reasonable and intended use is to practice the patent and it substantially embodies the essential features of the patented invention. *Quanta*, 553 U.S. at 631 (quoting *United States v. Univis Lens Co.*, 316 U.S. 241, 249–51 (1942)). There is no real

combination, but the only patent applicable to the meter is a design patent, U.S. Patent No. D546,216 (filed Jul. 11 2005), which is inapplicable to this case.

dispute in this case that the only reasonable and intended use of LifeScan's blood glucose meter is to practice the patent-in-suit. *See* Maj. Op. at 12–13. Therefore, this case turns on the question of whether LifeScan's meters or its test strips substantially embody the essential features of the patent. I conclude that the test strips, and not the meters, embody those essential features.

The majority apparently misapprehends the Court's guidance in *Quanta*, which causes it to incorrectly conclude that the meters, and not the test strips, embody the essential features of LifeScan's patented method. In *Quanta*, the Supreme Court explained that a product embodies the essential features of a method patent when the product contains or is involved in the inventive, as opposed to the standard, processes of the patented method. *Quanta*, 553 U.S. at 633 (“[T]he grinding process [in *Univis*] was not central to the patents. That standard process was not included in detail in any of the patents and was not referred to at all in two of the patents.”). The Court did not clearly demarcate a line between inventive and standard processes, but its analysis of the facts of that case is informative. In particular, the microprocessor and chipset, which “constitute[d] a material part of the patented invention and all but completely practice[d] the patent,” substantially embodied the inventive processes of the method patent at issue because “the only step necessary to practice the patent [wa]s the *application of common processes* or the *addition of standard parts*.” *Id.* (emphasis added). The addition of those standard components, memory and buses, was common and noninventive, and doing so required no creative or inventive decision on the part of the accused infringer. *Id.* at 633–34. The Court emphasized that it is the nature of the steps that is the relevant characteristic, rather than the patentability of the components themselves. *Id.* at 635 (“While each . . . microprocessor and chipset practices thousands of individual patents, including some [patents] not at issue in

this case, the exhaustion analysis is not altered by the fact that more than one patent is practiced by the same product.”). The Court’s analysis makes clear that the inventive contributions of the components to the method, as opposed to the inventiveness of the components themselves, determine their essentialness. The majority’s apparent misunderstanding of the Court’s guidance in *Quanta* causes it to err in two separate respects.

A.

First, the majority relies on *Quanta* to elevate the blood glucose meter over the test strip as the essential feature of the patented method. Because of the majority’s belief that LifeScan’s blood glucose meters “control and carry out” the functions described in the patents, it reasons that the meters alone embody the essential features of the method patent. While the majority correctly identifies the objective of LifeScan’s inventive method, reducing errors in blood glucose readings caused by insufficient sample liquid and defects in the production of test strips, it incorrectly concludes that the “measuring,” “comparing,” and “giving an indication of an error” steps performed by the meter are essential to achieving the stated objective.

Prior art blood glucose meters relied on a test strip with only two electrodes—one reference and one working. U.S. Patent No. 7,250,105 col. 1 ll. 27-29 (filed May 7, 2003) (“the ’105 patent”). When the enzyme coating the working electrode reacted with glucose in the blood sample, it would release electrons that would result in an electrical current, which could be measured relative to the reference electrode. In contrast, the test strip utilized by the patented method in this case has three electrodes, two of which are working and capable of measuring an electrical current. This distinction is crucial. When the working electrode in a prior art meter would become severed because of a manufacturing defect or was insufficiently

covered with blood due to an operator error, the patient would have no way of knowing that the reading was erroneous. *See id.* col. 2 ll. 27-38. Once LifeScan developed its patented method that used two working electrodes, the meter could measure two separate blood glucose readings. *Id.* As a result, a difference in the readings would indicate an error condition—either insufficient blood covering one of the electrodes or a defective electrode—and the patient could be alerted accordingly. But for the specialized test strips required by LifeScan’s patented method, the blood glucose meter alone could not perform the “comparing” and “giving an indication of an error” steps viewed by the majority as essential to the patented method.² Accordingly, LifeScan’s test strips substantially embody the essential features of its patented method.

