5.A request to participate in the PPH 2.0 program must be filed.

6.The applicant must submit a copy of the office action issued just prior to the "Decision to Grant a Patent" for the application before the PPH 2.0 participating office.

In addition to the eight participants in the PPH MONTTAINAI program, the European Patent Office ("EPO") has announced that it will participate in the new version of the pilot program ("PPH 2.0").

7.The applicant must submit an information disclosure statement ("IDS") listing all documents cited in the office action of the PPH 2.0 participating office, unless such an IDS has already been filed.

8.The requirements above extend to Requests for Continued Examinations but not to continuing applications where these requirements must be met anew.

Once these requirements are met and the request has been granted, the U.S. application will be examined out of turn. The claims examined must correspond to the allowed claims submitted and the applicant must submit a certification statement to that effect. All duties of disclosure and candor according to current U.S. practice stay in effect.

Nonobviousness

Practical Guidelines to Defeating an Obviousness Rejection

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Contributed by Kenneth Horton, Kirton McConkie

One of the common obstacles preventing a patent application from being issued by the U.S. Patent & Trademark Office ("USPTO") is the dreaded "obviousness rejection," where the examiner rejects the application on the basis that the invention is "obvious" in light of one or more prior art references ("prior art"). As a former patent examiner, there are several guidelines I follow when replying to these rejections.

Analyzing the Rejection

First, read the rejection and make sure you understand what the examiner says, and more importantly, what the examiner does not say. There are often hints embedded in the rejection. Sometimes, you may not appreciate those hints until you have started preparing your reply to the obviousness rejection.

Next, read the claims and compare them with the rejection. Is there an element in the claims the examiner has missed and has not shown to be described by the prior art references? Usually, the examiner runs through the list of elements in the claim and compares each element to the cited prior art, but then ignores one or more of the elements partially or completely as if it did not exist. Focus your analysis on that discrepancy since even a single word can provide excellent arguments against the rejection. At this point in the analysis, you don't even need to know what the prior art says if the examiner skips a claim element. The goal in this step is to determine whether the examiner has, as the very least, argued a plausible rejection, i.e. has the examiner argued that each limitation in the claims is either taught or suggested by the cited prior art?

Then, read the "entire" prior art references, focusing on those areas relied on by the examiner. Understanding the prior art as well as the examiner's interpretation of the prior art is paramount to success. Is the examiner correct in the categorization of the prior art? In this step, determine whether the examiner has actually proven the rejection. Has the examiner proven the

arguments with sufficient evidence within the cited references? As part of this analysis, you should focus on the sufficiency of the arguments submitted by the examiner in the rejection.

Read the claims again. Do the claims and their elements "gel" with the examiner's arguments in the rejection? If so, is there an element in a dependent claim on which you could focus your reply instead?

Read the specification in the application to determine if there is a feature described in the specification that is not described in the prior art. If so, amend the claims so they contain that element and then focus your arguments in the reply on that new element.

Writing the Reply

When actually writing the reply to an obviousness rejection, the objective is to show the examiner is wrong. So, if the examiner does not raise an issue, do not raise it yourself. Do not cite other parts of the prior art the examiner does not rely on, unless they support your arguments.

When writing the reply, take the position the patent examiner is usually correct in the substance of the rejections, at least in the examiner's mind. Your job is to change the mind-set of the examiner, so only provide arguments with this goal in mind.

Use technical arguments whenever possible since they are much more persuasive to an examiner than legal arguments. But, this does not mean you can forget about potential legal arguments. One legal argument that was given new life recently is whether the prior art cited in an obviousness rejection is analogous. In *In re Klein*,[1] the Federal Circuit overturned an obviousness rejection, holding that the prior art relied on by the examiner was not analogous. The court noted that two separate tests define the scope of analogous prior art. First, whether the art is from the same field of endeavor as the claims, regardless of the problem addressed. Second, if the prior art is not within the field of the inventor's endeavor, whether the prior art is reasonable pertinent to the particular problem with which the inventor is involved. Focusing on the second test, the Court determined that many of the cited prior art in *Klein* were not reasonably pertinent to the problem that the inventor aimed to solve and, therefore, were not properly combined to reject the claimed invention. The Federal Circuit did not address whether the prior art was in the same field of endeavor (i.e., the first test) because the USPTO based its rejection only on the second test.

To arrive at such a decision, the Federal Circuit first characterized the problem the inventor was trying to solve. The court then distinguished that problem from the problem the cited references were trying to solve. Specifically, the court reasoned in *Klein* that the claimed container was designed to *separate* its components, as opposed to the prior art containers that were designed to facilitate the *mixing* of their contents.

With this line of argument, you will likely need to spend more time understanding the problem to be solved by the claimed invention and categorizing it as different than the problem to be solved by the prior art. Of course, the arguments you submit will have to consider the Manual of Patent Examining Procedure (M.P.E.P.) § 2141.01(a), which details what the USPTO views as analogous art. As well, any arguments about the problem to be solved by the claimed invention will have to be carefully crafted to minimize or eliminate prosecution history estoppel.

