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BioPharma Patents Quick Tips and News-July/August 2014

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I. THREE NEW CASES FROM THE FEDERAL CIRCUIT

UNEXPECTED RESULTS

1. In *Allergan v. Apotex,* 754 F.3d 952 (Fed. Cir. 2014), claims to a method of growing eyelashes by administering a broad genus encompassing thousands of prostaglandin drugs were held invalid for obviousness. The patentee attempted to use unexpected results to show nonobviousness, but the results concerned just one prostaglandin species (bimatoprost). **Holding:** Unexpected results concerning one drug were not enough to support the nonobviousness of a genus encompassing thousands of drugs.

PRACTICE TIPS:

When using unexpected results to rebut a conclusion of obviousness for a claim to a genus, if possible submit data for several different species, preferably from different ends of the genus. Ideally, one of the species tested should be the species that is allegedly obvious, or at least closely related to the allegedly obvious member of the genus. Of course, including and enforcing mid-scope and species claims continues to be important.

2. In *Bristol-Myers Squibb v. Teva,* 752 F.3d 967 (Fed. Cir. 2014), the court applied the "lead compound" test to conclude that BMS's claims covering entecavir—an anti-viral nucleoside analog—are invalid for obviousness. While the court's application of the "lead compound" test appears to be in line with caselaw, this case illustrates **an alarming trend in recent chemical obviousness cases**—the court's tendency to give less weight to unexpected results. In this case, the patentee presented the following evidence of unexpected results: (i) that entecavir was effective against hepatitis B virus (HBV), which has a very different nucleotide replication process than HSV; (ii) entecavir shows a larger-than-expected therapeutic window and (iii) entecavir shows an exceptionally strong genetic barrier to HBV developing drug-resistance. Even though the court acknowledged that such results were indeed unexpected, the court found that the underlying argument for obviousness was so strong that essentially no amount of unexpected results could outweigh the conclusion of obviousness. This decision came only two months after *Hoffmann-La Roche v. Apotex*, 748 F.3d 1326 (Fed. Cir. 2014), which also found that the unexpected results did not rebut the strong combination of references. In other words, the Federal Circuit appears to be giving less weight to unexpected results when an allegedly strong showing of *prima facie* obviousness is present.

PRACTICE TIPS:

Both Roche and BMS emphasized that the unexpected results did not outweigh the "reasonable expectation of success" that one of ordinary skill could have had from the cited art. Therefore, it is important to focus on this aspect of the argument for *prima facie* obviousness when presenting unexpected results. For example, BMS might have emphasized the differences between HSV replication (dsDNA genome replicated by DNA polymerase) and HBV replication (ds/ssDNA genome replicated through a two-step process of transcription to RNA, followed by reverse-transcription back to DNA), to establish that results with 2'-CDG against HSV give no reason to expect that 2'-CDG or 2'-CDG derivatives would have any effect against HBV.

INFRINGEMENT BY ANDA FILING

3. In *Ferring BV v. Watson Labs,* no. 2014-1416 (Fed. Cir. 22 Aug 2014), the court reversed the district court's holding that Watson's ANDA infringed Ferring's claim to a delayed released tranexamic acid tablet. To make its tablet, Watson first makes a core comprising the drug and certain binders, and then coats the core with delayed-release layers. The relevant claims included limitations about how quickly the tablet dissolves under certain temperature and agitation conditions. Both parties agreed that the cores satisfy all claim limitations, but that the fully coated tablets do not. Ferring argued that the claims embrace a tablet "comprising" various substances, and that Watson's tablet comprises the infringing core. The district court agreed and ruled that Watson's tablet, which includes the infringing core, infringes Ferring's claim. **The Federal Circuit reversed, holding that the only product that can be considered when evaluating the infringement of an ANDA filing is the complete product that will be sold to the public. Even though the uncoated cores infringe, the uncoated cores cannot be sold to the public, and therefore they may not be considered when determining ANDA infringement.**

PRACTICE TIPS:

When addressing a paragraph IV certification in an ANDA filing, focus on the final product that will be sold to consumers. Do not consider individual elements of the final product, except as they relate to the final product for sale.

II. INTER PARTES REVIEW IN THE BIOTECH ART

In the recent release of the **first three IPR decisions** in the biotech art (PCR gene-sequencing technologies), 100% of the challenged claims were invalidated.

PRACTICE TIPS:

While this percentage will likely come down as more decisions are released, these initial decisions highlight the importance of telescoping claims, running from broadest achievable down to the narrowest claim that still covers the commercial embodiment. This is particularly important in the pharmaceutical arts, because even if one claim survives IPR challenge, the regulatory hurdles associated with FDA approval may likely be enough to prevent a competitor from simply designing around the surviving claims.

Stay tuned to HDP's IPR/PGR blog for further developments.

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