OBLON

IPUPDATES

JULY 22, 2024

USPTO UPDATE

The End of Chevron Deference and the Proposed Terminal Disclaimer Rule

BY RICHARD KELLY

The In *Loper Bright Enterprises v. Raimondo, 603 U.S. ___ (2024)* the Supreme Court overruled its 1984 decision in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), requiring federal courts to defer to agency statutory interpretations where a statute is ambiguous. The issue of deference owed to USPTO decisions pre-*Loper* applied solely to "interpretive" decisions involving procedure but not "substantive" rule making, see Cooper Techs. Co. v. Dudas, 536 F.3d 1330 (Fed. Cir. 2008). (giving Chevron deference to PTO's interpretation of "original application" under the reexamination statute). However, that deference is no longer applicable. *Loper* is not retroactive and thus previous decisions based on Chevron are not affected. The USPTO should re-think its proposed rule on terminal disclaimers since there is no ambiguity in the statute, the patentability of "Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim." 35 U.S.C. 282(a). The USPTO is engaging in administrative overreach when promulgating a rule which negates a statutory provision. It also is an attempt to overturn Federal Circuit decisions such as *Ortho Pharm. Corp. v. Smith*, 959 F. 2d 936, (Fed. Cir. 1992).

If the USPTO considers double patenting to be a problem, maybe it should look at itself in a mirror. Since 1990 the number of litigated patents with a terminal disclaimer went from less than 10% to about 50% in 2023, and from less than 20% to over 60% in Orange Book patents. (See Patently-O **here**). In my over 50 years of experience as both a patent examiner and patent attorney, I have seen the concept of what constitutes double patenting by the examiners abused. Examiners are now using double patenting rejections to reject claims to new and unobvious uses of drugs where they make no effort to show why the use is obvious but simply point to the earlier patent showing drug for other uses. In the pharmaceutical art, drugs take years from discovery to FDA approval with clinical testing occurring late in the process where many times new uses or modes of administration are developed. This is not gaming the system as authors have suggested, but the natural result of our regulatory environment designed for proving drug safety and efficacy before sale of a drug to the public is authorized.

JPO UPDATES

17th IP5 Heads of Office Meeting

BY KASUMI KANETAKA

From On June 20, 2024, the KIPO hosted the 17th meeting of **the IP5 Heads of Office** (the JPO, the USPTO, the EUIPO, the CHIPA, and the KIPO) in Seoul, Korea. At the meeting, the IP5 discussed the role of IP in fostering the growth of small- and medium-sized enterprises (SMEs). The JPO leads a project for AI-related inventions, and a new comparative table with a detailed classification of the examination cases was approved during the meeting.

Please see **here** for the Joint Statement from the IP5 and **here** for the report from the JPO.

IP5 Trial and Appeal Board's High-Level Meeting

BY KASUMI KANETAKA

On June 11, 2024, the IP5 Trial and Appeal Board's High-Level Meeting was held in Seoul, Korea, hosted by the KIPO. There was an exchange of opinions on the use of AI technology in business operations and promotion for digitalization. The JPO introduced digitalization of examination processes and action plans for utilizing AI technology.

Please see **here** for the report (in Japanese).

AI UPDATE

USPTO Issues AI Subject Matter Eligibility Guidance

BY SAMEER GOKHALE

The U.S. Patent and Trademark Office (USPTO) has issued an update to the guidance on patent subject matter eligibility to address artificial intelligence (AI). This update provides further clarity and consistency on how the USPTO and applicants should evaluate subject matter eligibility of claims in patent applications and patents involving inventions related to AI technology. The guidance update also announces three new examples of how to apply this guidance through a few key technologies.

The guidance update provides a discussion on certain areas of the guidance that are particularly relevant to AI inventions, including discussions of Federal Circuit decisions on subject matter eligibility.

The three new examples provide hypothetical claims in certain situations, and offers exemplary determinations as to whether a claim recites an abstract idea or whether a claim integrates the abstract idea into a practical application. These examples are meant to assist USPTO personnel in applying the USPTO's subject matter eligibility guidance to AI inventions during patent examination, appeal, and post-grant proceedings.