> The USPTO reiterated that the reasoning behind an obviousness rejection must be explicit, even where the examiner relies "on intangible realities such as common sense."

When possible, submit evidence in your reply to the rejection. Your opinions (and often times your arguments) carry little weight with the examiner. Where appropriate, provide objective evidence of unexpected results, comparative data, scientific arguments, supporting declarations, etc. Some of the best evidence can even be found in the prior art that has been cited and, in rare instances, in prior art that has not been cited in the rejection.

If you must use legal arguments, M.P.E.P. § 2100 is your bible. Do not cite case law to the examiner since they typically only believe what they have been taught in the Patent Academy and what they learn is usually limited to just the legal principles. But the examiner cannot ignore the M.P.E.P. and section 2100 contains great ammunition for you to rely to defeat the obviousness rejection.

With increasing odds against you after *KSR v. Teleflex*,[2] consider arguing that there are not sufficient reasons to combine the prior art in the manner proposed by the examiner to arrive at the claimed invention. The 2011 updated examination guidelines for obviousness under 35 U.S.C. §103 are especially relevant for this consideration. These guidelines reviewed 22 decisions handed down by the Federal Circuit since *KSR*, The updated guidelines, while noting that the teaching-suggestion-motivation ("TSM") test can still be used as a rationale to support an obviousness rejection, categorized these 22 decisions as supporting six rationales for finding obviousness:

1. Combining prior art elements according to known methods to yield predictable results;
2. Simple substituting one known element for another to obtain predictable results;
3. Using a known technique to improve similar devices, methods, or products in the same way;

4. Applying a known technique to a known device, method, or product that is ready for improvement to yield predictable results;
5. Obvious to try; and
6. Known work in one field of endeavor may prompt variation of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to the skilled artisan.

Each of the decisions are summarized by "teaching points" falling within the six categories and are noted at the very end of the Federal Register noticed where the guidelines were posted.[3] The updated guidelines make clear that the teaching points are not *per se* rules. The USPTO reiterated that the reasoning behind an obviousness rejection must be explicit, even where the examiner relies "on intangible realities such as common sense." The updated guidelines also confirm that factual findings are also necessary in an obviousness rejection. If a rejection omits one of the required factual findings, and you point out that omission in your reply, the examiner should withdraw the rejection or repeat the rejection including all required factual findings.

The updated guidelines recognize that an examiner can rely on these teaching points without reading the actual decision. At the same time, they caution examiners that the teaching points should not be used as a substitute for reading the actual decision. It is likely, though, that the examiners will do just that by reciting the teaching point, citing to the case, and then ignoring anything and everything else for which the decision stands. Have a quick reference guide to these 22 decisions and the teaching points so when the examiner cites a teaching point, you can read the underlying decision for appropriate arguments.

When actually writing the reply, keep it as short as possible. Besides being more persuasive, each and every word in your reply creates file history estoppel and raises the costs for the client. Get directly to the point; provide support for your arguments in the prior art, and then move on. Any statement in the reply "can and will be used against you" during litigation.

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[1] 647 F.3d 1343 (Fed. Cir. 2011).

[2] 550 U.S. 398 (2007).

[3] http://edocket.access.gpo.gov/2010/pdf/2010-21646.pdf.

Hatch-Waxman Act

AstraZeneca's Hatch-Waxman Patent Action Dismissed for Lack of Personal Jurisdiction

Aude Gerspacher | Bloomberg Law

AstraZeneca Pharmaceuticals LP v. Intellipharmaceutics Corp., No. 11-02973, 2012 BL 36332 (D.N.J. Feb. 15, 2012)

Granting a motion to dismiss, the District of New Jersey found that AstraZeneca had not established sufficient contact by the defendant in New Jersey in connection with a Hatch-Waxman patent infringement action.

The U.S. District Court of New Jersey dismissed a Hatch-Waxman act patent infringement action brought by AstraZeneca Pharmaceutical LP and AstraZeneca UK Limited (collectively, "AstraZeneca") against Intellipharmaceutics Corp. and Intellipharmaceutics International, Inc. (collectively, "IPC") for lack of personal jurisdiction.

> The court noted that AstraZeneca failed to identify the type of tax payments, which turned out to be sales taxes paid for products purchased.

AstraZeneca's ANDA Litigation

In its complaint, AstraZeneca alleged patent infringement based on Intellipharmaceutics Corp.'s filing of an Abbreviated New Drug Application ("ANDA") seeking approval from the Food and Drug Administration to market a generic version of AstraZeneca's SEROQUEL XR. IPC immediately challenged personal jurisdiction, seeking to dismiss the complaint or transfer the case to the Southern District of New York. AstraZeneca subsequently filed an amended complaint adding Intellipharmaceutics International, Inc as a defendant. AstraZeneca then filed a "protective suit" in the Southern District of New York in order to preserve its rights to the statutory 30-month stay of approval of IPC's ANDA, which the New York court stayed pending the outcome of this action.