

## Why Provisionals Need Claims

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### Abstract

Obtaining patent protection for a university invention can be a costly and time-intensive proposition, so many universities file provisional patent applications. But provisionals should not be considered “quickie” patent applications as the resulting application probably will neither satisfy potential licensing partners nor provide a sufficient platform on which to build a patent portfolio. Regardless of whether the US Patent and Trademark Office *can or will* accept a provisional application as a valid filing, even without any claims or sequence listings, there are still other patentability requirements, namely the written description requirement and the enablement requirement, that must be met for a regular patent application, filed at around the one-year date, to claim priority to the provisional filing date.

### Introduction

Most veterans of technology transfer are fairly well-acquainted with the benefits of using provisional applications. The filing fee is much less, you defer examination by a year, and there is less paperwork since declarations and assignments don't have to be filed. Some even know that it's a good idea for non-US companies and universities to file a US provisional because foreign references are only effective as of their US filing date under 102(e), and this is a great way to stay ahead of the competition. However, there is a worrisome line of thinking that provisionals can also be “quickie” patent applications, where all you do is slap a cover sheet on a professor's draft manuscript, and voilà, you have a filing date.

But what about including claims? sequence listings? deposits of microorganisms?

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Unfortunately, the answers to the above questions are (1) definitely, yes!; (2) probably a good idea; and (3) ditto—a good idea. This is unfortunate because it puts all of those quickie applications on the risk-management track instead of the licensing track.

If you're short on time, but still want to know the reason why provisional applications should include claims and, in the case of biotechnology applications, sequences, here it is: Regardless of whether the US Patent and Trademark Office *can or will* accept a provisional application as a valid filing, even without any claims or sequence listings, there are still other patentability requirements, namely the written description requirement and the enablement requirement, that must be met for a regular patent application, filed at around the one-year date, to claim priority to the provisional filing date. And, without the earlier date, any publication of the invention can be a bar to patentability.

### **Claiming Priority**

Claiming priority is governed by 35 USC 119(e), which allows a provisional and subsequent application for examination to link to one another such that the regular patent application can adopt the earlier filing date of the provisional. In other words, applicants who file a provisional can maintain their original filing date when they resubmit the application to enter the examination process. Without a claim to the earlier date, patent rights would be jeopardized by papers and abstracts being published, posters being presented, or third-party patents being granted.

There are only four requirements to be able to claim this earlier date: (i) there must be at least one common inventor between the two applications, (ii) there must be some common inventive disclosure in the two applications, (iii) the two applications must overlap in time, i.e., be copending, and (iv) the applicant or his or her attorney must amend the regular application to reference the earlier one. It helps to remember these requirements by thinking of them as The Four Cs: common inventor, common invention, copendency, and contains reference to the earlier filing.

### **Provisional Requirements**

Provisional patent applications are governed by another law, 35 USC 111(b). This is in contrast to section 111(a), which governs regular patent

applications, also known as examination patent applications.

Section 111(b)(1) requires that a provisional application *shall* include (1) *a specification as prescribed by the first paragraph of section 112* (emphasis added) of the patent laws and (2) drawings as necessary. Section 111(b)(2) also specifically says that a claim shall not be required in a provisional application. Thus, it is optional, right? Maybe, I don't recommend taking the bait.

### **Enablement and Written Description**

All patent applications—provisional and regular—must comply with the enablement and written description requirements, namely the first paragraph of section 112 of the patent laws.

Enablement, in short, is a term of art used to describe when a patent specification contains “full, clear, concise, and exact” enough directions that any person skilled in the art to which it pertains can make and use the invention. I like to think of it as a box of parts with the step-by-step instructions for connecting each part to the next along with a description of how to use the final product.

