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INTELLECTUAL PROPERTY & Life Sciences

The Intellectual Property Audit: A Preventative Medicine in Health Care

The audit is a valuable tool for the health care industry

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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.” But why wait for the world to break you in some way if you can find the broken places first and fix them, before the pain and expense of loss. In the area of intellectual property, 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 health care providers and others in the health and life science business.

Such audits are of particular value to those in the field of health care, which has become increasingly information-oriented and business driven over the last few years. For example, today virtually every hospital that exists, and most physician practices, have Web sites.

Every Web site raises intellectual property issues related to trademark, copyright, privacy and litigation concerning them has begun. *See Eagle Hosp. Physicians, LLC v. SRG Consulting, Inc.*, 2007 WL 789006 (N.D.Ga. 2007).

Indeed, with industry Web sites like Physicians’ New 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. Likewise, hospitals and physicians alike develop treatment techniques and care management approaches that could merit intellectually 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.

Finally, with so much of the health care industry (from providers to pharmaceutical companies to payers) 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. 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.

So, 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.” Rich, “Why An Organization Needs An Intellectual Property Audit,” 25 Colorado Lawyer 37 (1996). Perhaps because it is less common than a financial audit or because of the negative connotations associated

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with “being audited,” it is an underutilized tool for many businesses. And appropriately conducted, it is actually a process that can increase the recognized value of your business.

So why conduct such an audit? You should do so to understand what your business’s intellectually property assets actually are. Do you actually own them, or are they legally the property of an employee of yours or of some independent consultant that had provided services to your business? If the former, you perform the audit to assure that you have on file yourself and with appropriate governmental entities the right documentation. 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 be invested in getting such documentation.

You also do such an evaluation to understand your business’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 business so that you can assure 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.

“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.” (Rich, “Why An Organization Needs An Intellectual Property Audit,” 25 Colorado Lawyer 37 (1996).)

So what other events or circumstances suggest that an IP audit is time-

ly. For instance, if you are about to acquire, through ownership or license, a significant intellectual property asset, you should audit your existing portfolio. Likewise, if you are contemplating or negotiating a merger, acquisition, financing or re-financing, or significant employee hiring, it is the right time for an IP audit otherwise you cannot appropriately value what you or what you will get out of the contemplated transaction. Finally, once you do your first intellectual property audit, you should develop a cycle for re-doing one every three-to-five years.

Many may wonder how involved such a process is, and whether there is any need to do one if they do 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 going through some checklists. Once that step is completed, the next steps follow in short order: policy assessment, policy development, documentation, 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 business 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 business’s relevant agreements and provides recommendations for how those agreements might be amended or improved.

In the health care arena, it is especially important that intellectual property counsel involved in such an audit also be sensitive to the issues that arise that may be specific to health care

clients. For instance, when one considers what marketing materials bearing a trademark will be used to demonstrate use in commerce, one must be sensitive to the fact that evidence of use in the form of preprinted forms, explanation of benefits, insurance cards, and similar documents are likely ones containing personal health information covered by HIPAA, and must be redacted before being submitted to the United States Patent & Trademark Office as evidence of use. See Bankendorf, Elliott and Rollo, Sherry, “Hopping the HIPAA Hurdle: Proving Trademark Use in the Healthcare Industry,” *Intellectual Property Law & Technology Journal*, October 2004. Likewise, if one is going to consider ways to minimize possible exposure to unfair competition claims in the health care arena, one must familiarize one’s self with, for example, nursing regulations. See *Alvarado v. Selma Convalescent Hosp.*, 153 Cal.App.4th 1292, 64 Cal.Rptr.3d 250 (2007). 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 health care arena.

So in closing, we return to Hemingway, who also noted in that book that “Life isn’t hard to manage when you’ve nothing to lose.” The point here, of course, is that, whether your business is in the health care arena or not, it must be managed. So 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 a lot to gain. But even if it means a little extra work and a little extra expense, an intellectual property audit in the end saves a great deal more. ■