

PREPARE FOR A CLASH OF IP CULTURES IN THE MEDICAL DEVICES SECTOR

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There is an epidemic raging in the industrialized world that is driving explosive growth in a multi-billion-dollar segment of the consumer electronics market. This epidemic is poor health, caused by a sedentary lifestyle, over-consumption of convenience foods, and an aging baby boomer generation. As a consequence, there is a growing demand for consumer-grade medical devices – gadgets that enable the average person to monitor their own health and manage conditions such as diabetes and hypertension.

The medical devices sector represents the convergence of healthcare technology and electronics. Many traditional medical technology companies, including pharmaceutical firms, are making big investments in the sector in hopes of capitalizing on the trend towards personal wellness and home-based self-care. Similarly, traditional semiconductor and consumer electronics giants are leveraging their technology to penetrate these markets. For example, wireless technologies first developed for WAN (cellular), LAN (wifi) and PAN (Bluetooth) purposes are rapidly appearing in personal fitness and medical devices ranging from heart rate and vital sign monitors, to blood glucose meters and wireless stethoscopes.

As these companies converge on this market opportunity, expect a “clash of cultures” when it comes to managing intellectual property (IP). The medical devices sector is fast becoming a high-volume, consumer electronics market for which technical innovation, cost control and IP management are competitive imperatives. Companies failing to employ a rigorous program to protect, manage and assert their intellectual property rights (IPR) risk costly litigation, lost revenue and weakened market share. When entering the medical devices sector they must be aware of the well-honed IP practices from the semiconductor and consumer electronics domains and prepare for the aggressive use of IP for business purposes.

Even companies well-versed in IPR and patent protection, such as drug developers and professional-grade medical instrument makers, may not be ready for the challenges of the consumer medical electronics market. The typical drug-coated stent, for example, may have dozens of patents attached to it. A sophisticated blood glucose monitor, on the other hand, can have thousands, related to its user interface, software, battery, memory, power management system, integrated circuits (ICs) and wireless or internet connectivity.

Based on an analysis of approximately 1000 patent families in each industry with a priority earlier than 2008, it is clear that pharmaceutical and semiconductor firms have taken dramatically different approaches to protecting IP. Pharmaceutical companies have focused on depth of coverage for each invention (median number of global patents per family of 8) and have filed in a median of 7 jurisdictions to protect the variations of their innovations in many countries. They have attempted to tightly lock-up their market positions and maximize product sales opportunities in an industry in which R&D investment is enormous and the pace of new product introduction is slowed by safety and regulatory concerns.

In contrast, companies in the semiconductor industry, with its frenetic innovation and new product introduction, have spread IP protection across a broader range of inventions (median number of global patents per family of only 3) but have been more selective about the countries in which they file (median of 2 jurisdictions). Their strategy has been to create patent “thickets” through which product competitors can navigate only with difficulty. With a less stringent regulatory and safety approval regimen than the pharmaceutical industry, and widespread use of semiconductor technology, the patent environment of the consumer medical devices sector will likely bear stronger resemblance to the semiconductor sector.

So how does a medical device maker effectively manage and police innovation to both protect its IP and ensure rock - solid defense against allegations of patent infringement from competitors? Using reverse engineering (RE) to inform strategy and decision-making across the IP lifecycle is an important part of the answer. RE is the systematic tear down and analysis of what lies inside a particular device to understand how it works and what IP went into its creation. This is a legal and proven method to:

- Benchmark a product against others in the market
- Identify technology trends and key innovations that could impact market dynamics
- Determine if a competitor's product is implementing patented inventions

Product teardown analysis lies at the core of the RE process. By disassembling and analyzing the device in detail to identify the materials, manufacturing processes and components used, it is possible to develop an estimated bill of materials (BOM) – an essential benchmark for product competitiveness. RE is also particularly effective for gathering evidence of prior art to invalidate assertions of infringement, as well as for underpinning assertions against a competitor that is posing a threat to market share. Using RE to generate evidence of use of patented technology is a key to successful assertion of patents and, therefore, to maximizing the return from innovation.