In contrast, the blood glucose meter cannot be fairly viewed as embodying the essential features of LifeScan’s patented method. The steps performed by the meter,

² The majority understands the examiner’s statement of his reasons for allowance to be that he allowed the method claims as distinguishable from the prior art because they contained the “measuring,” “comparing,” and “giving an indication of an error” steps. Maj. Op. at 16. In fact, the examiner was commenting on the patentability of LifeScan’s product claim, rather than distinguishing LifeScan’s method claim from other prior art methods. Accordingly, his statement gives no indication either way which steps are essential to the patented method. In any event, “[t]his court has recognized that an Examiner’s Statement of Reasons for Allowance ‘will not necessarily limit a claim.’” *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1345 (Fed. Cir. 2005) (quoting *ACCO Brands, Inc. v. Micro Sec. Devices, Inc.*, 346 F.3d 1075, 1079 (Fed. Cir. 2003)).

“measuring,” “comparing,” and “giving an indication of an error,” are only made possible by the unique configuration of the three electrode test strip, as explained above. A diabetic patient with a LifeScan test strip, a pencil, a pad of paper, and an ammeter (a device used to measure electric current) could “measure an electric current at each working sensor part,” “compare the electric current from each working sensor parts to establish a difference parameter,” and “give an indication of an error if said difference parameter is greater than a predetermined threshold,” all without the assistance of a blood glucose meter. *See Gottschalk v. Benson*, 409 U.S. 63, 65 (1972) (A digital computer . . . operates on data expressed in digits, solving a problem by doing arithmetic as a person would do it by head and hand.”). Accordingly, LifeScan’s blood glucose meter does not embody the essential features of its patented method because the steps it performs are common and noninventive. In fact, the meter is more fairly characterized as a standard component in the system and only involves the application of common processes. *See Quanta*, 553 U.S. at 633.

B.

Second, the majority misinterprets *Quanta* by requiring that the “essential, or inventive, features” of a method patent be contained in a separately-patentable component covered by a product patent. Because LifeScan abandoned its patent applications covering its test strip, the majority concludes that the strip cannot embody the essential features of LifeScan’s method patent. This reasoning is inconsistent with the Supreme Court’s guidance in *Quanta*. In that case, the Court focused on the inventiveness of the steps in the claimed method, rather than the patentability of the underlying components themselves. *Quanta*, 553 F.3d at 635. The Court’s analysis, as opposed to the majority’s reinterpretation of it, is fully consistent with the statute. Section 100(b) of the Patent Act explicitly provides that an entity like LifeScan

can obtain a patent for its method that “includes a new use of a known . . . machine.” 35 U.S.C. § 100(b). Accordingly, the majority was incorrect to place any significance on the patentability of LifeScan’s test strip. What matters is whether the test strip embodies the steps that are essential to the patented method. As noted above, LifeScan’s test strips are essential to the patented method.³

The majority relies on this court’s recent decision in *Keurig, Inc., v. Sturm Foods, Inc.*, No. 13-1072, __ F.3d __ (Fed. Cir. 2013), which held that the sale of a coffee brewer exhausts the patentee’s rights in a method covering the use of the brewer with a disposable cartridge. But that case is distinguishable from this case. Unlike this case where the inventiveness of the method lies in the test strip, every step of the claimed method in *Keurig* is performed by the brewer with the cartridge merely serving as a passive participant. *Id.* at 2–3. Tellingly, the panel in *Keurig* focused on whether the brewers had substantial noninfringing uses (which is not at issue here) rather than whether it embodied the essential features of the patented method (which is at issue here). Furthermore, both the brewer and the cartridge are separately patented (by apparatus patents), yet the majority in this case does not explain the effect this has on which component embodies the essential features of the method patent.

³ LifeScan sells 40% of its blood glucose meters below cost, but without test strips. The essentialness of the test strips is made evident by the fact that a patient could not practice the steps of LifeScan’s patented method with the meter alone because every step except the last requires a “measuring device” (i.e., a test strip) or a “working sensor part” (i.e., an electrode) on the measuring device. *See* ’105 Patent col. 6 l. 55 to col. 8 l. 4.

