Product Development and IP Considerations: A Marriage Made in Heaven?

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Typically, R&D and the legal department don't mix well. Some folks say it's akin to oil and water, while others say it's more like oil and vinegar. These two departments interact, but only after some vigorous mixing.

Two reasons for this sometimes conflicting relationship are: 1) R&D's desire to move quickly on projects and 2) legal's perceived "say no to risk" mentality. In other words, R&D is charged with the timely design and development of new products, while legal is tasked with ensuring that the company's risk level is managed. Obviously, these two roles do not always align.

This article outlines the stages of the R&D process and the corresponding parallel issues that the legal department would want addressed either prior to or at the same time. The product development process for companies varies depending on upper management's philosophy and experience. Some companies use the Single-Gate® system developed by Robert G. Cooper in which five gates exist, with each consisting of: 1) a deliverable (visible), 2) a criteria (test and meet) and 3) an output (decision – go/kill/hold/recycle). Other companies follow a modified version of the gate system, like the seven step program I will outline in this article.

Given that the U.S. is now a first-to-file country, it is critical to file early and often when working in the fast-paced medical device space.

No. 1: Concept/Disclosure/Initial Assessment

R&D may develop an internal idea on a product, or an outside physician may disclose a product concept. R&D will examine the idea and perform an initial assessment of whether the idea fits a need and is worth further evaluation.

At this first stage, legal will want pre-disclosure, a *Non-Disclosure* or *Confidentiality Agreement* (NDA) in place with the physician. Key elements covered by the NDA include the idea or technology, the identity of the discloser, the term of the agreement, the length of time that confidentiality will last and that the company has no obligation to move forward with development of the idea. If the physician is a regular contributor or consultant to the company, legal will want to ensure that a current *Consulting and Assignment Agreement* or a *Product Development Agreement* (PDA) is in place. Key elements that should appear in both of these agreements include duty to assign all IP to the company, reasonable non-compete with a tail, a right of first refusal on new ideas, royalty payments, terms and ownership rights to all improvements.

If the idea contributor is an employee, legal will need to confirm that the employee has either a signed employment contract in place or other documents that provide that the employee has (or will) assigned all ownership rights for all IP to the company and that all work is being done on a "work for hire" basis. Additionally, a reasonable non-compete and confidentiality agreement should be executed by the employee.

If the discloser is a University, legal will definitely need to be involved before any ideas are exchanged. Universities are notoriously difficult to work with because of their historical resistance to assign ownership rights of IP to a company.

In adding to the above agreements, legal may want to perform an initial IP landscape search to see what else is out there and to help R&D identify white spaces. Further, before too much time is invested, legal will also likely want to run a patentability search to see if the idea is actually protectable. Both of these searches would increase the efficiency of R&D during the initial assessment evaluation stage.

No. 2: Research and Development

The product development process commences once the idea is greenlit for further development and evaluation. Companies will likely assign a product development engineer to lead internal efforts of taking the idea from napkin sketch to a workable model. The legal department will definitely want to make sure that an up-to-date Consulting and Assignment Agreement or PDA is in place with the physician and that it covers improvements or additional discoveries that may occur during this second stage. Such an agreement must be signed before extensive R&D efforts are put into the project, because as the project evolves, the company will lose valuable negotiating leverage with the physician.

If the design concept was generated internally, legal will want to confirm that the employee's assignment and other obligations are up to date. Also, the employment status of the idea discloser should be reviewed, because if this person has left, other legal documents must be confirmed to have been

put in place, including a confidentiality agreement and a non-compete.

As the R&D stage moves along, the engineering team should have full access to the searches run during Stage 1, as these will help guide the development process and assist with avoiding "landmines." The patentability search, in particular, may be helpful in pushing the engineers in a new and non-obvious direction with the invention development.

During this second stage, legal will likely want to file a provisional patent application. Given that the U.S. is now a first-to-file country, it is critical to file early and often when working in the fast-paced medical device space. It is also important to remember that legal will want to get a signed assignment from all of the inventors before any application is filed. Getting assignment signatures pre-filing ensures the company is not put in a disadvantageous negotiating or ownership position.

No. 3: Proof of Concept

In this stage, the product development engineer has built the prototype and shown that it works as intended. Showing proof of concept is a critical milestone in the process.

Legal will require R&D to have NDAs in place with anyone who will be shown the prototype or with whom discussions about the idea/prototype are occurring. R&D must also take great care in documenting, if necessary, suggestions or design input from third parties, because this could lead to later inventorship issues. It is strongly suggested that at this stage, the only people to whom the prototype is shown are outside individuals who have a pre-existing PDA or Consulting and Assignment Agreement.

