Physician Inventions: When that Great Idea Strikes – Start Here.

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A ha! It is that moment when an idea strike for that next great medical device or medical application. For many physicians, the problem is not in coming up with new ideas, the confusion and difficulty comes in analyzing what to do next once an idea for an invention has hit. The process for protecting a medical invention can be a maze — not unlike the healthcare system itself — with dead ends and trap doors.

The purpose of this article is to provide physicians with a summary of pitfalls and best practices when considering a new invention.

Pitfalls and Best Practices.

1. Who owns the invention? When a physician creates an invention, a key question is "who is the owner of the invention?" If the invention was made during the course and scope of the physician's employment, the employer may be the owner of the invention. However, an employment agreement may provide otherwise. Was the invention created on the physician's own time, using the physician's own materials? If so, there may be argument that the physician exclusively owns the invention apart from his or her employer.

2. Consider establishing a new entity and separate bank account for the business of the invention. If the invention is the physician's own work, a protective early step to take is to form an entity to own the invention. Once the entity is established, an assignment should be made of the invention from the physician (and/or any other owners of the invention) to the new entity. The creation of the entity creates a layer of liability protection from the physician's assets and those of the new business (absent fraud or other wrongdoing). With a new entity created, a new bank account can be established and funds can be deposited. This bank account should be kept wholly separate from any personal account.

3. Don't engage an independent contractor without a written agreement that contains an intellectual property assignment provision. This can be an expensive error that is typically made right at the beginning of the development of a new idea. An inventor has a great idea and then hires an artist or computer programmer to work on the new idea based on an oral agreement. Then, the inventor, without an understanding of copyright law, pays the artist or programmer for the work and both sides go on their way. Unfortunately, under copyright law, absent an employer-employee relationship or a written agreement transferring ownership, the creator of copyrighted material is the owner of the work. In the example above, the artist or the programmer walked away with both payment for the work and the ownership of the copyright! Now, imagine that 10 years go by and the inventor is on the verge of a sale of the invention for a significant sum. The first item of diligence that the buyer will conduct will be on the title chain of the intellectual property. The buyer will ask — was the work created by an employee or an independent contractor? If an independent contractor developed the work, was a written agreement obtained? If not, the buyer will likely demand that the inventor go back to the artist or programmer to obtain an assignment of all associated intellectual property rights. Given that the invention is now worth a significant amount of money, the inventor will have put the artist or the programmer in the position of being able to demand a ransom in order to sign the assignment, when the artist or programmer likely would have signed an assignment without hesitation back when the work was performed.

Save yourself from significant grief and expense – whenever you have work conducted on an invention, make sure that the work is performed by an employee or that you have a written agreement transferring ownership of the work of the independent contractor to you.

4. Conduct a patent search. Many inventors assume that their invention must be the only thing like it ever conceived of in the world. Today, wholly new (otherwise referred to as "novel") inventions are generally rare — inventions usually build upon an existing platform of prior inventions. Before running out and filing a patent application, an inventor would be well-served by having a patent search conducted and the results analyzed by a patent lawyer. This initial search will provide key insight into the state of the marketplace and the differentiation that will be required in order to secure a patent. Without such a search, an application would be filed without any strategic considerations and will have a much more difficult time making its way to registration. Patent work can be expensive, but an initial search is the starting place to know whether further steps in prosecuting a patent will be worthwhile.

5. Don't use a name for the product without a formal trademark search. Similarly, a preliminary trademark clearance search is an important step in analyzing and then securing protection for a trademark. Many companies think up a new brand name or logo and immediately rush into the marketplace with the brand name or logo without an assessment of whether the new trademark infringes on others' intellectual property rights. A relatively inexpensive initial trademark search will serve to help analyze the question of whether the proposed trademark infringes or has the potential to infringe on the intellectual property rights of a third party. While any search has limitations, the search results will present the best information available as to possible competing marks. The development of a brand name, logo or trademark can cost thousands, tens of thousands, hundreds of thousand or even millions of dollars. Intellectual property litigation costs are skyrocketing and the fees associated with average cases are deep in six figures. Before making a big investment or risking litigation, a trademark search report, along with analysis of that report by a trademark attorney, represents a wise investment that can mitigate the risks of potential infringement claims in the future.

6. Use a confidentiality agreement to protect conversations with third parties about the invention. Inventors are often so excited about their invention that they have a burning desire to tell others about what they have done. This reaction is contrary to the inventor's best interest. Letting everyone know about the invention eliminates the possibility of trade secret protection and heightens the risk that someone will take the idea and try to commercialize it and protect it. Before disclosing the invention to anyone, ask them to sign a confidentiality agreement that documents your ownership of the intellectual property and confidentiality obligations.

7. Don't sell interests in your invention without considering the securities law implications. Inventors are sometimes quick to use equity like a checkbook. They pay the consultant working on the prototype "10% in return for a working model," or the newly hired sales person "5% in stock." Even more problematic can be the sales of "8% of the Company" to a cousin for $50,000. The sale of ownership is generally considered to be the sale of securities.

The basic definition of a security under federal and state law is (a) an investment, (b) made in an enterprise, (c) with the expectation of profit, (d) through passive activity of the investor. Once it is determined that what was sold is a security, the basic premise of the securities laws in the United States is that a sale of securities must be registered with the Securities and Exchange Commission, unless an exemption from registration exists. Exemptions from federal and state securities registration requirements can often be found to exist for early sales, but it important that an analysis on those issues be performed. A key exemption is found under

Regulation D under the Rules promulgated under the Securities Act of 1933, which creates a safe harbor for certain sales of securities. Penalties for violation of the securities laws can be extreme, including criminal penalties in certain instances.

From an inventor's perspective, it makes both legal and business sense to carefully consider grants of ownership in the invention or the entity that owns the invention. Owners become permanent partners that may be difficult or impossible to remove in the future. In addition, the risks associated with improper sale of securities make compliance an absolute must for a new entity.

8. Keep records of your invention. Record keeping at the early stage of an invention can be a problem. Inventors are generally more concerned about the novelty and technical aspects of their invention rather than maintaining a record of when the invention was first created. As discussed above, the date of creation of intellectual property, the date of first commercial use or the date of publication can be critical to protection of the intellectual property. Inventors should keep careful records of their inventions and when certain events occur in the life of the invention.

9. Mark the invention with appropriate notices. When an inventor rushes to get a product to the market, steps in the process can be ignored. One important step that should be observed is the marking of the product with appropriate notices. As discussed above, a copyright notice may be appropriate. It also may be necessary to mark the product with customs or other regulatory notices.

Conclusion.

Intellectual property protection for physician inventions is filled with tricks and traps. Missteps in the early stages can be expensive, if not fatal, for a new enterprise. However, by carefully managing the process of protecting intellectual property, a physician can turn a late night idea into a force to be reckoned with in the marketplace. ru

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