through proof of concept, then sell or license the idea along with the patent filing and initial engineering work. Not only will valuation depend on the relative strength of the idea as compared to existing competitor technologies and patents but there are many unknowns at this point – what is the right design, can it be manufactured, how will it compare to existing (predicate or analogous) technology, what is the path through the FDA (510k or PMA), how will reimbursement be achieved? These unknowns will reduce valuation of even the best idea.

Filing a patent application at this stage is essential because that may be the only thing to sell. But securing actual patent protection and confirming the freedom to practice (that the product won't infringe other patents) will not likely be possible since the product design is not finalized. This brings the added risk that the patent application may not even cover the right thing – only further development will identify whether all the crucial concepts are identified in the patent application. The surgeon inventor should expect that any initial investment can be lost simply because it is too early, unless she has the wherewithal to take the project further if an early deal cannot be struck. Testing the inventor's openness to making deeper financial commitments beyond the patent filing will help drive the decision as to the go or no-go with the patent application filing.

Considerations for Late(er) Exit

At the other extreme, the surgeon inventor may be inclined to fund a development project from the point of initial patent filing through engineering, design, testing, validation and FDA clearance and into manufacturing and distribution. Whether the surgeon inventor goes all the way to market or seeks to exit somewhere along the way, the upside to this later exit is the opportunity for much higher valuation because the opportunity has been derisked – the buyer is getting a lot more certainty. Of course, the downside is that the surgeon must commit much more cash and time with no guarantee of commercial success.

While IP is by no means the only, or even the most important, factor for success along this longer path, the competitive strength of the product will be directly influenced by the robustness of the IP protection and by a concrete knowledge of freedom to practice. Attractiveness to an investor or acquirer will necessitate that the IP position is clearly understood and the protection strategy is well-developed. Thus, the surgeon inventor will also need to consider investing in a broader suite of IP services to augment the investment in the development project.

Alignment of Expectations

Whatever exit plan the surgeon inventor contemplates, understanding the steps to commercialization and considering the risks specific to the opportunity can help influence how to proceed, and when to stop. I encourage the surgeon inventor to engage within a network of professionals – each with their own business and unique training – who understand design and engineering, testing, regulatory processes (FDA), manufacturing and reimbursement, among others. Even if the surgeon inventor's plan is to exit early. Brief consultations with these experts can yield huge returns, which is why my practice includes maintaining a robust network of medical device experts among whom there is a shared philosophy to establish meaningful and realistic expectations. These conversations will reinforce the most important fundamental of medical device development: Even with the most clever invention and best plan, there are no guarantees that a product will be made, or that it will make any money. In knowing the path, a surgeon inventor will be able to rationally gauge whether it even makes sense to file a patent application on an idea, much less commit what will be tens of thousands of dollars to *start* the design process.

If I have done a good job in these early conversations, the surgeon inventor's point of view on patent filing will have changed a good deal, and she will know that the approach to patent filing is anything but static. By considering the path to market, the surgeon inventor will realize that the process is iterative, and her design *will* change over time. And a patent, no matter how strong, is only part of the equation for getting a medical device product to market. A few will thank me and walk away, deciding that the idea, no matter how good, is not the right investment for them at that time. Many more will say, "Thank you. Let's do this!" In those instances, we proceed with filing the first patent application, prepared to shift and adapt to balance risks with the potential for success.

INFORMATION GOVERNANCE INSIGHTS

By David White

Data with a Difference

Today's headlines are filled with the news, stories and predictions of the power and value of big data analytics. Most companies are scrambling to develop new ways to monetize their information assets. Yet often, big data seems to be falling off the radar when it comes to legal and risk compliance. As big data becomes operational, it needs the same governance disciplines that we apply to traditional data management. Unless compliance managers fully understand what makes big data different from traditional business analytics, and how these differences impact the way we approach big data governance, they will not be able to successfully govern them. This understanding can also help inform us as to how we can make big data platforms work to our advantage to reduce overall risk.

Contrary to common misunderstanding, big data does not simply refer to bigger database systems nor to business analytics efforts that leverage larger data sets. Big data projects often share these same attributes, but they neither define big data nor distinguish it from traditional relational databases. Beyond the technology itself, the primary distinction that sets big data apart is the way that information is ingested into and stored by the platforms. Traditional databases are highly structured systems based on interrelated tables of predefined fields. To work, data must first be made to conform to this known structure

Big data requires that we appreciate what differentiates it from traditional data analytics.

and be shoehorned into it using a process called extract, transform and load (ETL). Having been initially built as a solution for searching the Internet, big data platforms do away with this necessity. Instead, they are able to ingest massive amounts of raw data, much of which has no preexisting need or use, in just about any format it comes in. Structure isn't applied until the analysis phase, which changes the approach to extract, load and transform (ELT).

This single distinction of loading data before transforming it has massive consequences for information governance and privacy compliance. ETL allows you to work within a predefined environment where the tables and fields holding sensitive or regulated data, such as PII, are known and easily located. This lets you wrap proper controls around them. With massive amounts of raw data being ingested through ELT, often from real-time data feeds and a variety of internal and external sources, the content of the data remains unknown until analysis is conducted, and then only within the scope of that analysis. This results in large data pools with little understanding of what is in them or what compliance obligations attach. The distinction also leads to a wide array of predictions and conclusions that were previously impossible, and that are based on new and often unknown sources of information. This very point is what prompted the Federal Trade Commission to issue guidance last month on what uses of big data could run afoul of consumer protection laws.

Big data does not need to be a big headache. It just requires that we appreciate what differentiates it from traditional data analytics, and how these distinctions impact our compliance programs. It also requires counsel to get involved during the early program design phases and build privacy and compliance in from the start. Successful work with big data begins with having a clear understanding of the data being ingested and ensuring that the analytics layer includes a compliance component for masking, anonymizing and otherwise securing sensitive data as it comes into the company. The saving grace is that big data is inherently suited to do just that. It just needs the right stakeholders involved to ensure that it is done right.

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