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Swimming Upstream: Developing and Commercializing Diabetes Products in a Patent Protected World

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Abstract

Many, if not most, commercially available diabetes treatment products are protected by some form of intellectual property. This article discusses the development and commercialization of products in view of the state of intellectual property for the diabetes treatment market, with respect to possible discouragement, for some, from seeking patent protection or commercializing a new product under the belief that patent protection is either unavailable or difficult to come by, or for fear of infringing existing patents. Upon closer investigation, the evolution of technology almost always creates opportunities for new improvements, which likely can be patent protected. Furthermore, while avoiding the claims of existing patents is sometimes challenging and opinion based, and thus not a guarantee of avoiding a patent litigation, patent litigation may be delayed and is often settled early on.

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Any intelligent fool can make things bigger, more complex, and more violent. It takes a touch of genius—and a lot of courage—to move in the opposite direction.[1]

Most commercially available diabetes treatment devices are protected by some form of intellectual property, with utility patents being a considerable form of protection that are routinely sought (design patents may also be used to protect the aesthetic, ornamental design of a product/device; other forms of intellectual property may also be available, including trademarks, copyrights, and trade secrets; this paper only discusses utility patent protection). Patents are a form of intellectual property protection that confers upon the patent owner a legal right to exclude others from making, using, offering for sale, selling, or importing into the United States the claimed invention (i.e., composition of matter, a process/method, a machine, and an article of manufacture/product) for a limited period of time (generally, 20 years from when the patent was applied for). This legal right is granted in exchange for disclosing to the public how to make and use the claimed invention.

Critically, however, a patent does not confer upon the patent owner or licensee an absolute right to make, use, offer for sale, or sell, for example, a device covered by the claimed invention. For one to sell any device, the device should not infringe the claims of existing third-party patents. Otherwise, one could find themselves a defendant in a patent infringement action. This is a significant issue with respect to diabetes technologies since unexpired granted patents for glucose monitors, testing strips, and insulin dispensing devices are numerous and often comprehensive in scope.

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Abbreviations: (DOE) doctrine of equivalents, (FDA) Food and Drug Administration, (FTO) freedom to operate

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Without careful analysis of such existing, unexpired patents, a market entrant could find themselves a defendant in a patent infringement suit or many such suits. (One should always seek intellectual property counsel to provide legal advice with respect to infringement issues. It is suggested that such advice be sought prior to and/or during development of a new product, as well prior to commercialization.) However, even in view of such a competitive commercial and patent landscape, diabetes technologies continue to evolve and patent applications covering these new offerings continue to be filed.

Existing and emerging diabetes technologies generally fall within a finite number of categories:

- sensing/monitoring devices (e.g., glucose monitors),
- drug delivery devices (e.g., syringes, pens, pumps), and
- support accessories and components (e.g., infusion sets, catheters, and test strips).

Such devices can be further characterized, for example, as implantable and nonimplantable devices, with nonimplantable devices generally including the support accessories. There is also an all-inclusive category considered to be the "Holy Grail" of diabetes therapeutic devices—the artificial pancreas, or closed-loop treatment system. A closed-loop treatment system combines real-time sensing/monitoring functionality and dosage determination with drug/insulin delivery.

Table 1 is an illustrative snapshot of the number of issued U.S. patents pertaining to diabetes treatment issued to Medtronic. (**Table 1** is not meant to be an exhaustive list but merely exemplary of the U.S. patents in the diabetes treatment space for Medtronic. The search itself was performed using Thomson Innovation™, and a separate search was performed for each company using the keywords "diabetes" and "device or apparatus or system." The products described are predominantly those intended for personal use rather than for professional use in hospitals. U.S. patent information was obtained via the U.S. Patent and Trademark Office website: www.uspto.gov.) This is only a fraction

Table 1.
Number of Issued United States Patents Pertaining to Diabetic Treatment Issued to Medtronic

