Kratz, Quintos & Hanson, LLP – IP Newsletter

A CLAIM THAT INCLUDES A COMPUTER-IMPLEMENTED MEANS-PLUS-FUNCTION TERM IS <u>INDEFINITE</u>
IF THE ONLY SUPPORT IT HAS IN THE SPECIFICATION IS DESCRIBED AS A "CONVENTIONAL
MICROPROCESSOR" THAT PERFORMS IN A "CONVENTIONAL MANNER" by Mel R. Quintos

n June 13, 2014, the Court of Appeals for the Federal Circuit decided the case of *Triton Tech of Texas*, *LLC v*. *Nintendo of America*, *Inc.*, Triton Tech having appealed a district court's judgment that the means-plus-function term "integrator means" renders the claims of Triton's U.S. Patent No. 5,181,181 invalid for indefiniteness under 35 U.S.C. §112.

Triton sued Nintendo alleging that Nintendo's Wii RemoteTM, when used with another accessory, infringes Triton's patent. An element in the claimed input device of a representative claim recites:

integrator means associated with said input device for integrating said acceleration signals over time to produce velocity signals for linear translation along each of . . . first, second and third axes. [Emphasis added.]

Unfortunately, although each asserted claim recites an "integrator means," the specification calls for a preferred embodiment that is a "conventional microprocessor" where numerical integration is performed in a "conventional manner."

<u>Decision</u>: The court affirmed the district court's decision that Triton's claims "are <u>indefinite</u> because the specification does not disclose an algorithm for performing the claimed integrating function of the 'integrator means'" (emphasis added).

More particularly, the court held that: (1) numerical integration is not a specific algorithm, but is instead a broad class of different possible algorithms for performing integration; (2) the broad class of algorithms "places no limitations on how values are calculated, combined, or weighted" and thus, "insufficient to make the bounds of the claims understandable;" (3) the broad class of "numerical integration" for supporting the claimed "integrator means" does not limit the scope of the claim to the "corresponding structure, material, or acts," as required under 35 U.S.C. §112, 6th paragraph; and (4) in citing the 2007 Federal Circuit case of *Biomedino*, *LLC v. Water Techs. Corp.*, "a bare statement that known techniques or methods can be used does not disclose structure" and thus fails to support the claimed means-plus-function language under 35 U.S.C. §112, 6th paragraph.

IF THERE IS MOTIVATION TO SELECT A "LEAD COMPOUND" AND THIS LEAD COMPOUND CAN BE MODIFIED BY CONVENTIONAL MODIFICATIONS TO PRODUCE A CLAIMED COMPOUND, THEN THERE IS PRIMA FACIE CASE OF OBVIOUSNESS by Daniel A. Geselowitz, Ph.D.

n June 12, 2014, the Court of Appeals for the Federal Circuit decided the case of *Bristol-Myers Squibb Company v.* Teva Pharmaceuticals USA, Inc.

Bristol-Myers Squibb (BMS) owns U.S. Patent No. 5,205,244, with compound claims, and in particular, with claim 8 claiming a single compound corresponding to entecavir, which BMS markets as Baraclude® for hepatitis B. Teva wanted to market a generic version of entecavir, and BMS sued Teva for infringement.

Teva argued that the patent was <u>not</u> enforceable because the claims were obvious. Teva's argument was that 2'-CDG could be selected as a lead compound from the prior art, and that it was obvious to modify this to add an exocyclic methylene group, thereby yielding entecavir.

The district court found that 2'-CDG was a lead compound for the development of antiviral drugs. Moreover, based on a reference (the Madhavan reference), the district court found that the exocyclic methylene substitution would be a "small, conservative change" and that a skilled artisan would have been motivated to modify 2'-CDG to entecavir with a reasonable expectation of success of creating a compound with antiviral properties. The district court found that there was clear and convincing evidence that claim 8 would have been obvious.

<u>Decision</u>: On appeal, the Federal Circuit affirmed the district court's decision, and found claim 8 of the BMS patent to be obvious and thus invalid.

The issue in this case is the finding of obviousness of an organic pharmaceutical based on: (1) selecting a lead compound; and (2) modifying the lead compound. Several recent cases have focused on this issue, including the Federal Circuit cases of *Takeda Chem. Indus. Ltd. v. Alphapharm Pty. Ltd.*, and *Eisai Co. Ltd. v. Dr. Reddy's Labs, Ltd.*

Teva argued that the prior art compound 2'-CDG was a lead compound. 2'-CDG is a potent antiviral carbocyclic nucleoside analogue of deoxyguanosine and was known well before the priority date of the BMS patent to have excellent *in vitro* activity against herpes virus. Teva also argued based on a reference (the Madhavan reference) that the substitution of an exocyclic methyene for the 5' position on the carbocyclic ring on the nucleoside aristeromycin led to an analogue (Madhavan 30) with superior properties. This modification is the same modification as made to 2'-CDG to form entecavir.

BMS attacked the lower court's determination by contending that a skilled artisan would have to make too many decisions to arrive at entecavir, these decisions including the selection of 2'-CDG as a lead compound and the particular modification. However, the Federal Circuit found <u>no</u> clear error in the district court's findings.

As a result of the evidence presented, the Federal Circuit agreed with the district court that "a skilled artisan would have selected 2'-CDG as a lead compound and made the minor modification to arrive at entecavir" (emphasis added).

BMS also made several contentions of unexpected properties of entecavir, including: (1) high potency against hepatitis B; (2) a large therapeutic window; and (3) a high genetic barrier to resistance. The district court had found that some of these properties were "not unexpected" and that some were unexpected, but taken together, these arguments were <u>not found sufficient</u>. The Federal Circuit deferred to the district courts findings; and therefore, the secondary considerations did <u>not</u> overcome the *prima facie* case of obviousness.

ADMINISTRATION SECTION by Kozue Nogami

- (1) **First Action Allowance:** Our firm has **Rank No. 28** among all U.S. law firms in receiving First Action Allowances from the U.S. Patent and Trademark Office. Please see the following article: http://www.ipwatchdog.com/2012/03/07/a-patent-bigfoot-the-mythical-first-action-allowances-do-exist/id=22628/.
- (2) We will also begin to update you on changes in U.S. intellectual property rules and laws through our *blogs* in our firm's mobile website.

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