The written description requirement of the first paragraph of section 112 is more of a comparison of the final product to how the patent claims are worded. The patent laws, regulations, and court decisions have had an awful lot to say about this requirement, but suffice it to say that the test has been one of possession and completion. If an applicant has actually made a working prototype and has described in words, structures, figures, diagrams, or formulas how a person of skill will know that the invention, as claimed, was put together correctly, the requirement is satisfied. In other words, written description concerns the distinguishing and identifying characteristics of the final product, or as I think of it, how do you know that you have built what is claimed?

But how can a provisional without claims lead to an invalid patent and what does the written description requirement have to do with anything?

The short answer is that there is an inconsistency between the US Patent and Trademark Office (USPTO) “allowing” applicants to file without claims or sequences and the priority requirements that have an underlying requirement to have claims to satisfy the written description and sequences to satisfy enablement.

### **The USPTO Position**

To support this proposition, I offer the USPTO's own rules on this matter. The USPTO publishes rules concerning patentability and patent examination procedures in a volume called the *Manual of Patent Examination Procedure* (MPEP). The MPEP is the USPTO's official publication on the patent laws and rules and also is its opinion on various unsettled points of law. It is, to the USPTO's credit, a fairly accurate description of "the law" subject to a few exceptions.

The MPEP has twenty-seven chapters, seven appendices, and is regularly updated to reflect changes in case law. In particular, MPEP 608.01(k) discusses when a patent application is complete (or incomplete) and states that "the claims define the invention." Taken the other way around, without claims, an invention is undefined. But here's the rub—if a provisional has no claims and the invention is, therefore, "undefined," then how can the same application also be said to be "fully, clearly, concisely, and exactly" described as required under section 112, first paragraph? The answer is that it probably can't. It's like a box of parts with no drawing of what it should look like once the parts are connected. Therefore, the application wouldn't satisfy the first paragraph of section 112 and, further, would not be entitled to support a claim of priority for a regular application that was relying on it for a filing date approximately one year earlier. Oops. Companies' fortunes and entire patent portfolios have been lost by being one day short in the race to get a patent application on file. Imagine what picking up your filing date flag and moving it forward an entire year along the timeline can do to patent rights?

### **Facts of Life: Raising the Bar**

In this regard, one fact of life in the patent/research world is that you're never alone: there are a lot of very intelligent people trying to find solutions to the same problem at the same time. Given that it is a near certainty that there are other inventors working in the same field, there will probably be one or more publications that come out during that one-year provisional period, maybe even your own publications, that can be expected to act as a publication bar once your filing date moves forward one year.

Another section of the MPEP, MPEP 2163.03, states it even more forcefully and recites several famous federal cases to the effect that "to satisfy the

written description requirement, a patent specification must describe the *claimed* invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the *claimed* invention.” Further, “compliance with the written description requirement is essentially a fact-based inquiry that will necessarily vary depending on the nature of the invention *claimed*” (emphasis added).

Now, you might be asking yourself, why would the USPTO mislead applicants and allow them to file provisionals without claims? Good question. The following case is illustrative.

#### **Written Description and Provisionals: New Railhead Manufacturing**

New Railhead Manufacturing LLC owns US Patent Nos. 5,899,283 and 5,950,743, drawn to a drill bit for horizontal directional drilling of rock formations and a method for horizontal directional drilling. New Railhead sued Vermeer Manufacturing Co. and Earth Tool Co. for infringement in the US District Court for the Northern District of Texas because VerMeer and Earth Tool were manufacturing and distributing a competing drill bit. However, both patents were invalidated at trial. New Railhead appealed to the Federal Circuit Court of Appeals and, in a decision in July 2002, lost when the appeals court affirmed that the lack of priority invalidated the patents.

Why were the patents invalidated? Because the patents lost their claim to priority by failing to satisfy written description in the underlying provisional.

The patents in suit were filed as continuation-in-part applications that claimed the priority date of a provisional application filed by New Railhead on February 5, 1997.

The Court of Appeals correctly stated the law, namely for the nonprovisional utility application to be afforded the priority date of the provisional application, the two applications must share at least one common inventor and the written description of the provisional must adequately support the claims of the nonprovisional application.

