Nov/Dec 2013
Newsletter

United States

BioPharma Patents

QUICK TIPS & NEWS

HARNESS DICKEY

QUICK TIPS

A. THREE TIPS FOR OVERCOMING U.S. OBVIOUSNESS REJECTIONS

TIP

1) **Argue no PFO first:** Always argue down existence of an Examiner-asserted presumption of prima facie obviousness (PFO), before going on to second-step providing PFO-presumption rebuttal-evidence, e.g., "secondary considerations" such as unexpected results.

2) **Use a selection argument**: Map out each step an artisan would have to make to arrive at the claimed invention amongst all the choices available in the cited art with no guidance to make all of the selections to arrive at the claim as a whole.

3) **Teaching away** is still most persuasive. Invest a couple of hours searching the art or ask inventors to find (1) teaching away statements or (2) statements to rebut the Examiner's assertions.

B. RESTRICTION PRACTICE IN ART UNIT 1600 (BIOTECHNOLOGY AND ORGANIC CHEMISTRY)

TIP

Try petitioning to have restriction requirements withdrawn.

Harness Dickey recently successfully petitioned to have improper restriction requirements withdrawn, and to have others converted into requirements for election of species. Also, currently Art Unit 1600 is discouraging Examiners from imposing restrictions between products and methods of using the product. Therefore, if you are facing a restriction requirement between a product and a method of using the product, consider filing a petition to have the requirement withdrawn, unless a divisional application is desired.

QUICK NEWS

A. PHARMACEUTICAL COMBINATIONS: RECENT CASE LAW

There have been four post-KSR Federal Circuit decisions on obviousness of claims to combinations of old drugs useful for related indications.

TAKE AWAY

Claims that specify a new benefit appear to have a better chance of surviving a challenge for obviousness than claims that do not specify a benefit.

Examples: longer room-temp shelf life in *Leo Pharma. Prods. v. Rea*, 726 F.3d 1346 (Fed. Cir. 2013), longer lasting efficacy in *Allergan v. Sandoz,* 726 F.3d 1286, 1294 (Fed Cir. 2013) and *Pozen v. Par,* 696 F.3d 1151, 1164 (Fed. Cir. 2012). *But see, Novo-Nordisk v. Caraco,* 719 F.3d 1346 (Fed. Cir. 2013).

B. NEW REPORTING REQUIREMENTS FOR TRANSFERS OF PHARMACEUTICAL PATENT RIGHTS

The U.S. Federal Trade Commission (FTC) has announced final changes to the pre-merger notification rules for pharmaceutical companies. This is especially noteworthy as it applies to **exclusive patent licensing** between pharmaceutical companies even without a corporate merger, and even if the patent holder retains some manufacturing rights or co-rights for the joint development, marketing or commercialization of the patented drug. This means that certain exclusive patent licenses may require notification to the FTC and the Antitrust Division of the Department of Justice ("DOJ").

TAKE AWAY

Patent holders should be aware of potential antitrust issues prior to entering into an exclusive patent licensing arrangement, which may be a reportable transaction.