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Patents

The author explores how implementation of the new first-inventor-to-file regime changes the playing field for life sciences patent applicants and their counsel.

Life Sciences and First-to-File: Predictable Problems

By David P. Halstead

Introduction

For most life sciences companies, first-to-file has a familiar feel. Because new medical treatments typically are marketed on a worldwide scale, life sciences companies have long sought patent protection on a global scale. First-to-file is the metric system of patents: Outside the United States, first-to-file is the standard of patent law. Life sciences companies are familiar with the race to the patent office and the need to carefully vet publications to avoid disclosure of unfiled inventions.

But the new U.S. first-to-file system is not quite in line with the rest of the world, as if the United States switched to liters and meters but not grams. One of the ways the U.S. system sets itself apart is in retaining grace periods for inventor disclosures. Although much more limited in scope under the first-to-file system, these grace periods have no counterpart in Europe, whose importance is probably second only to the United States for most life sciences companies. Grace periods exist in Japan and Israel, but are notoriously difficult to utilize. Even with the new, more limited grace periods, U.S. patent law still is more forgiving than much of the rest of the world.

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Subtle Pitfalls in U.S. System

In contrast, the new U.S. system presents subtle pitfalls when it comes to assessing obviousness. The first-to-file system streamlines the complex and intricate system of prior art that existed under the first-to-invent system. Now, information either is prior art or it is not; everything relevant to novelty is relevant to obviousness. Outside the United States, though, earlier-filed but not-yet-published patent filings are prior art for the purpose of assessing novelty but not obviousness. This approach limits the impact of the 18 months' worth of unpublished prior patent filings that each application faces. Even minor differences between the claims and this prior art will support patentability. In Europe, applicants can excise the prior art disclosure from their claims using provisos, even if the proviso is not supported by the specification of the application as filed.

Not so in the new U.S. system. Because these unpublished prior patent filings are relevant to obviousness as well, a proviso limited to the precise disclosure of the prior art does not address the full prior art effect of these documents. Moreover, under U.S. law, any proviso must be supported by the application as filed. Since by definition this prior art was unpublished at the time the application was filed, applicants will have had no opportunity to consider and address these documents

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when drafting their applications. As a result, prior art that leaves pockmarks in European claims will leave craters in U.S. claims.

Impacts on Life Sciences Companies

This difference will impact life sciences companies in different ways. When it comes to biologic inventions, there often is a close relationship between the human biological entity or target and the commercial therapeutic. Early filings in this area often are based on either animal homologs or the same human entity/target. While a proviso that excludes only an animal homolog likely would leave all coverage commercially relevant to human medicine intact, this proviso would not exclude what is made obvious by our current understanding of most biological pathways. Preserving commercially relevant coverage while addressing the novelty and obviousness impact of a prior art document will be difficult if not impossible in this situation. Being first to file is critical.

In small molecule technologies, the chemical scope of the claim typically is defined in a core Markush structure with several individually defined substituents. Prior art in this area commonly takes the form of a few compounds that fall within the Markush structure. A proviso that excludes only these compounds may have little effect on the overall scope of the claim. But each of these compounds arguably suggests a plethora of other similar compounds, ranging from minor structural variants to analogs with substituents borrowed from other related disclosures. Fighting an obviousness rejection can be an uphill battle; amending the claims can require ceding large swaths of claim scope. While a company may have the flexibility to pursue a lead protected by the reduced scope of the claim, the loss of broad-based coverage for the related chemical space can leave the door open to unwanted competition.

This application of unpublished prior art to obviousness in the United States is not new to the first-to-file system. What is new is the inability to disqualify these references based on a prior date of invention. This change is a particularly strong blow to the life sciences.

Long Development Time, Unpredictability

Life sciences inventions often have rather long development timelines. In addition, life sciences inventions are considered ''unpredictable'' under the law, meaning that obtaining broad claims typically requires making and testing many different molecules for the desired biological effect. Amassing enough data to support a good patent application—to say nothing of drafting the application—can easily take several months. Accordingly, under the first-to-invent system, a large fraction of the unpublished prior art for any given life sciences invention often could be disqualified by providing evidence generated during development of the invention. By comparison, more ''predictable'' physical and electronic inventions typically have shorter development timelines; fewer data are needed to support broad claims and demonstrate the operability of the invention, so an application can be filed much closer to the time of invention. This discrepancy means that the loss of the grace period hits life sciences inventions harder than other technologies.

