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PATENTS: PITFALLS TO AVOID

For any company hoping to sell pharmaceuticals, patents are not an afterthought—they are the primary mechanism for allowing the company to recoup its investment in drug development. Often a single patent is the only thing standing between a successful drug and generic competition. (Contrast this with the norm in high tech, where there can be hundreds or even thousands of patents covering a single device.) And that single pharma patent is the product of time and money and strategic thinking spent very early in the process, at a time when the company may not have any idea which of many compounds will be the lead, much less whether it will make it through development and clinical trials and emerge as a successful product. Even inexperienced clients generally recognize that they will need patents at some point, but many have no clue about the process or when to start thinking about it. Developing a patent strategy (and the costs associated with doing that) can't be postponed—it has to be addressed right from the beginning. In fact, my PITFALL #1 is...

PITFALL #1: Winging it, with no overall patent strategy.

--If your business is based on a platform—e.g., licensing a platform to other companies, or doing contract work or collaborations based on a proprietary platform—patenting that platform will require a lot of thinking (*read*: expensive and time consuming) about what it will be and how it will be used. Will it be patentable at all? If not, can it be kept as a trade secret? Will filing on it early in the process be shooting yourself in the foot when it turns out you want to alter the platform in ways not imagined in your patent filing?

--If your business is developing and selling pharmaceuticals, you need to plan regarding when and where to file and how broadly to claim. Lots of competing considerations. I'll mention just two: filing *too early* and filing *too late*:

PITFALL #2: Filing too early. You just made a breakthrough discovery about an important new biological pathway (such as NFkB). You want to jump in and file a patent application claiming all drugs that block activation of NFkB, even though you don't have any yet. Too soon. Those claims will be rejected as claiming things by what they *do* rather than by what they *are*. But balance that against PITFALL #3:

PITFALL #3: Filing too late. If you are going to publish your work, the timing of publishing vs. filing your patent application is critical. You need to file your patent application *before you make your invention public* if you want patent coverage in most non-US countries (including Europe), and you need to file *within a year of your own publication* in order to qualify in the US. This applies to any kind of public disclosure--not limited to journal articles.

PITFALL #4: Relying solely on broad claims. Yes, broad claims are seductive, but they are also more vulnerable to invalidation. Your litigators will curse your patent attorney later (silently, at least) if you don't also get a claim narrowly limited to the product that is on the market.

PITFALL #5: Failure to keep the patent family alive by filing continuations. Even after issuance of what you think are satisfactory claims, if those satisfactory claims go down in flames (in litigation or re-examination or Inter Partes Review), or even if you simply realize after issuance that you wish you had claimed differently, having a pending continuation available as a vehicle to obtain better claims will be a godsend. The litigators will bless your patent attorney. Speaking of blessing your patent attorney, that brings me to **PITFALL #6**:

PITFALL #6: Delaying hiring patent counsel, or hiring someone based primarily on price rather than excellence. To guide you in all this strategic thinking, not to mention doing the patent prosecution itself, you'll need someone experienced in biotech/pharma prosecution, and with an ironclad docket system. Too often young biotech/pharma companies try to get by without patent counsel, or use somebody's brother-in-law, in an effort to save cash up front. This is understandable, but dumb. I am working with a startup client who had been using a very nice patent attorney with a low-billing rate, but minimal competence. We're still dealing with the fallout of badly drafted applications that were probably cheap to get on file, but are rife with problems making them expensive to prosecute and, worse, will not give the coverage the client should have been able to get. We're also dealing with an astonishingly misguided original foreign filing strategy that cost the client hundreds of thousands of dollars in needless filing fees, but involved missed deadlines that resulted in loss of rights in some important countries. Speaking of cheap, see **PITFALL #7**:

PITFALL #7: "Saving money" by filing minimalist provisional applications. The US patent system permits filing of provisional applications that are not examined and expire after one year, but can serve as a priority place-holder if one files the "real" application within that year. There are some important advantages of utilizing this procedure, if it is done properly. But too often, clients believe they can get away with a bare-bones (i.e., cheap) provisional application, since it will never be examined. This is a very bad idea. The priority is worthless if the provisional application doesn't adequately disclose everything that is later claimed in the "real" application. Adequate disclosure includes details of what the invention is, and how to make and use it.

PITFALL #8: "Saving money" by not doing a patentability study before you file. Knowing what has already been published before you draft your application is tremendously helpful, not only for guiding the drafting and knowing what to avoid claiming, but also for the company in selecting a lead compound. A colleague tells a nightmarish story of a client who was in a rush to file on an exciting group of compounds, so told the patent attorney not to slow things down with a patentability study—just get the dang application on file. The client chose its favorite drug candidate out of the disclosed drugs, put its limited resources behind developing that candidate, and within a few years was ready to

launch clinical trials. Right about that time, the application was first examined by a patent office, which did the search for prior art that was never done by the client's attorney. You can see what is coming. The search identified a prior art publication of the favorite drug candidate, meaning that any claim that covered that compound would be unpatentable everywhere. There was no hope of getting around this problem and obtaining a patent covering that candidate. Since a patent is essential for any drug, the client had to throw out years of work and start from scratch with a new drug candidate.

There are also pitfalls that relate more to not knowing the rules. For example,

PITFALL #9: Getting inventorship right. There may be a temptation to tweak the list of inventors to include someone whose contribution does not rise to "invention"—such as the head of the lab, who contributed only grant money, or a technician who just followed instructions. Conversely, there may be a desire to omit someone who did make an inventive contribution—maybe a person who is at another institution, and there is a reluctance to share ownership. Inventorship is a legal determination that is supposed to be based solely on inventive contribution. Incorrect inventorship can sometimes be fixed later, but fixing it can be a huge problem if the inventors are not in agreement. And if you fail to include a true inventor and that inventor ends up assigning her rights to an infringer, you won't be able to assert the patent against the infringer.

My last two pitfalls relate to how the claims are worded:

PITFALL #10: Obtaining claims for which it will be impossible to prove infringement. Such claims will be worthless, since they can't be enforced against an infringer. Examples of such a situation include

-- methods that an infringer will carry out in secret, such as a screening assay

-- claims that describe a compound or method in terms of a complicated in vivo effect (such as molecular interactions that will happen inside a cell in the body, and can't be measured)

-- claims that require the absolute absence of some effect (e.g., "kills cancer cells but has no toxic effects on any other cell type")

PITFALL #11: Poor wording can be deadly, so read the claims carefully. An incorrect preposition in one of the steps of a claim meant the claim covered a method no one would ever infringe:

"...heating the resulting batter-coated dough **to** a temperature in the range of about 400°F to 850°F..."

The patentee argued in litigation that this clearly meant heating "at" the temperature, since the dough would be incinerated if actually heated **to** 400°F. The court said too bad—this is what the claim says.

I'm dealing with a case now in which a competitor's claim requires treatment with a particular class of compounds, but then goes on to say "**of formula I or II**". The problem is that formula I does not encompass the specified class of compounds, so the claim is nonsensical. Someone was asleep at the wheel, and the claim is probably invalid.