Legal may also want to file a subsequent provisional patent application to ensure that all engineering developments have been captured and covered. Please note the importance, as discussed above, of getting assignments executed pre-filing for any subsequent provisional filings.

It is at this third stage that a Freedom to Operate (FTO) (or clearance) search should be performed. The purpose of an FTO search is to look for any in-effect patents that would block one's ability to make, use or sell the new device. This type of search is usually not performed until the design has been developed to the point where it is deemed viable but not final. This assists the company with mitigating its risk and R&D investment in the event that a third party patent is found that would prohibit further development of the product unless a license is granted. It also gives R&D engineers the opportunity to design around any blocking IP without unduly delaying the Product Development Process.

No. 4: Field Review and Assessment

This one causes legal the most headaches. Why? Because the invention is brought out from behind closed doors and shown to chosen outsiders for review and feedback. The R&D engineers must be diligent to ensure that NDAs are in place in advance of showing the device to anyone. R&D must also be incredibly careful with regard to any suggestive design changes from these target outsiders, especially if no Consulting and Assignment Agreement or PDA is in place. If a design change were to be used, this would trigger the need to obtain an assignment and possibly expose the company to royalty obligations.

Legal will need to review all filed provisional patent applications to ensure that pending applications cover the product as being shown. If the product is not fully protected, then legal must file additional provisional applications (and get assignments) to correct any deficiencies. Remember, first-to-file is now the rule.

Legal should also start to discuss with the marketing department the plan to commence the branding due diligence process, and decide whether to perform potential trademark knock-out searches on marks that may be used with the new product.

No. 5: Product Refinement

This stage is mainly an internal function, in which product development engineers take feedback received during field review and decide whether to incorporate any suggested changes or keep the invention as is. This "tweaking" step may be minor or involve a major overhaul. All of this is dependent upon feedback and marketing input received during Stage 4.

The legal department must be kept informed of any modifications to ensure adequate provisional patent coverage. The assignments for all provisional patent applications should be double-checked to confirm that the assignments for all of the filed provisional applications have been signed and recorded with the U.S. Patent and Trademark Office.

No. 6: Design Freeze and Limited Market Release

This is the actual endpoint in the product development process for R&D, as the idea has now morphed into the final product. With the design frozen, legal can now review and evaluate what physicians may be eligible for royalty payments. In addition, if the physicians were on a Consulting and Assignment Agreement or PDA with no royalty payment provision, they may need to be transitioned to a *Royalty Agreement* or a *Combination Product Development and Royalty Agreement*. Legal will need to make sure that any agreement that provides for compensation to be paid based on the sales of a product is executed in advance of the market release. From a negotiating standpoint, these types of agreements should be signed as far in advance as possible to avoid last-minute negotiations with the inventor/physicians.

Other items that the legal department must address at this last stage is a final review of all pending provisional patent applications to ensure that the final design is disclosed, as well as any possible design around embodiments. In addition, the FTO search should be updated to confirm that selling the final design will not infringe any third party in-effect U.S. patents. Discussions should take place with marketing regarding the sales and distribution plan for product in order to develop the filing strategy for *all* of the IP. This would encompass all utility and design applications both in the U.S. and internationally. Further, the filing strategy (U.S., Madrid Protocol or CTM) for any associated trademarks must also be considered.

Finally, legal must confer with the marketing department further to update the trademark knock-out searches and file all associated trademark applications.

No. 7: Commercial Launch

Although the actual final stage of the product development process for R&D is Stage 6, the full commercial market release signifies the transition of product responsibility from R&D to the marketing/sales department. Legal, though, now has many other tasks to undertake following launch.

The first one is to file all trademark applications prior to the product launch. In addition, a watch service should be considered to monitor whether any applications that include marks similar to the chosen trademark are filed, or if someone is using the chosen or similar mark. Additionally, legal will need to monitor all agreements that include a non-compete provision to ensure that all inventors are not working with other companies in violation of the agreement and that the royalties being paid are correct. Finally, if the inventors' agreements cover product improvements, the whole process may start anew with a second generation idea that is presented to R&D following the launch of the first generation product.

Alignment of the tasks performed by R&D and the legal department, including identifying the necessary agreements that must be put in place, at the various stages of the product development process will go along to building an efficient process. Having both departments understand what the other is doing and why they are doing it will facilitate a seamless and well-protected journey from the napkin sketch of an idea to the first sale of a new device.

This article was written for informational purposes only and should not be interpreted as legal advice. Please consult with a licensed attorney if you have any questions.

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