

Smart Medicine: Understanding the Role of Intellectual Property in the Business of Modern Healthcare

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In a *Farewell to Arms*, Ernest Hemingway wrote, “The world breaks everyone and afterward many are strong at the broken places.” Perhaps that is the way that a Nobel Laureate says “learn from your mistakes,” or “we are strengthened by adversity.” Why wait for the world to break you in some way if you can find the broken places and fix them first—before the pain and expense of loss? In the area of intellectual property (IP), the mechanism for finding the broken places before they hurt you is the intellectual property audit, a valuable tool for any business, but especially for healthcare providers and others in the health and life science business.

Such audits are of particular value to those in the field of healthcare because the field has become increasingly information-oriented and business-driven over the last few years. For example, today virtually every hospital and most physician practices have websites. Every website raises intellectual property issues related to trademark, copyright, and privacy, and litigation concerning these issues has begun.¹ Indeed, with industry websites like *Physicians’ News Digest* promoting the notion of “branding the identity of your practice,” the necessity of physicians and other providers understanding and securing intellectual property rights is manifest. With so many different providers and others using a limited number of words that connote health and good living, the need for an analysis of a mark’s or proposed mark’s strength is clear as well. Likewise, hospitals and physicians develop treatment techniques and care management approaches that could merit intellectual property protection, but they are going to be unprotected and perhaps unprotectable if certain policies and procedures are not followed to document how they are developed, when they can be discussed, and where and how they may be written about. While the old academic saw says “publish or perish,” a patentable idea can actually be killed by publication, and those at academic medical centers should well understand that.

With so much of the healthcare industry (from providers to pharmaceutical companies to payors) involved in “strategic alliances”—[j]oint ventures, [research and development] partnerships, corporate venture capital, spin[-]offs, startups, licensing deals, and ‘out-sourcing arrangements’—in which intellectual property rights play a central role,” the need to operate one’s business appropriately depends more and more on understanding its intellectual property.² This is true even for academic medical centers and other teaching institutions, where courts have recognized that investment in intellectual capital, protecting



referral sources, and promoting an academic/teaching mission are protectable interests.³ Indeed, the industry itself has come to realize the synergistic impact that relationships with IP counsel can have for academic medical centers, noting that those in charge of such institutions must “[u]nderstand that it will be necessary for your institution to work with outside legal counsel in order to advance its mission. This means working to raise awareness within your institution—for example among scientists, of the necessity of understanding the importance of IP management and therefore the responsibility to work with patent counsel on IP and patenting issues” and that the “relationship between the technology transfer office and external counsel is synergistic, with each party contributing.”⁴

With these ideas and issues in mind, let us turn to a consideration of the intellectual property audit. An intellectual property audit is, as the name suggests, “an appraisal and valuation of the organization’s intellectual property assets and an evaluation of the organization’s policies and procedures for the creation, protection and management of these assets.”⁵ Perhaps because it is less common than a financial audit or because of the negative connotations associated with “being audited,” it is an underutilized tool for many businesses. If appropriately conducted, it is actually a process that can increase the recognized value of your business.

Why conduct such an audit? You should do so to understand what your hospital’s intellectual property assets actually are. Do you own them, or are they legally the property of an employee of yours or of some independent consultant that provided services to your business? If the former, you perform the audit to ensure that you and appropriate government entities have the right documentation on file. If the latter, you come out of the audit with an understanding of what documentation you will need to procure, and what expense and time will need to be invested in getting such documentation.

You also do such an evaluation to understand your hospital’s policies and procedures for creating and protecting its intellectual property rights in its intellectual property assets, and fix those procedures and policies where improvement and strengthening is needed. You also do such an audit so that you can understand how you are using others’ intellectual property in your hospital so that you can ensure that you do not let the right to use such property lapse and that you

do not otherwise exceed the allowed use of such property. Third-party infringement claims can be avoided by such proactive steps.

What events or circumstances suggest that an IP audit is timely? “There is no particular time when an IP audit should be undertaken. However, if the organization has never had an IP audit or an audit was accomplished in the distant past, an IP audit should be undertaken” now.⁶ If you are about to acquire a significant intellectual property asset through ownership or license, you should audit your existing portfolio. Hospitals, for instance, may have ownership interests in various inventions developed by their staff, or may have a need or desire to license patented technology for use by their medical staff. Understanding and keeping track of these matters is necessary to assess the economic benefits of such relationships. Indeed, if one looks at the example of Cincinnati Children’s Hospital Medical Center, one sees an example of a sort of ongoing and permanent intellectual property auditing process. For a long time, that institution had its own Intellectual Property and Venture Development Office to manage and control the intellectual property that it brings in through licensing arrangements, as well as the IP that it licenses out.⁷ It now has a full-fledged Center for Technology Commercialization.⁸ This means, for example, that licensing income for the fiscal year 2005 was \$1.96 million, compared with \$1.78 million for the previous year and \$1.35 million for fiscal year 2003. “This was the fifth consecutive year that licensing revenues exceeded \$1 million. In the last five years, the Cincinnati Children’s technology licensing program has brought in a total of \$8.44 million in revenue, a rate of return expected to grow in the coming years,” according to Joseph D. Fondacaro, PhD, director of Intellectual Property and Venture Development at Cincinnati Children’s Hospital.⁹ This institution not only tracks developed intellectual property already reduced to practice, but also has a formal invention disclosure process that allows it to foster continued creativity and maintain a pipeline of innovations and income. Lest one believe that such efforts can only be carried out by the largest of institutions, one should note that Cincinnati Children’s Hospital is only a 475-bed facility.¹⁰

