

Avoiding the obvious

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Obviousness is one of the most common reasons for examiners rejecting patent applications. What can you do to limit the chances of such a setback?

After years of hard work, you finally have an invention and file for a patent application. Some time later, the application is reviewed by an examiner at the US Patent and Trademark Office (USPTO), and an Office Action is issued that states various reasons why the application is being rejected. One of the reasons is that your invention is 'obvious'.

Obvious? How is that possible?

The patentability requirement of nonobviousness is a hurdle often faced by inventors negotiating meaningful patent protection from the USPTO. Recent decisions from the courts have made an obviousness rejection more difficult to overcome (Box 1). But, as we outline below, a better understanding of the obviousness hurdle and how to overcome it may mean the difference between success and failure in the prosecution process and ultimately obtaining protection for your innovations.

I could have thought of that

The legal analysis underlying a conclusion of obviousness is complex, and the USPTO, courts, attorneys and commentators have grappled with the concept for just about as long as patent protection has been available in the US¹. Therefore, we start with a gross oversimplification: obviousness is exactly what one would think. In essence, it is the examiner concluding, 'I could have thought of that'.

To be more technically correct, obviousness is the legal conclusion that (back when the invention was made) a hypothetical person with adequate background and skill in the relevant technical field would have followed an existing motivation to solve a known problem in order to combine the teachings from

the references (unearthed by the examiner) that were in existence at the time of filing, and thus create the invention (note that the 'known problem' does *not* have to be the same problem that the inventor is solving).

In practice, an examiner may peruse the application, look at the listing of claims being made and pick out certain aspects of those claims. He or she may then search the literature that was available prior to the filing date of the application and find those aspects, piece by piece, in one or more references. In drafting the obviousness rejection, the examiner will articulate some rational basis as to why one might combine these references to produce the claimed invention.

As is apparent from such a scenario, the conclusion of obviousness is necessarily made looking back, and therefore, hindsight is an important problem. Examiners do what they can with their limited time to review the application and the plethora of papers thrown at them by attorneys. However, to overcome such a rejection, the inventor may need to explain to the examiner (and to the attorney) why the conclusion of obviousness is not a reasonable one and why the picture painted by the examiner is not an accurate portrayal of the state of the technical field at the time of invention.

Prepare to attack

As an inventor, you may think, "Okay, so the examiner takes two or three patents (or other references) that do not even deal with the same problem as my invention and then calls the invention 'obvious'? That must be easy to overcome." Not necessarily. That is why your input is key.

After the initial obviousness rejection from the USPTO, the 'burden of persuasion' is on you, the applicant. There are different ways to go about responding to the rejection, which can be generally divided into the two categories of 'attack' and 'rebut'.

To illustrate the difference in practical terms, which would you prefer: being asked by your attorney to talk about the field and state of the art at the time of filing (gathering evidence to attack) or being told to conduct a complicated and expensive set of experiments in a short, fixed time period (gathering evidence to rebut)? Naturally, attacking is preferable. Therefore, the discussion that follows is focused on this. Do remember, however, that you are attacking the rejection, not the examiner. It is the examiner's job to play the devil's advocate, and by doing this job properly, the examiner can actually make your patent (once issued) stronger by building a strong foundational administrative history².

The presentation of evidence against obviousness—that is, a presentation of relevant facts from which a legal conclusion of nonobviousness should follow—is an area of frequent deficiency among applicants. For many years, a *de minimis* approach has generally been used to respond to obviousness rejections. However, recent developments in the law instruct otherwise.

Therefore, it is important for you—the inventor—and your attorney to dig deep and present the best evidence in support of your invention. Furthermore, the best evidence and arguments should be presented sooner rather than later during prosecution.

Consideration of what evidence to present against a finding of obviousness should be done in concert with the attorney's arguments and overall strategy. Evidence is normally presented into the prosecution record by submitting published articles, affidavits or declarations, which are testimonial evidence and/or testimonial presentation of other evidence (e.g., unpublished results; Box 2), and/or by visiting the USPTO and meeting with the examiner (Box 3).

Upon presenting evidence and arguments against the obviousness rejection, the examiner must consider all evidence anew and determine

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Box 1 The ugly 11: recent decisions on obviousness of biotech inventions

Recently in *KSR v. Teleflex*⁸, the US Supreme Court struck down a patent on adjustable gas and brake pedals for vehicles. In doing so, the court declared a more flexible test of obviousness, which now makes a finding of obviousness easier to accomplish across technological fields.

As a testament to this trend, in February 2008, Bruce Kisliuk, a director of US Patent and Trademark Office Technology Center 1600 (Biotechnology and Biochemistry), listed 11 recent decisions, 10 of which were rendered in 2007, that examiners were to refer to for their determination of obviousness. These decisions tally as follows:

Won (not obvious)

Takeda v. Alphapharm: for ACTOS thiazolidinedione, used to control blood sugar in patients with type 2 diabetes, no motivation was found to select this particular compound as a lead compound because related literature mentioned unwanted side effects and because of unexpected results of nontoxicity.

