First to File in the Unpredictable Arts: Change in Law Requires Balancing of Competing Interests

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Currently pending before Congress is the "America Invents Act." Although patent reform has been proposed several times in the past decade, this year its imminent passage is widely expected. Among the bill's dramatic changes is a switch from our patent system's current first-to-invent regime (a feature unique to American patent law) to a first-to-file system. This hotly-contested change aligns the United States with the way the rest of the world determines priority for patent rights among competing applications filed by different inventors for the same invention.

Instead of maintaining the arcane "interference" procedure to analyze priority by determining which party invented first, the change awards priority to the entity that first gets their application filed with the patent office. In competitive technology fields this move puts additional pressure on companies to quickly make critical patent strategy decisions about how to protect newly-conceived inventions. Among the most important are decisions about how best to balance the need for winning the race to the patent office with completing the work required in a patent specification.

Patent specifications must include a detailed description of the claimed invention according to the requirements of 35 U.S.C. Section 112, which states that the patent specification "shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art…to make and use the same." The written description requirement is satisfied if a person of ordinary skill in the field can determine that the inventor was "in possession" of the claimed invention. The showing required to satisfying this "possession" test varies among fields according to their degree of unpredictability.

In the "predictable" arts, such as software and mechanical sciences, the bar is relatively low. For example, for software patents, simple flow charts can provide sufficient disclosure in the absence of any source code to enable a software developer to practice the invention and to show that the inventor was in possession of the invention. Biotechnology, chemistry, and life sciences, on the other hand, are treated as "unpredictable" arts, as scientists are often unable to precisely predict how simple changes in temperature, pressure, and pH can affect biological processes. Thus, patents in unpredictable arts are routinely subject to stricter scrutiny under the written description requirement. This requirement can be satisfied by one or more examples providing detailed experimental results showing possession of a working invention. It can also be satisfied via a biological deposit of the invention. Functional descriptions alone, however, are often inadequate.

And of course, one cannot describe what has not yet been conceived. "In some unpredictable areas of chemistry and biology, there is no conception until the invention has been reduced to practice." *MacMillan v. Moffett*, 432 F.2d 1237 (CCPA 1970). In addition, if the experimental results reveal factual uncertainty with respect to the functional descriptions, then this data "so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice." *Burroughs Wellcome Co. v. Barr Labs. Inc.*, 40 F.3d 1223 (Fed. Cir. 1994). These decisions provide the basis for the doctrine of "simultaneous conception and reduction to practice" in unpredictable arts, where an inventor is unable to establish a conception until he has reduced the invention to practice through successful experimentation. *The Regents of the University of California v. Synbiotics Co.*, 849 F.Supp. 740 (S.D.Cal., 1994).

Filing a provisional application with prophetic examples of the invention is one way to meet this requirement and to obtain the earliest filing date. Upon collecting experimental data, a utility application can be filed sometime during the next 12-month period that claims priority to the earlier-filed provisional application. In this situation, the applicant would assert that the experimental data merely confirms what was described in the prophetic examples, indicating that the inventor had possession of the invention at the time of the provisional application filing.

However, the time required to perform additional work to develop the invention to the point where such confirmatory data are obtained can sometimes take more than a year. In such case, conversion to a utility application could be risky because the absence of experimental data could lead an examiner to reject the claims for inadequate written description or expose issued claims to similarly-based validity challenges. Under these circumstances, the better course could be to allow the provisional application to go abandoned, and re-set the one year clock by re-filing a second provisional instead of a utility application. The price paid for this approach is loss of the first priority date and its substitution with another, one year later.

Under the current first-to-invent patent system, losing the benefit of a provisional application date to ensure that the application is optimally enabled before filing a utility application with the U.S. Patent and Trademark Office is less risky. Published prior art that may bar patentability can be monitored to assess the level of pressure to convert a provisional application to a utility application. Meanwhile, any unpublished applications to the same or a similar invention could be overcome with a showing of prior conception and diligent reduction to practice (*i.e.*, first-to-invent). In contrast, under a first-to-file patent system, an unpublished application directed to the same or a similar invention could become an absolute bar to patentability, a possibility that increases the pressure to obtain the earliest filing date possible. Complicating matters, the heightened level of uncertainty and pressure to file early must still be balanced with a careful approach to ensure adequate written description support in the utility application.

A "rolling provisional" strategy provides an approach for maintaining optimal balance between these competing needs. Following this strategy, an applicant files a number of provisional applications within one year of the first-filed provisional. Each subsequent provisional application includes additional data that increases the likelihood that the application provides adequate written description support for the invention. This could be a costly and time consuming process, but may be worthwhile for selected inventions, as it will provide several balance points between written description support and filing date which can be relied upon. The utility application must still be filed within one year of the first-filed provisional to maintain a proper priority claim.

On the other hand, merely re-filing a provisional application every couple of months is a cheap strategy and one that will at least take the pressure off of a specific conversion date. Under this strategy, an earlier-filed provisional must be explicitly abandoned before the next one is filed so that the one-year conversion deadline for filing the utility application is extended without jeopardizing the priority claim to the subsequent provisional application filing date. Pushing the conversion date can be a sensible option when confirmatory data cannot be obtained within one year of first-filed provisional. This strategy allows an inventor to hedge between loss of a few months priority, and improving the quality of written description through incorporation of confirmatory data.

The proposed and likely-to-pass patent reform bill will present some intriguing twists to the careful balance between competing validity requirements in strategic patent prosecution. It will be interesting to see how the balance between a first-to-file requirement with a very clear and unambiguous date cutoff balances against the competing, yet sometimes vague, written description requirement under 35 U.S.C. Section 112 for patent prosecution in unpredictable arts such as biotechnology and life sciences. As U.S. practice conforms with the rest of the world's first-to-file system, strategies that balance the competing interests of securing an early filing date and satisfying the written description requirement should be carefully considered in securing patent protection for inventions involving unpredictable arts.

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