Likewise, if you are contemplating or negotiating a merger, acquisition, financing or refinancing, or significant employee hiring, it is the right time for an IP audit; otherwise you cannot appropriately value what you will get out of the contemplated transaction. Finally, once you do your first intellectual property audit, you should develop a cycle for doing one every three to five years.

Many may wonder how involved such a process is and whether there is any need to do such an audit if your organization does not already have registered trademarks, copyrights, or patents. First of all, the process is not complicated, and can begin with a simple interview with experienced counsel and by going through some checklists. Once that step is completed, the next steps follow in short order: policy assessment, policy development, documentation, and negotiation. Second, such assessments are of particular value to those who have never registered anything—you may be failing to capture the full value of your intellectual property, and the audit helps you discover and protect that value. A well-executed audit allows a hospital to identify one’s complete intellectual property asset portfolio, and evaluate its policies and procedures for the protection and management of its intellectual

property assets. It also documents the hospital’s relevant agreements and provides recommendations for how those agreements might be amended or improved.

In the healthcare arena, it is especially important that intellectual property counsel involved in such an audit be sensitive to issues specific to healthcare organizations. For instance, when one considers what commercial marketing materials bearing a trademark will be used to demonstrate use, one must be sensitive to the fact that evidence of use in the form of pre-printed forms, explanation of benefits, insurance cards, and similar documents are likely to contain personal health information covered by HIPAA—and this information must be redacted before being submitted to the United States Patent & Trademark Office as evidence of use.¹¹ Likewise, if one is going to consider ways to minimize possible exposure to unfair competition claims in the healthcare arena, one must familiarize oneself with nursing regulations, for example.¹² Examples like this expand exponentially when one considers trademarking the name of any drug regulated by the FDA, of course. These examples are simply to show that intellectual property management takes on particular importance for those in the healthcare arena.

In closing, we return to Hemingway, who also noted that “[l]ife isn’t hard to manage when you’ve nothing to lose.” The point here, of course, is that whether your business is in the healthcare arena or not, it must be managed. Maybe we need to paraphrase Hemingway to say that “life must be managed if you have something to lose.” Your business may actually have a lot to lose and lots to gain. Even if it means a little extra work and a little extra expense, an intellectual property audit saves a great deal more in the end.

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- 1 See *Eagle Hosp. Physicians, LLC v. SRG Consulting, Inc.*, 2007 WL 789006 (N.D. Ga. 2007).
- 2 Gardner, “A Role For The Business Attorney In The Twenty-First Century: Adding Value To The Client’s Enterprise In The Knowledge Economy,” 7 *Marq. Intell. Prop. L. Rev.* 17, 48.
- 3 See *The Community Hospital Group v. More*, 183 N.J. 36, 57-58 (2005); Walsh, “If You Think More Is Less, Think Again: The Supreme Court Has Significantly Expanded The Circumstances In Which Restrictive Covenants May Be Enforced,” *New Jersey Law Journal*, April 11, 2005; Flynn, “More Or Less Enforceable: Non-Compete Provisions In Physicians’ Employment Contracts,” 2 *Bloomberg Corporate Law Journal* 303 (Summer 2007).
- 4 IP Handbook of Best Practices © 2007. MIHR and PIPRA. Retrieved from www.iphandbook.org/handbook/ch06/p09/eo/.
- 5 Rich, “Why An Organization Needs An Intellectual Property Audit,” 25 *Colorado Lawyer* 37 (1996).
- 6 Rich, *supra*.
- 7 See www.cincinnatichildrens.org/about/news/release/2005/10-technology-licensing.htm.
- 8 See www.cincinnatichildrens.org/research/ipvd/default.htm.
- 9 See www.cincinnatichildrens.org/about/news/release/2005/10-technology-licensing.htm.
- 10 See www.cincinnatichildrens.org/about/corporate/facts.htm.
- 11 See Bankendorf, Elliott and Rollo, Sherry, “Hopping the HIPAA Hurdle: Proving Trademark Use in the Healthcare Industry,” *Intellectual Property Law & Technology Journal*, October 2004.
- 12 See *Alvarado v. Selma Convalescent Hosp.*, 153 Cal. App. 4th 1292, 64 Cal. Rptr. 3d 250 (2007).