Building an effective drug franchise: a transatlantic perspective

Wolf Greenfield attorneys C. Hunter Baker and Daniel Young explain how to build an effective patent portfolio in the pharma and drug industry

Ben Wodecki reports

What approaches should patentees take to create a robust patent portfolio in this industry?

C. Hunter Baker: The most important thing for any company is to have a good line of communication between their scientific development team and their legal department. Anytime inventors or scientists at a company have challenges—particularly anything unique or unexpected—the company should see that as a potential opportunity to protect IP, for example by filing a patent application. It's all about developing IP to extend patent exclusivity.

Daniel Young: Companies and research institutions seeking to protect inventions must have a proactive mindset concerning their goals, particularly with respect to commercial interests. They must then devise a plan for how to achieve the best exclusivity package for a particular product.

This links back to the need to have good communication within a company, regardless of the size of its employee base. Even in small companies, it can be a challenge to have constant close communication between IP attorneys and research and development teams. To have an effective lifecycle management scheme, those pieces need to be in place, including development goals. Companies must ensure that all these functions work together to create the right IP strategy.

What advice would you give to those looking to protect their pharmaceutical patents?

Baker: Having regular meetings with research and development teams is absolutely critical. It is also important to align your patent strategy and portfolio, not only in terms of what you file and when, but also aligning your regulatory strategy with your patent strategy so that you are getting the benefit of both exclusivities.

Young: The people involved in making decisions around IP must stay informed about the innovations that can be protected and can bring value. It's important to understand the type of filings that can bring value to a portfolio, whether directed to platform technology or a number of different products and market areas—all of which contribute to broadening the exclusivity package around a product. Overall you must stay abreast of what is relevant, interact closely with outside counsel, examine different types of strategies and approaches, and implement the best solution for your company.

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Baker: The typical steps that people think of in terms of developing a patent portfolio for a drug product are the compound, a new subgen or species, salt formulations, methods of use, synthesising intermediates, metabolites, and directing its use in a certain patient population. Those are certainly things that any company will typically consider before producing a product on a large scale. There is also opportunity that falls outside of those areas, as well as difficulties in the development of a drug, such as the quality control of a biologic or small molecule. Companies should keep their eyes and ears open, talk to scientists, and ensure they capture all of those challenges, because they may be patentable discoveries.

What issues are arising in this industry that could affect patent portfolios?

Young: Section 101 issues are a big deal right now. Section 101 is the statutory scheme that governs what kind of subject matter is eligible for patent protection. This is really an evolving area, heavily driven by case law. An important area impacted by this is diagnostics, which plays into the personalised precision of combining a drug with a particular method of identifying a patient population. In the current framework, it can be a challenge to get claims that tie those two things together. But it's an evolving framework, and there are efforts to develop and improve new statutory programmes to address some of these things. That's a hot area right now, and patentees must really be on their toes in terms of understanding what is realistic today regarding the attainment of protection, or understanding the scope of an issued patent. They must also have a sense of where things are headed, to ensure that, when looking at new innovations, they think about how things are likely to progress. Taking that into account when filing will help companies understand validity, so if things change along the line, they will be able to adapt.

> ***People should consider filing on inventions that may not be patentable under the current law, because that law may change in the next six months***

Baker: The one thing that always comes up in patenting and diligence is filing technicalities. Whenever you are developing a patent portfolio, as you make serial filings based on the same drug, you must be aware of what you have already put in your prior applications. Therefore, you do not want the initial application to be too broad; you may want a narrower or more limited initial filing so as not to create prior art for yourself later on. The same thing goes for molecules; when you're patenting the initial small molecules and describing the initial genus. You may not want to have a lot of detail covering lots of subgen; you want to leave that open so you can go back and file a later application on a more specific subgen. You don't want to get caught up in your own prior art.

To what extent is section 101 reform "driving the US patent system into uncharted territory"? How badly could it affect this specific industry?

Young: I wouldn't use the word 'badly', although it will definitely affect this industry. We will just have to deal with it; it may shift the relative value of different filings. Staying abreast of that law is crucial. As Hunter alluded to, there will be innovations along the development of the product. It's a matter of ensuring you are capturing the right ones within the realities of the law today. I personally don't believe it will have negative effects, but the biggest challenge will be the uncertainty, which could potentially make it difficult for companies and practitioners to appropriately manage decision-making around what and how to file in an efficient manner. The unpredictability is something people want to eliminate or reduce, which is one of the drivers for efforts to deal with this at a statute level.

Baker: It's a rapidly changing area of the law. Hopefully, things are becoming a little clearer as time goes on and we get more cases from the Federal Circuit. However, there is definitely some uncertainty, which means that people should consider filing on inventions that may not be patentable under the current law, because that law may change in the next six months.

What issues are you seeing as practitioners in this sector?

Young: The rapid evolution of technology. Significant developments have happened in the last decade.

Practitioners should stay abreast of this to understand how innovation fits into the broader marketplace, and what kinds of innovation are coming down the pipeline. From a practical perspective, you need people who have technical knowledge. It's a very dynamic area.

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