Assuming that the patentability of the test strips in this case was relevant to exhaustion and determined whether that component could embody the essential features of a patented method, since LifeScan's blood glucose meter is not patented, it too would not exhaust the method patent. In brief, while the majority devotes significant attention to the patentability of the test strip, it fails to demonstrate that LifeScan's meter is separately patentable. The evidence suggests that it is not. *See supra* note 1. By assuming that the meter was patentable by finding it essential to the patented method in this case, the majority, in effect, allows LifeScan to sue competitors that employ any blood glucose reader that measures electric currents, compares the electric currents, and give an error indication if they differ. This overextension of the patent grant violates the principles of every exhaustion and combination case decided by this court and the Supreme Court. *See, e.g., Quanta*, 553 U.S. at 626. Had the majority properly focused on the inventiveness of the method steps rather than the patentability of the underlying components themselves, this misstep would have been avoided. For the reasons given, the majority's decision to make inventiveness for exhaustion purposes coextensive with patentability, *see* Maj. Op. at 14, cannot be squared with Supreme Court precedent.⁴

⁴ The majority asserts that this formulation of its holding is "demonstrably inaccurate." Maj. Op. at 17 n.5. I agree that this formulation of its holding is itself a misstatement of the law and inconsistent with *Quanta*, which is why I am perplexed that the majority would hold that "[w]hat is 'inventive' about patent claims in the patent exhaustion context is what distinguishes them from the prior art," i.e., makes them patentable. *See id.* at 14. Perhaps the majority means "what is 'inventive' about *method* patent claims in the patent exhaustion

II.

Applying exhaustion to a case such as this one is especially inappropriate because the essential features of the patented method are embodied in test strips that are immediately consumed during performance of the method even though LifeScan has received little to nothing in return for its blood glucose meters. Despite that, the majority concludes that patent exhaustion applies to the meters that LifeScan sells at below cost without test strips and that cannot practice the patented method right out of the box, *see supra* note 3, as well as the promotional meters that LifeScan distributes for free as part of a Starter Kit. The majority reasons that LifeScan has “received [its] reward” for its patented method even on the meters it gives away for free because it retained the “hope of obtaining a future benefit” on those meters. Maj. Op. at 25 (citing *Univis*, 316 U.S. at 251). What benefit that is remains a mystery. Once a patient’s use of the meter consumes the ten free strips included in LifeScan’s Starter Kit,⁵ the patient will be able to practice the method with impunity using Shasta’s generic test strips that are

context is *which claim steps distinguish this method claim from other prior art method claims.*” I would agree to this formulation, but do not ascribe it to the majority because it is inconsistent with that majority’s persistent focus on the patentability of the strips themselves.

⁵ It is immaterial that LifeScan distributes the first ten test strips for free because it intends for the patient to use those strips to perform its patented method. I do not understand LifeScan to argue to the contrary. Rather, LifeScan insists that its patent rights are not exhausted with respect to additional strips that a patient combines with the meter after the initial ten strips have been consumed.

designed to mimic LifeScan's OneTouch® Ultra® strip. In such instances, LifeScan will not receive any cognizable reward from the meters it distributes for free and, hence, any purported "future benefit" is speculative and entirely theoretical.