Forest Labs, Inc. v. Ivax: for Lexapro selective serotonin reuptake inhibitor, used to treat depression, no motivation or reasonable expectation of success was found to resolve a racemate of citalopram.

Lost (obvious)

Pharmastem v. Viacell: treatments using stem cells from umbilical cord blood for hematopoietic reconstitution were found to be merely confirming what was already expected in the literature.

Pfizer v. Apotex: for Norvasc, a high blood pressure treatment, motivation was found, given the problems faced, to select the anion from a limited list of FDA-approved anions to form the pharmaceutically acceptable salt.

McNeil-PPC v. Perrigo: for Pepcid Complete antacid, motivation was found in the art to use impermeable coating on the antacid to make it more palatable.

In re Omeprazole: for Prilosec OTC, a heartburn treatment, the court found it obvious to substitute one active alkaline-reactive compound for another.

Ex parte Kubin: a sequence of polynucleotides encoding NAIL polypeptides was found obvious in view of the known amino acid sequence and given the state of the art at the time of invention.

Daiichi Sankyo v. Apotex: treating bacterial ear infection with topical administration of the antibiotic ofloxacin was found obvious in view of a similar antibiotic used to treat middle ear infection.

Aventis v. Lupin: for ALTACE, a high blood pressure treatment, the purified stereoisomer was found obvious, predictable and separable by conventional methods. (Compare to *Forest Labs*.)

Syngenta Seeds v. Monsanto: for a transgenic corn plant that produces an insecticidal protein, it was found obvious to substitute codons having higher guanine-cytosine content in order to create plant-preferred codons.

On remand (to be determined)

In re Sullivan: for antivenom used to treat rattlesnake bites, it was remanded to the US Patent and Trademark Office because rebuttal evidence submitted by the applicant must be considered on the record.

obviousness based on the entire record. The examiner may thereafter maintain the rejection, withdraw the rejection or issue a new rejection. However, the examiner should clearly state his or her findings of fact, both to allow an opportunity to challenge those findings and to build a clear record³.

Inventor insight

How can you help as an inventor? Prepare for the rejection early. Thoroughly search the literature and discuss possible arguments with the attorney. Tell the attorney any information that may be useful in attacking an obviousness rejection, such as your reasoning or other evidence that one trained in the field would come to a different conclusion after consideration of the references used by the examiner.

For example, in the case of *Forest Laboratories, Inc. v. Ivax*⁴, the US Court of Appeals for the Federal Circuit, in considering whether it would have been obvious to resolve the positive enantiomer compound found in citalopram (named escitalopram), examined the state of the science at the time of invention and

found that a person with ordinary skill in the art would generally have been motivated to develop new compounds rather than undertake the difficult and unpredictable task of resolving a known racemate. The court also found that a person of ordinary skill would have had no reasonable expectation of success in resolving the racemate, given the relatively new and unpredictable technique of high performance liquid chromatography at the time of the invention and evidence of failed attempts to purify the citalopram racemate at that time (in the mid-1980s).

The *Forest Labs* case highlights the importance of painting a picture of the state of the art when the invention was made. One commentator has likened the inventive moment to finding just the right needles in the haystack⁵. If the roadmap to those needles was available after the fact (hindsight), it may be easy to forget the massive haystack that had enveloped those needles before the roadmap was known.

Along these lines, good record keeping is important. You should save the praise the invention received after it was unveiled. Publications

in top journals and overall praise from peers are good forms of evidence against obviousness. Also save the comments of the peers who doubted your predictions. One of the best weapons against a conclusion of obviousness could be a rejected grant proposal with a comment from a peer stating the invention won't work.

You, the inventor, can play devil's advocate too: if you received your invention as a grant proposal, what criticisms might you make? How would you back up those criticisms? This thought process can be extremely effective in generating the type of evidence your attorney needs to attack the rejection.

Consideration of commercial impact, to the extent that the commercial impact can be attributed to the invention (and not merely to aggressive marketing), may also lead to evidence in the form of unexpected results or technological advantages not previously appreciated by peers.

Whenever possible, evidence should be presented with arguments that are clear, succinct and easily understandable. Technical jargon should be avoided. Though examiners are

Box 2 Interviewing with the examiner

At some point during prosecution, you might take a trip to the US Patent and Trademark Office (USPTO) with your attorney and talk to the examiner face-to-face. This allows the inventor to tell the examiner the story behind the discovery in person. Alternatively, a video conference or telephone interview may be conducted.

The key to success in interviewing with the examiner is to do the interview when the time is right. The time is *not* right, for example, when there are many rejections or if they are better dealt with by correspondence.