	U.S. patents granted[a]	Products[b]	Product type
Medtronic Inc.	196	Guardian® REAL-Time Continuous Glucose Monitoring System	Personal continuous glucose monitor
		mySentry™ Remote Glucose Monitor	Personal bedside continuous glucose monitor
		iPro Evaluation	A three-day evaluation conducted by a health care provider with his/her own continuous glucose monitoring device
		CareLink® Personal Therapy Management Software	Care management software
		MiniMed Paradigm® Revel™ Insulin Pump	Insulin pump with continuous glucose monitor
		MiniMed Paradigm® REAL-Time Revel™ System	Combined insulin pump with continuous glucose monitor and therapy management software
		QUICK-SET® Infusion Set	Insulin infusion device
		SILHOUETTE® Infusion Set	Insulin infusion device
		SURE-T® Infusion Set	Insulin infusion device
		MIO® Infusion Set	Insulin infusion device

[a] Based upon search of granted patents as of August 2012. Please note, the listed number of granted U.S. patents are for informational purposes only; we make no representation as to whether such patents are directed to or cover the noted products.
[b] Based upon company Web site information.

of the patents that have been issued in the diabetic treatment space, as there are many other patents belonging to competitors of Medtronic, as well as smaller entities and/or individuals. It is safe to assume that at least 1000 U.S. patents have issued in the diabetic device space since 2003. (While the term of U.S. patents are generally 20 years from their earliest effective filing date, patents can expire early because of the failure to pay maintenance fees due at predetermined time intervals after issuance, as well as expire due to terminal disclaimers. Moreover, U.S. patents can be invalidated in court proceedings, and therefore, such invalid patents cannot be enforced.) With all these issued patents, one may inquire if it is worth pursuing patent protection. Moreover, can one commercialize a device without infringing upon one or more of these patents? With respect to the former, the simple answer is yes. The latter inquiry, however, is a more challenging issue to answer.

With respect to patentability, while currently available diabetes treatment devices address a great many user/patient needs, there is still desirable functionality that has yet to be commercialized, developed, or perfected (or even determined). As projected by medical device experts at the U.S. Food and Drug Administration (FDA),[2] and as reflected in issued patents, current innovations appear to be focused on

- wireless and Internet-based functionality (e.g., electronics and software),
- continuous detection coupled with instantaneous drug delivery (i.e., closed-loop treatment systems),
- minimally invasive implantable devices, and
- advances of materials science applied to the treatment of diabetes.

While some "new" ideas may not actually be new (i.e., there is prior published information that discloses, teaches, or suggests the concept; a great number of concepts disclosed in patents and published patent applications are never commercialized), it is generally the case that certain problems in current products/devices or in the subject matter as a whole have yet to be addressed or have not been adequately addressed and thus create the opportunity for patentable improvements or new devices. As many will appreciate, this is routinely seen with developments in the mobile communications arena.

As with many devices and products, it is the end users who ultimately drive demand. While a fully functional and therapeutically effective closed-loop treatment system may be many years away (e.g., the Juvenile Diabetes Research Foundation's Artificial Pancreas project, available at www.jdrf.org/index.cfm?page_id=106383), current patient demands are fueling the trend toward making diabetes treatment devices smaller, faster, and smarter to ultimately devise devices that are simple and painless (or less painful). Of course, considerable costs arise when developing and marketing improved devices, especially for medical devices that require FDA (or foreign government entity for regulating therapeutics) approval before selling any such device in the United States. It is estimated that the cost to commercialize a 510k FDA-approved device from concept to sale is approximately $24 million (on average). The cost to commercialize a premarket approved device (premarket approval) is, on average, three times as much—or approximately $75 million.[3] Since such costs are considerable, there must be value (and in most circumstances, great value) associated with developing devices for companies to take such financial leaps, outside of general business overhead costs, in moving forward. This value is, of course, the intellectual property developed with the device. Protection of the intellectual property of newly developed devices by procuring patents ensures that market entrants have an opportunity to recover the costs of research, development, and FDA evaluation in giving market entrants a monopoly on their improvements.