"The declared purpose of the patent law is to promote the progress of science and the useful arts by granting to the inventor a limited monopoly, the exercise of which will enable him to secure the financial rewards for his invention." *Univis*, 316 U.S. at 250 (citing U.S. Const. art. I, § 8, cl. 8). A patent system premised on granting the patentee a "hope of receiving a future benefit" is one where there is no secure benefit to be had and that does not promote the progress of the useful arts. The majority's reasoning is particularly problematic in this context where a method patent is involved. For method patent claims, infringement occurs when a party performs all of the steps of the claimed method. *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993); *see also Mirror Worlds, LLC v. Apple Inc.*, 692 F.3d 1351, 1359 (Fed. Cir. 2012) ("Direct infringement of a method claim can be based on even one instance of the claimed method being performed."). Accordingly, each time an individual practices a patented method, the individual infringes the patent. *Beedle v. Bennett*, 122 U.S. 71, 78 (1887). ("The patent covers the process of drawing water from the earth by means of a well driven in the manner described in the patent. The use of a well so constructed is, therefore, a continuing infringement, as every time water is drawn from it the patented process is necessarily used."); *see also Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1766 (2013) ("Rather, 'a second creation' of the patented item 'call[s] the monopoly, conferred by the patent grant, into play for a second time.'" (quoting *Aro*, 365 U.S. at 346) (alteration in original)). In a case such as this one where the essential component is consumed in the patented process, it is inappropriate to limit that patentee to a single reward for

the sale or giveaway of the first component. *See id.* (“[T]he patent holder has ‘received his reward’ only for the article sold, and not for subsequent recreations of it.” (quoting *Univis*, 316 U.S. at 251)). Each successive performance of the method would be an infringement unless licensed by the patentee, either explicitly or implicitly. On the facts of this case, the only means for a patient to obtain a license for subsequent performances of LifeScan’s patented method would be through purchasing additional LifeScan’s OneTouch® Ultra® test strips, but based on the majority’s conclusion, the fact that no license flows from the purchase of Shasta’s generic test strips is rendered meaningless because use of those strips are held not to be infringing. Accordingly, exhaustion should not apply in a case such as this one where the essential features of a patented method are embodied in a component that is immediately consumed during performance of the method. This is true whether the initial component is given away for free, sold under cost, or sold at a premium.

Although the contexts are different, the Supreme Court’s reasoning in its recent decision in *Bowman* does not support the majority’s conclusion that exhaustion applies to method patents the practice of which consume its essential component.⁶ In *Bowman*, the Court refused

⁶ The principle case involving consumables on which the majority relies, *Morgan Envelope Co. v. Albany Perforated Wrapping Paper Co.*, 152 U.S. 425 (1894), is inapposite. Unlike this case that involves a method patent, which is infringed every time the method is practiced, that case dealt with an apparatus patent covering the combination of a roll of toilet paper and a dispenser. *See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311 (Fed. Cir. 2005) (“[A] rule that governs infringement of a method claim may not always govern infringement of an apparatus claim.”).

to find Monsanto's patent rights exhausted when Mr. Bowman purchased seeds from a grain elevator even though those seeds were grown from patented seeds Monsanto had sold to other farmers. While Monsanto received its reward for the first seeds it sold, the Court reasoned that the other seed companies (i.e., Monsanto's competitors) would reproduce the seeds themselves and sell them to farmers who would only need to buy them once and reproduce them for future plantings. *Id.* at 1767. Monsanto would be deprived of its exclusive rights in all of these subsequent sales and reproductions of its patented seeds. *Id.* Accordingly, the Court held that "[t]he exhaustion doctrine is limited to the 'particular item' sold to avoid just such a mismatch between invention and reward." *Id.* A contrary holding would have caused the patent to "plummet in value after the first sale of the first item containing the invention," and the patentee's exclusive rights would last only one transaction. *Id.* at 1768.

The majority's holding in this case will unquestionably cause LifeScan's patented method to plummet in value and result in its exclusive rights over the method lasting only one transaction. Similar to *Bowman*, after patients consume the ten test strips in the Starter Kit, or none, they will be able to continue practicing LifeScan's patented method using generic test strips supplied by LifeScan's competitors. Yet the mismatch between invention and reward in this case is even starker than it was in *Bowman*. While Monsanto received a reward for the first set of seeds it sold, LifeScan receives no reward whatsoever on the Starter Kit. Additionally, LifeScan will be deprived of its exclusive rights in all of the subsequent performances of its patented method after the giveaway sample test strips are consumed. Because LifeScan's test strips embody the essential features of its patented method, the majority erred by finding exhaustion applied once

the meter is sold (or given away). Accordingly, I respectfully *dissent*.