The long development timeline of life sciences inventions exacerbates other challenges of the first-to-file system, too. Development typically continues long past that initial provisional filing date, with more therapeutic candidates being prepared and tested to select the best one for human therapy. The importance of backing up an invention with data in the ''unpredictable'' life sciences often means that these newer data typically are added to a subsequent non-provisional application to supplement the data included in the provisional application. But claims of the non-provisional application are entitled to the provisional filing date only when they are described and enabled in the provisional application.

Claims to biologic inventions typically expand out from a core structure based on hybridization or percent identity to that core structure. The amount of expansion is limited by the variety of examples demonstrated to preserve the desired functionality. A provisional application with fewer examples may not support the broader claims of a later non-provisional application with more examples. In this case, the broader claims will face up to a year's worth of additional prior art: documents filed or published after the provisional filing and before the non-provisional.

When it comes to chemistry, the situation is trickier still. Additional compounds tested after a provisional filing may not fall within the original Markush structure set out in the provisional, necessitating extending the definitions of one or more substituents, or even expanding the core structure. The ability to rely on the provisional filing date is in serious jeopardy when this occurs. For this reason, expanding a provisional chemistry application becomes an extremely complicated exercise. The contents of the provisional application must be retained in an unadulterated form that gets the benefit of the provisional filing date, and any newly added material should be presented in a way that supports claims that exclude the contents of the provisional to fend off any prior art that arises between the provisional and non-provisional filing dates.

Foreign jurisdictions also closely scrutinize the contents of provisional applications to assess the proper priority date for a given claim. This scrutiny is not entirely new to the United States either, but assessments in jurisdictions like Europe and Japan historically have been far less forgiving. It remains to be seen whether the U.S. Patent and Trademark Office will heighten the scrutiny it applies under the first-to-file system. However, under any standard, the loss of a priority date empowers additional documents to serve as prior art against an application. As described above, these documents can be used for both novelty and obviousness rejections under the first-to-file system, with no opportunity to disqualify them based on an earlier date of invention. And the loss of a priority date carries an additional and irreversible consequence for transitional applications.

Consequences for Transitional Applications

Transitional applications are those applications filed under the first-to-file system but that claim priority to a first-to-invent application. So long as a transitional application claims only subject matter supported in the first-to-invent application, it too is treated as a first-to-invent application. But the moment a claim is presented

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that is *not* supported in that first-to-invent priority application, the transitional application becomes a first-to-file application—the entire application, not just the claim that lacks support in the priority application. Once a transitional application becomes a first-to-file application, it can never regain its first-to-invent status. This is the additional stake that rides on the priority claim of a transitional application.

First-to-invent status means that the resulting patent cannot be challenged in a post-grant review. It means that applicants can utilize the familiar process of disqualifying prior art based on an earlier date of invention. It means that certain foreign prior art simply is not prior art at all. For many applications, first-to-invent status simply means access to broader claims than would be available under the first-to-file system.

And so applicants who filed their applications over the last year in hopes of reaping the benefits of the first-to-invent system face a difficult decision a year later: Keep the application as-is, forgoing the additional support or scope new data might provide, or update the application and put the priority date—and the first-to-invent status—at risk. Some situations might call for both: paired applications, one updated and one untouched. More expensive to be sure, but, in some circumstances, worth it.

The tightrope walk continues for the life of the application. Every claim that is ever presented in the application must find its support in the first-to-invent priority application. Support in this context means both written description and enablement—the two criteria where the closest scrutiny is reserved for ''unpredictable'' life sciences inventions. Simply put, transitional applications for life sciences inventions will need to be treated with the utmost care at every turn to emerge as a first-to-invent patent that can withstand the pressures of litigation.

Conclusion

Patent reform applies equally to all technologies, but some of the changes present particular challenges to life sciences companies. The way life science inventions are developed and claimed makes devastating hazards of unpublished prior art, and the suspicion with which courts view broad claims in the ''unpredictable'' life sciences technologies complicates prosecution of transitional applications. Despite apparent harmonization with the prevailing worldwide standard of first-to-file, the peculiarities of the U.S. system will require some time for attorneys to adjust and for the courts to fully interpret. For now, life sciences companies can only proceed cautiously and prepare for surprises. Much of the seeming familiarity of this new first-to-file system is a mirage.