As noted earlier, one way to provide an improved device is by making it smaller. But can simply making an insulin pump (for example) smaller be patented? Although miniaturization in and of itself is unlikely a basis for patentability,[4] it is often the case that miniaturization of a device will necessarily involve overcoming technological obstacles. When such obstacles are conquered, the solutions that arise often involve novel and nonobvious features that can be patented. Even if miniaturization does not *per se* yield new features, it may still be patentable if the miniaturization

produces unexpected results (e.g., increased speed, energy efficiency, or elimination of a rate-limiting step in a process performed by the larger device; in rebuttal of an obviousness rejection from an examiner of the U.S. Patent and Trademark Office, the applicant may provide evidence of secondary considerations, including superior properties or unexpected results; see the Manual of Patent Examining Procedure at Section 2145).[5]

After tackling patentability, the inquiry is then how one contends with possible infringement issues due to the sheer number of earlier patents that may cover the new device. First, only unexpired, current patents can be infringed. Thus any patents that are expired (either due to patent term having expired or for failure to pay maintenance fees; a patent can be revived for failure to make a maintenance fee if made within 24 months of the 6-month grace period; see 35 USC 41[c]) can largely be ignored, as can any patent that is set to expire prior to commercial launch of the device (with respect to time before expiration, see "safe harbor" discussed later).[6] Other patents may also expire early due to other circumstances (e.g., terminal disclaimers; see 37 CFR 1.321). In an effort to avoid unexpired (or soon to expire) patents, companies often utilize legal counsel early on during the device's design phase to work with engineers to "design around" the claims of patents.

To infringe a patent, an accused device must come within the scope of one or more claims of the patent. The claims of a patent are the actual property right awarded to the patent owner by the U.S. Patent and Trademark Office (or relevant patent office of the country to which the patent is issued), with each claim describing a particular embodiment of the invention. Merely because the abstract, drawings, or specification of the patent broadly describe features of one's new device does not mean the claims of the patent have such broad scope to cover such features. The disclosure is provided to enable one of skill in the art to make and use the invention; the claims are the property right. Specifically, in the United States, the determination of infringement of a patent claim is a two-step analysis: (1) the limitations of each claim are construed to determine its scope and meaning[7] and (2) the construed claim is then compared with the accused infringing device. The scope and meaning of the limitations of the claims are generally determined by intrinsic evidence, that is, the claim language itself, and the written specification and drawings of the patent. In addition, when a patentee narrows a limitation of a claim during prosecution for a reason related to patentability, the patentee is then "estopped" (prosecution history estoppel) from later interpreting the limitation broadly under the doctrine of equivalents (DOE) to recover surrendered subject matter. For example, if the patentee amended the claim with a new limitation in order to avoid what is already known in the technology space (e.g., in view of an earlier patent), the patentee cannot later expand the limitation's scope under the DOE to cover equivalent structure/functionality.

Infringement is found in one of two ways: by literal infringement or by infringing the claim under the DOE. Under literal infringement, every limitation of an asserted claim must be literally present in the accused device.[8] If any one (or more) limitation is missing from the accused device, the device cannot literally infringe the claim. However, under the DOE, even if the accused device does not literally infringe the claim, but structure of the accused device performs substantially the same function in substantially the same way and obtains substantially the same result of the missing limitation, the accused device could infringe the claim under the DOE.[9] Thankfully, the application of the DOE is limited. Specifically, the DOE cannot be applied to find infringement if to do so would effectively read a limitation out of a claim ("all-elements rule"). Take, for example, the following patent claim:

1. A diabetes treatment device comprising

   element A,

   element B, and

   element C, wherein element C includes a single prong only for interlocking with element B.

This claim should be avoidable if one were to design a treatment device where element C includes a plurality of prongs to interlock with element B or did not include any prongs to interlock with B. Literal infringement is avoided since the claim specifically requires element C to include only a single prong to interlock with B. Moreover, under the DOE,

and under the all-elements rule, element C having no prongs or a plurality of prongs could not be an equivalent to "element C includes a single prong only," as one would necessarily have to read the limitation of out of the claim, which is not permissible.