Keep the following points in mind when interviewing at the USPTO:

- Be prepared; you have a fixed period of time.
- Bring only those items that are essential, including people. Usually that means you, your attorney and sometimes one or two others.
- Treat the examiner as a partner, even when things are not going your way. If you become too adversarial with the examiner, your attorney may need to 'switch sides' and defend the overall process to get things back on track.
- Stay in tune with the overall progress of the interview and whose turn it is to speak. At some point, the attorney needs to be quiet and let you tell the story of your invention. The attorney steps in on legal issues.
- Do not expect immediate gratification. The attorney and examiner may focus on reducing the substantive portion of the meeting to writing for the prosecution record. In addition, the examiner may want to consider the arguments further, do more research and discuss the case with supervisors. This is okay; your goal is to educate the examiner, not achieve a hasty win.

technically trained, they have only a limited period of time to become acquainted with the technical details of your particular invention. Even more importantly, in litigating the issued patent, the validity decision falls on judges, who, for the most part, are not technically trained. According to Judge Arthur M. Smith, "This is a challenge which can be met only by very clear writing addressed to this 'non-technical' audience"⁶.

A stitch in time saves nine

If this all sounds hard, there are things that can be done to make it easier. You can build a plan of response to the obviousness rejection into the application at the time of initial filing—a poorly or hastily written application cannot be fixed later!

Have in-depth discussions with your attorney to prepare a comprehensive and accurate patent application that will explain

the invention in the proper context and aid in attacking an obviousness rejection during prosecution. For example, the application may detail the general state of related technology at the time of filing and how the invention is unique. The application should give the reader an accurate picture of the haystack of ideas you faced at the time your invention was developed. This picture not only will set the stage for the presentation of the invention to the examiner but also will serve to refresh your and your attorney's memory when faced with an obviousness rejection some years later.

Keep in mind that the patent application "constitute[s] one of the most difficult legal instruments to draw with accuracy"⁷. Many other (less meritorious) patent applications are written so that even an experienced patent attorney is left to wonder, "What is the invention, anyway?"⁶. Careful research and preparation will make your well-drafted application stand out on the examiner's desk at the outset of prosecution.

Conclusion—inventors taking action

Inventor input is crucial to overcome the obviousness hurdle during patent prosecution. When faced with a rejection based on obviousness, it is important for an inventor to consider and discuss with an attorney the available evidence that may be used to attack the rejection. In view of the available evidence, the inventor and attorney should review the examiner's stated reasoning behind the rejection and point out flaws in that reasoning. Inventors should also participate in drafting and editing any prepared declaration and be prepared to speak directly with the examiner in an interview.

Active participation by the inventor in attacking an obviousness rejection not only will aid in procuring the patent but also will build a strong prosecution administrative history for a patent that may later be litigated.

1. Federico, P.J. in *Nonobviousness—The Ultimate Condition of Patentability* (ed. John F. Witherspoon) Part 1 101–111 (Bureau of National Affairs, Inc., Washington, DC, 1980).
2. Lupo, R.V. in *Nonobviousness—The Ultimate Condition of Patentability* (ed. John F. Witherspoon) Part 4 201–218 (Bureau of National Affairs, Inc., Washington, DC, 1980).
3. Rollins, A.D. *J. Pat. & Trademark Off. Soc.* **70**, 403–407 (1988).
4. 501 F.3d 1263 (Fed. Cir. 2007).
5. Arnold, T. & Nation, F.R. in *Nonobviousness—The Ultimate Condition of Patentability* (ed. John F. Witherspoon) Part 4 1–44 (Bureau of National Affairs, Inc., Washington, DC, 1980).
6. Smith, A.M. & J. Pat. Off. Soc. **41**, 24–25 (1959).
7. *Sperry v. State of Florida*, 137 USPQ 578, 580 (S. Ct. 1963) (quoting *Topliff v. Topliff*, 145 U.S. 156, 171).
8. 550 U.S. 398 (2007).
9. Imwinkelried, E.J. in *Evidentiary Foundations*, 5th edn. 352 (LexisNexis, New York, 2002).

Box 3 Rule 132 declarations—laying a proper evidentiary foundation

A declaration is testimonial evidence, typically from an inventor but often from other qualified experts or witnesses. As such, a proper 'evidentiary foundation' should be laid to qualify the evidence as reliable. For instance, who is speaking? Why is the speaker qualified to be making these statements? Are there any possible biases of this speaker that should be taken into consideration?

Not to say that a patent examiner is going to apply the intricate Federal Rules of Evidence in his consideration of a declaration. However, the same sort of evidential foundations are needed to explain to the examiner why he or she should consider and trust the information stated within.

Therefore, the declaration should begin by identifying in detail *who* is speaking and possible biases of which the examiner should be aware. Next, *what* is being discussed (journal articles, experimental results or other documentary evidence) is offered and properly identified in terms of *when*, *where*, *how* and *why*⁹. According to Edward Imwinkelried, a noted writer on legal advocacy, "the testimony therefore covers five topics: the witness's qualification as an expert, the general theory, the facts of the case, the opinion and the explanation of the opinion"⁹.

Careful review of the declaration for content and accuracy cannot be overstated. Be truthful and honest, and avoid selective presentation of data. Remember, if the patent is litigated, you will be cross-examined on your statements by an experienced attorney who is being paid a lot to make you look bad.