Rigorous management of a patent portfolio becomes all the more important as the state - of - the - art becomes more sophisticated. When it comes to MEMS and bio - electrical technology, the very materials and manufacturing processes used can be subject to patent protection. Beyond the data gathered from visual inspection of a device's components through a product teardown, advanced processes to analyze semiconductor technology must be employed for detailed cost estimation, competitive analysis, and patent infringement analysis. These technical analysis processes include semiconductor structural analysis and circuit extraction.

Structural analysis reveals construction and fabrication details as well as the elemental composition of various materials using techniques such as mass spectrometry, scanning electron microscopy and energy dispersive x-ray

spectroscopy. This depth of analysis is particularly important when dealing with devices such as MEMS with nano-scale moving parts, as well as sterile sealed packaging designed to go inside the human body. It can show if a patent is being infringed and provide the technical intelligence needed to bring a product to market that does not violate existing patents.

Circuit extraction involves taking apart a chip, layer by layer, to study its design and functionality. A complete circuit extraction yields all the information necessary to reproduce the chip. It can provide solid evidence that is admissible in court to defend or assert a claim of patent infringement.

A well targeted and executed IP program, supported by a combination of technical and patent analysis, can help a company achieve strategic goals in a highly competitive market place. It can serve as the basis for forging favorable business deals and establishing advantageous competitive positions. It can diminish a competitor's business momentum or undermine the confidence of their business partners. It can block a competing product's market entry or delay introduction by forcing product redesign. It can also impose significant cost disadvantages on the competing product by levying royalties.

Semiconductor and consumer electronics companies are particularly adept at employing IP programs for these purposes. In wireless technologies, an area most relevant to the medical devices market, heated battles have occurred between major players. RIM settled two patent suits with close to a billion dollar US settlement, and then spent hundreds of millions to acquire patents to avoid further litigation. Qualcomm and Nokia recently settled a multi-year litigation case with patent licensing and business deals. And Qualcomm and Broadcom previously settled a dispute through business agreements and a US\$890 million payment by Qualcomm. Even the darling of consumer electronics, Apple, isn't immune to the high costs of IP litigation. Nokia is suing Apple for patent infringement on 3G technologies while Apple sues HTC claiming infringement of over 20 patents. In all cases, both financial and strategic goals are achieved upon settlement.

In the fast changing consumer medical devices market, companies must seriously ponder how to use their IP assets strategically. Successful IP programs require systematic planning and preparation, with the key elements of the IP lifecycle considered. First, a competitive and technology landscape should be performed to assess strength, weakness, opportunity

and threat. Then, an IP strategy developed that is consistent with corporate business goals. Once the strategy is in place, the right patent portfolio can be built through innovation and acquisition, evaluating technical merit, market impact, evidence of use supportability and claim language.

The final critical piece of the IP lifecycle is to put the patent portfolio to work through well planned and executed IP programs. This is where many semiconductor and consumer electronics firms have historically excelled. An effective program includes selecting the appropriate patents and the right products to target while considering business goals and strategy. Performing upfront research and analysis on target products based on comprehensive knowledge of the industry, its products and technologies, pays off in results.

This article sounds a warning for companies entering the burgeoning medical devices space. In what will

inevitably become a rapidly evolving, high-volume, consumer electronics market, the stakes are high. Early players can gain substantial competitive advantage by effectively leveraging their IP. It should be expected that the IP management practices honed by semiconductor and electronics companies over the past 20 years will be aggressively applied, despite the added complexities of the regulatory environment. In addition to patent filing practices, this includes the use of product teardowns and advanced semiconductor reverse engineering techniques for competitive intelligence and IPR initiatives. Competitors, especially those whose previous experience is derived from the pharmaceutical industry, need to prepare by adopting similarly rigorous and proactive IP management policies including a structured, IP lifecycle approach that aligns with corporate goals.

ABOUT THE AUTHOR

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