Even if one is able to "design around" certain patents, inevitably there are always a few patents that still might be problematic and require a freedom-to-operate (FTO) opinion. (One should always seek intellectual property counsel to provide legal advice with respect to infringement issues. It is suggested that such advice be sought prior to and/or during development of a new product, as well prior to commercialization.) An FTO opinion is an opinion of counsel that construes the claims of reviewed patents and compares them with a product that is contemplated for commercial sale and provides arguments of noninfringement and/or invalidity. [Invalidity arguments contend that the claims of a patent are not valid because they are not patentable over prior art (e.g., prior published information, general knowledge).] However, a FTO opinion on a patent is no guarantee that a company would still not be sued for patent infringement on the patent. Freedom-to-operate opinions are just that, opinions, and are primarily obtained in the United States to avoid a finding of willful infringement and the possibility of treble (triple) damages in patent litigation.[10] (In startup companies, FTO is often also obtained to provide potential investors with information on risk assessment with respect to third-party patents.) While the realization that a FTO opinion does not save one from litigation, there are other considerations that may make the litigation risk more palatable. For example, a patent owner may delay or decline to bring a patent infringement claim if

- the potentially infringing device has yet to be offered for sale,
- damages would be less than the estimated cost of litigation, and/or
- the device falls within a safe harbor provision.[11]

Specifically, depending upon the dollar amount in controversy, plaintiffs can expect litigation costs (through trial) to be between $650,000 and $5 million.[12] Thus, to offset such costs, the potential damages value should be at least greater than that which is spent in litigation and, in most instances, a considerable percentage greater. Given such extreme costs, the threat of litigation is less likely where the commercial device does not exist or where there are only limited sales. Moreover, under current provisions of U.S. patent law, prior to FDA approval, "It shall not be an act of infringement to make, use or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug and Cosmetic Act and the Act of March 4, 1912) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs" or medical devices [35 USC sec. 271(e)(1)].[13] Thus making, using, or selling an unapproved device for uses reasonably related to information for FDA approval is not grounds for infringement. (The development phase is considered to be a "safe harbor.")

In view of such risks and odds, importantly, should a new device demonstrate such a vast improvement over the current paradigm that it will likely be accepted as the new standard, patents and applications that are created to protect the new device can be used as leverage against a plaintiff competitor having earlier patents on the basic device. This leverage can be used in settlement negotiations for patent infringement (e.g., setting up a cross-licensing situation with the patentee). It is worth noting that the vast majority of patent infringement actions in the United States settle.[14]

Regardless of the potential of infringing upon another's patent, in many instances, the value created in developing a better product can often offset patent infringement obstacles. As the expression goes, "Build a better mousetrap, and the world will beat a path to your door."[15]

References:

1. Schumacher EF. Small is beautiful. In: The radical humanist. 1973; 37:22.
2. Herman WA, Devey GB. Future trends in medical device technologies: a ten-year forecast. *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM238527.pdf*. Accessed August 20, 2012.
3. Makower J, Meer A, Denend L. FDA impact on U.S. medical technology innovation.
4. Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955).
5. Dillon, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990).
6. Bristol-Myers Squibb Co. v. Royce Labs., Inc., 69 F.3d 1130 (Fed. Cir. 1995).
7. Carroll Touch, Inc. v. Electro-Mechanical Sys., Inc., 15 F.3d 1573, 1576 (Fed. Cir. 1993).
8. Dolly, Inc. v. Spalding & Evenflo Cos., 16 F.3d 394, 397 (Fed. Cir. 1994).
9. Graver Tank & Mfg. Co., Inc. v. Linde Air Products Co., 339 U.S. 605, 608 (1950).
10. Seagate Tech., LLC, 497 F.3d 1360 (Fed. Cir. 2007).
11. Bristol-Myers Squibb Co. v. Royce Labs., Inc., 69 F.3d 1130 (Fed. Cir. 1995).
12. American Intellectual Property Law Association. 2011 report of the economic survey.
13. Eli Lilly and Company v. Medtronic, Inc., 496 U.S. 661, 110 S.Ct. 2683, 110 L.Ed.2d 605, 58 USLW 4838, 15 U.S.P.Q.2d 1121 (1990).
14. Kesan JP, Ball GG. How are patent cases resolved? An empirical examination of the adjudication and settlement of patent disputes. Washington University Law Review. 2006;84:237–312.
15. Lienhard JH. Inventing modern: growing up with X-rays, skyscrapers, and tailfins. New York: Oxford University Press; 2003.