The full text of the guidance update is available on the USPTO's **Latest AI news and reports webpage** and the corresponding examples are available on the **AI-related resources** webpage. The USPTO will accept public comments on the guidance update and the examples through September 16, 2024 (see the **Federal Register Notice**).

We will take a deep dive on the new examples provided by the USPTO in upcoming publications to the AI Patent Blog.

CAFC UPDATE

Another "Not A Skinny Label" Case - *Amarin v. Hikma*

BY RICHARD D. KELLY

Amarin v. Hikma, (Fed. Cir. June 25, 2024, Appeal No. 2023-1169) may look like a skinny label case but it isn't. Amarin's complaint was based on 35 U.S.C. § 271(b) for inducement and was after Hikma had launched its generic product, a generic copy of Amarin's Vascepa®, a drug used to treat both the treatment of severe hypertriglyceridemia ("the SH indication"), a condition in which a patient's blood triglyceride level is at least 500 mg/dL, and a second use treating cardiovascular risks (i.e., myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization) in patients having blood triglyceride levels of at least 150 mg/dL ("the CV indication"). The patents on the SH indication expired before the CV indication and Hikma sought approval of its generic Vascepa®, to treat only the SH indication for which the patent had expired. About one month after Hikma's launch, Amarin sued for induced infringement by Hikma of the CV patents based on its drug's label plus its marketing materials. Hikma moved to dismiss under Rule 12(b)(6). The magistrate recommended denying the motion based on Hikma's marketing activities, but considered the skinny label not to be sufficient. The district judge on a *de novo* review agreed Hikma's skinny label did not induce infringement but found that its marketing materials were insufficient to show inducement and declined to accept the recommendation.

On appeal the Federal Circuit considered the issue to be whether Amarin's complaint plausibly alleged Hikma actively induced infringement under 35 U.S.C. § 271(b), despite Hikma's skinny label omitting the patented CV indication. The Federal Circuit held that the totality of Amarin's allegations -- based on Hikma's label, press releases, and website -- plausibly pleaded induced infringement at the motion stage sufficiently to defeat a 12(b)(6). The sufficiency could be tested later in summary judgment after discovery on inducement had been taken. The pleading referenced Hikma's repeated statements that its drug was rated equivalent to Amarin's without any limitation as to the indication, either SH or CV.

The major difference between this case and a skinny label case is that was based on § 271(b) and not under 35 U.S.C. § 271(e)(2) where the only evidence is the generic label (skinny label) as the evidence of infringement. Thus, the scope of the label was not dispositive since Hikma had engaged in marketing activities after FDA approval, not possible before the approval.

The takeaway is that a "skinny label" alone will not avoid a complaint for inducement under 271(b) if marketing activities are available to show active inducement. All that is necessary is to show a plausibility of the inducement for the case to proceed to discovery.

LES UPDATE

BY YORIKATSU HOHOKABE, PHD

The Licensing Executive Society (LES) of Japan held its annual meeting on July 12-13, 2024 at the Toki Messe Niigata Convention Center, Niigata-Prefecture in Japan. Dr. Yorikatsu Hohokabe, Senior Advisor of the Oblon firm, participated as a moderator as well as a speaker. Dr. Hohokabe

is a Director of LES Japan as well as Group Leader of each of U.S. Issues WG (Tokyo) and U.S. Issues WG (Osaka).

Regarding the topic of “Importance of inventorship,” a discussion was held on the significant impact on patent infringement litigation learned from U.S. CAFC case decisions (*HIP, Inc. v. Hormel Foods Corp.*, *Blue Gentian LLC v. Tristar Products, and Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co.*).

Regarding the topic “Inventorship Guidance for AI-Assisted Inventions,” new USPTO guidance was discussed as well as the practical implication on the prosecution of patent applications.

NEWSLETTER EDITOR: **SAMEER GOKHALE**