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INSIDE THIS ISSUE:

CURRENT & CRITICAL

Protecting Inventions and Brands: IP Due Diligence in the Product Development Process

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In the medical device market, product development is the engine that never quits. Refinements to this evolving process have sought to increase efficiencies, speed time to market and improve the quality of clinical results. One important constant remains, however: the need for focused, timely intellectual property (IP) due diligence.

Generally, the product development process with an outside inventor occurs in eight stages. Nowhere in any of these stages is there a specific IP "gate" or review stop, because some aspects of IP due diligence need to be done at every stage. That may sound a bit overwhelming, but in an application, it is not. This article recommends best practices for IP due diligence at each product development and launch stage, and names those who should be involved. This overview shows how IP due diligence and the product development process must walk hand in hand.

Stage 1: Disclosure by Physician to Company

Agreements in place between a physician and company will dictate the IP due diligence step to be taken. If the physician has signed a non-disclosure agreement, then he/she likely still retains ownership of the invention. If the physician is under a product development or consulting agreement, the company probably already owns the invention (or the physician is required to assign it to them). Of significance, if the physician is an employee of a university, he/she may be under a pre-existing obligation to assign rights to the university.

The company needs to carefully clarify ownership status when dealing with a physician -professor before *any* product development process starts. The **ownership determination** IP due diligence step should be an ongoing process, but must be looked at immediately upon invention disclosure to evaluate whether the company needs to buy or negotiate for the rights, or already owns them.

Even at this early stage, you may want to perform a **freedom to operate/clearance search** to see if third parties have issued patents that may cover the disclosed invention. Search results must be reviewed for potential patent infringement should they make, use or sell the disclosed product concept. The results also help identify possible competitors.

Stage 2: Marketing, Sales & R&D Perform Production Assessment

Marketing, sales and R&D must convene to see if the concept has viability. Marketing and sales may accomplish this through focus groups or discussions with physician consultants. R&D will likely ask patent counsel to perform a **landscape search** to identify "white spaces" in the target market and whether the disclosed product falls into a space as is or the design requires modification.

Landscape search results also benefit marketing, because they reveal competitors for the target market segment and what IP may be encountered in the future as the design evolves. Typically, in crowded segments, landscape searches are updated semi-annually to track competitive filings and possible IP encroachment.

Stage 3: Product Development Begins

Here, the disclosed idea is transformed into an inventive product by the development engineering team. They start with the napkin sketch disclosure and create CAD models for

discussions with manufacturing engineers on production viability and regulatory input. IP due diligence now involves evaluating the design to investigate whether it may be patentable. It is suggested that a **Patentability Search** be performed that will look at the novel aspects of the potential product and determine if any patents or materials in the public domain would preclude the inventor from obtaining a patent.

Patentability search results are also helpful to design engineers to see what other inventive concepts may be protected that are similar to the disclosed product. Often, product development engineers can exploit patentability search results to guide them in developing new, creative products.

Stage 4: Build the Prototype—Proof of Concept

After the CAD models are complete, a functioning prototype is produced with approval from the physician inventor, using a 3-D printer. "Reducing" the inventive concept to practice is an important milestone and should mark the start of the patent application filing process. Because patent law changed on March 16, 2013 from "first to invent" to "first to file," it is imperative that once the prototype has been produced and is taken outside the plant, IP counsel takes the step to **file a provisional patent application** to ensure you have the earliest filing date.

The provisional application should be drafted to fully describe the design and also cover any variations that the competition may contemplate. The application filing will provide protection from third parties trying to preemptively file on the device before the company does.

Stage 5: Prototype Review and Field Assessment

Design engineers will tell you that once a prototype is made, marketing folks constantly try to "borrow" it to show off to target physicians. It is critical that before the new prototype is shown to anyone, a provisional application is filed. It is also key at this point to start investigating product branding.

Marketing will likely start to brainstorm during field assessment on branding strategy and what trademarks may be used in association with the new product and instrument line. From an IP due diligence standpoint, it is prudent to initially perform **trademark knockout searches**, narrowing down the number of possible marks. Then, a **more robust trademark search** should be performed on the final pool of marks to ensure that another company or individual is not using the mark for the same class of goods or services. After determining that the chosen mark is clear, **an in-use or intent to use trademark application should be filed**. Having a cleared mark in place before product launch eliminates later costly surprises.

Stage 6: Design Refinement and Physician Recruitment

Now the design is "tweaked" to address target physician demands. Other physicians are brought in to join "the team" with the original disclosing surgeon to review and provide feedback on how the design may function. The corresponding IP due diligence step is for patent counsel to review the design and any improvements suggested by the physician team to **confirm that all new patentable ideas are captured** in the provisional applications that have been filed. Filing serial applications is an excellent tool to accomplish this.

In addition, invention ownership determination is an ongoing process; therefore, it is key that when new physician team members join and participate in early clinical evaluations, **appropriate contracts are in place** to guarantee that any and all new disclosures will be owned by the company. Failure to ensure that title to all the suggested designs changes/improvements is held by the company may lead to issues once product sales start.

Stage 7: Design Freeze and Limited Product Release

Following physician team feedback sessions and cadaver labs, the product design will be frozen to let manufacturing ramp up inventory production. Once this decision is made, IP due diligence will intensify. First, an **updated freedom to operate (FTO)/clearance search** should be performed to capture additions or improvements made since the initial FTO search. **Additional patent applications should be filed** to ensure coverage of the final implants and instruments, if necessary.

Protecting Inventions and Brands...

Decisions on **types of applications** (U.S. only or international) need to be made. Prior to filing these applications, all lingering ownership issues should be cleared and assignments filed with the patent office.

Finally, as surgical techniques are written and instructional videos produced, **copyright registration applications covering these creative works must be filed** with the U.S. Copyright Office. Remember, failure to register your copyrights will limit your legal remedies in the event that infringement or pirating occurs.

Stage 8: Launch Product

The idea has now matured into a product ready for commercialization. At this point, the IP due diligence steps that have been performed should ensure that the product is clear to sell without a risk of infringing any third-party patents.

In addition, all ownership rights in the product and improvement should be held by the company, free and clear. A comprehensive filing strategy of patent application(s) covering all products including instruments are pending in the pertinent countries in which sales or manufacturing will occur.

Finally, all trademarks that will be used in association with the products and technology have either been registered or the applications are pending in the trademark office.

The last IP due diligence step for this final stage is putting in place a consulting physician agreement and trademark monitoring system. This should ensure that any royalties due to the inventor physician(s) are paid appropriately. Monitoring should include an audit function that annually reviews amounts paid out.

Additionally, if any non-compete provisions are included in the physician consulting agreement, these should be policed to prohibit physician inventors from developing competing products. A best practice is to perform a monthly comprehensive search of the USPTO database to see if any trademarks have been filed that may infringe or dilute the company's newly registered or applied for trademarks.

IP due diligence is, and should be viewed as, an ongoing activity that works in conjunction with the product development process to capture and protect all of the design ideas of the new product and the associated goodwill created by innovative branding.

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The Hague Agreement more closely aligns U.S. design patent laws with the ex-U.S. community. It also provides flexibility when filing and can save money. *The Hague Agreement: It May Save You Money*

New regulations have converted U.S. patent law from a "first-to-invent" to a "first-inventor-to-file" system. Following best practices will ensure that your company doesn't miss out on IP. *The Race to the Patent Office Is On*