THE AIA: WHAT'S ON THE LITIGATION HORIZON

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The Written Description Requirement: Genus/Species Claims (Third and Final Post in Series on Written Description)

"Genus":	a class, kind, or group marked by a common characteristic(s)
"Species":	a logical subdivision of a genus marked by a specific attribute

Taxonomy (classifying things according to genus and species) also has a parallel in patent law. A patentee may use narrow species claims to distinguish against prior art, while at the same time seeking the broadest possible "right to exclude" with a genus claim(s). But there are trade-offs. First, the Patent Office can reject a broad genus claim if only one member of the genus was known in the art. Second, the patentee must provide a level of description proportional to the scope of the claim. In litigation, defendants accused of infringing broad genus claims often assert inadequate written disclosure, contending the patentee's reach in securing the patented claims exceeded its grasp.

For example, a court in one case invalidated a patent claiming a sequence of genetic material for manufacturing human insulin, because the patent's teachings focused mostly on rats. The court held the differences between rat DNA and human DNA prevented the disclosure from being adequate to describe what was claimed. In another case, similar reasoning was used to invalidate claims involving more traditional pharmaceutical products, where the court observed that an adequate description must convey what the chemical compound is, not just what it does.

Drug-eluting stents provide another example where genus-species issues have affected patent rights. A recent case arose from stents coated with an agent to limit the regrowth of arterial plaque. The narrow species claim was directed to using a compound known as rapamycin, while broader genus claims were directed to various chemical analogs having a similar structure as rapamycin. While the claim directed to rapamycin was adequately described, the court invalidated the broader genus claims for rapamycin analogs, because a jury could not have reasonably found

they were adequately described in the patent. The court observed that merely describing the function of all of those chemical analogs was insufficient, while noting that the technology field was still "nascent" and "in its infancy," thus requiring more disclosure – not less.

Besides illustrating the trade-off with genus claims, this case also provides an informative hypothetical illustrating written description issues under the AIA. Change the facts of the stent case slightly, and consider a parent application filed before the March 16, 2013 effective date of the AIA. In this hypothetical, the parent application claims a species (a rapamycin-coated stent) and a genus (a stent coated with any analog of rapamycin). Further, suppose that after March 16, 2013, the inventors obtained excellent results from a particular set of rapamycin analogs. Desiring to claim these as a broad genus, suppose the inventors decided to file a continuation application claiming these particular analogs and also keeping the claim directed to rapamycin.

The AIA affects the decision about filing such a continuation application without also keeping the original application in play. On one hand, it could be convenient and less expensive to maintain one continuation application that claims the parent's effective filing date. But think carefully before rolling everything into one continuation application and abandoning the parent application. Later, a patent challenger might contend the parent application only adequately described rapamycin itself – but not the analogs (as was the case in the stent case described previously). If the contention is correct, the likely result is that all the claims in the continuation application would be subject to the AIA's first-to-file system.

Earlier posts in this series discussed why this is significant. Consequently, the possibility of not being able to fall back on a prior date of invention to remove a reference would need to be considered before adopting a prosecution strategy. In such a case, the benefits to the patentee of maintaining the parent application separate from the continuation application might justify the additional prosecution cost.

While the posts in this series have focused mainly on the written description requirement claims have been invalidated for lack of enablement, in other court cases. Similar to written description, the enablement requirement might also provide a gateway for defendants' use to invoke the rigid AIA law. The developing case law will be a key vehicle toward implementing the AIA, and while some of these issues are not yet defined with total clarity, there is no doubt that AIA brings new challenges, concerns, and opportunities.

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