But what does that *mean*? It means that, for a patent specification to properly support claims, it has to be drafted using the exact same words in the body of the application that you plan to use in claims. For example, imagine trying to convince the examiner to let you overcome a piece of prior art by just inserting a new word into the claims that has never been used in the patent application. He might ask you, where did you get that word?

And, when you fail to point to a specific line and paragraph in the patent application, he will properly deny your amendment. Applicants are not allowed to use words in their claims that are not found in the body of the application.

Now, imagine this scenario: you've developed a fine new drill bit and your patent lawyer has done a good job describing it in a patent application. He has added all the new features of the commercial product into the later filed examination application. Unfortunately, the exact language to describe these features was not worked out a year earlier before the provisional was filed, but most of the concepts were there and, anyway, claims were not "required" in the provisional, right? The result: the patent that eventually grants will be invalid because the exact language used in the granted claims, although successfully written into the later examination application, were not included in the earlier provisional, so the claim to priority will fail; just like New Railhead.

It is important to note that it is the applicant's job to look out for himself because the patent examiners merely enter a priority claim as a procedural act, and they do not check your earlier filing to see if it actually supports your later filed claims.

### **Enablement and Provisionals: Invalidity from Missing Sequences in the Priority Document**

In *Fiers v. Sugamo*, 25 USPQ2d 1601 (Fed. Cir. 1993), the Court of Appeals for the Federal Circuit stated as follows: "An adequate description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself."

In *Fiers*, priority was denied to a claim because the DNA sequence coding for a specified protein was absent in the priority documents. When was the last time you heard of a university filing a sequence listing along with its provisional application?

And this is not an isolated case. In *Fiddes v. Baird*, 30 USPQ2d 1481 (Bd. of Appeals 1993), a similar decision occurred where the board of appeals stated that "knowledge of amino acid sequence of a protein coupled with the established relationship in the genetic code between a nucleic acid and a protein it encodes would not establish possession of a gene encoding that protein." In other words, priority was lost because the DNA sequence was not submitted

even though the complementary amino acid sequence was available.

### **Enablement and Provisionals: Ex parte Forman**

In *Ex parte Forman*, 230 USPQ 546 (Bd. of Appeals 1986), the board of appeals at the USPTO considered a claim a class of oral vaccines made from genetically engineered hybrid bacteria. To produce the hybrid, the inventors used a process that involved using mutant strain of typhoid *Salmonella* (*S.typhi*).

In biotechnology applications, where a patent application involves an organism, the applicants are required to provide a frozen sample of the organism to an approved facility, e.g., the American Tissue Culture Collection (ATCC), as a way to “enable a person in the field to make and use the invention.” Although, the final hybrid bacteria was deposited with the ATCC, the mutant strain used in the intermediate process was not.

The patent examiner rejected the claims because the *S. typhi* had not been deposited and, thus, the application was not enabled. The board of appeals upheld the examiner, since without the deposit of mutants of *S.typhi*, the invention could not be replicated by a person in this field. A tough result, given that the applicant had, in fact, provided a deposit commensurate with the final product, just not the process of getting there.

Now imagine trying to maintain a provisional filing date as a priority claim. When was the last time you have heard of a university making an ATCC deposit under the Budapest Treaty as part of the provisional filing? To be fair, this exact issue has not been litigated and become standard case law. However, *Ex parte Forman*, although it was only a case solely within the USPTO legal system, it was cited with approval by the Court of Appeals in another major enablement case, see e.g., *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

### **Final Thoughts**

Just because the USPTO will accept a provisional without claims doesn't mean that it's a good idea. Relying on the good will of a federal judge in a later patent proceeding to determine what you invented in the absence of any claims to guide him or her to save your provisional filing date also doesn't seem like a good idea.

*Portions of this article were previously published on the Internet.*