

JANUARY 17, 2024

USPTO UPDATE

<u>USPTO Releases Examiner Guidance for The Amgen</u> Enablement Decision

BY RICHARD D. KELLY

The USPTO published its guidance to the examiners on the impact of the *Amgen v. Sanofi*,143 S. Ct. 1243 (2023), on USPTO practice. The Guidance is basically steady as she goes but with the caveat that the enablement requirement and the *Wands* factors (*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)) apply across all technologies noting the



Court's reliance on cases involving the telegraph, incandescent lamp filaments and wood glue. The Guidance also noted that the post-*Amgen* Federal Circuit decisions had reaffirmed the continued validity of the *Wands* factors as consistent with *Amgen*, citing *Medytox*, 71 F.4th at 98-999, *Baxalta Inc, v. Genentech, Inc.*, 81 F.4th 1362 (Fed. Cir. 2023), and *In re Starrett*, 2023 WL 3881360 (Fed. Cir. 2023) (non-precedential).

A copy of the guidance is **here**.

JPO UPDATE



JPO Hosted the G7 Heads of IP Office Conversation in the Metaverse Format

BY KASUMI KANETAKA

On December 15, 2023, the Japan Patent Office (JPO) hosted the G7 Heads of IP Office Conversation, along with World Intellectual Property Organization (WIPO) Director General who participated in the Conversation as an observer, within the Metaverse space. See the full announcement here.

The G7 IP Offices adopted a Joint Statement following the Conversation. See the full Statement here. In the Join Statement, the G7 IP Offices recognize that an effective international IP ecosystem is necessary to incentivize innovation and creativity, which drive social and economic development worldwide. To accelerate innovation and creativity, a strong and active engagement is required not only from existing stakeholders within the IP ecosystem, but also from a wide

range of additional actors, who can benefit from IP. The Statement adds that it is also important to continuously improve the IP system so that it can respond to the latest challenges, such as IP issues in the new digital contexts, including the metaverse.

JPO Commissioner Mr. Koichi Hamano shared recent initiatives with the G7 IP Offices and WIPO, including various JPO measures to promote diversity and inclusion within the IP field, as well as revision of the Unfair Competition Prevention Act, which was promulgated in Japan in June 2023 to prevent counterfeiting within the digital space.

AI UPDATE

The UK Supreme Court Unanimously Holds that Al Cannot Be An Inventor

BY SAMEER GOKHALE

On December 20, 2023, the UK Supreme Court unanimously held that UK patent legislation does not permit an AI system to be named as the "inventor" in a patent application. The UK Supreme Court reaffirmed earlier decisions from the UK courts and UK Intellectual Property Office (UKIPO) that an inventor must be a natural person. The Judgment can be found here.



As background, this Al-machine-as-inventor proposition was tested by Dr. Stephen Thaler via the filing of patent applications in over a dozen countries for inventions allegedly invented by a neural-network-based Al machine ("DABUS"), and the listing of the inventor as "DABUS" on the patent application.

Two of the Main Issues before the Court were as follows.

- (a) Does section 13(2)(a) of the Patents Act 1977 (the "1977 Act") require a person to be named as the inventor in all cases, including where the applicant believes the invention was created by an Al machine in the absence of a traditional human inventor?
- (b) Was Dr. Thaler nevertheless the owner of any invention in any technical advance made by DABUS and entitled to apply for and obtain a patent in respect of it?

Regarding the first issue, the Court held an inventor must be a natural person, i.e. a human being. Regarding the second issue, the Court concluded that Dr. Thaler could not apply for or obtain the patents which were subject to the applications by virtue of Dr. Thaler's ownership of DABUS.

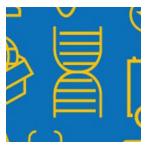
This ruling is consistent with findings at the USPTO, the US Copyright Office, The Court of Appeals for the Federal Circuit, and the EPO.

LIFE SCIENCES NEWS

Another Obviousness-type Double Patent (ODP) Decision

BY RICHARD D. KELLY

On December 13, 2023, the Delaware District Court in *Acadia Pharms. Inc. v Aurobindo Pharma LTD.*, C.A. No.20-985-GBW (copy **here**), decided cross-motions for summary judgment of patent invalidity filed by MSN Laboratories, co-defendant with Aurobindo, and Acadia's competing



summary judgment motion for patent validity where the sole validity issue was ODP. In deciding the issue, the Court considered the invalidity challenge based on two separate legal arguments.

The patent at issue was U.S.P. 7,601,740 ('740) filed January 15, 2004, challenged for ODP based on U.S.P. 9,566,271 ('271) originally filed as a continuation of the '740 application on May 3, 2006. A restriction requirement was required in the '740 application which resulted in the claims directed to compounds and compositions being elected and the

method of use claims being withdrawn. Subsequently an election requirement was issued in the '271 application and the method of use claims were elected, and the application amended to claim the method of use claims restricted out of the '740 application.

The first question decided was whether the safe Harbor Provision of 35 U.S.C. § 121 applied since the '271 application was filed before the restriction requirement in the '740 application and '271 was not amended to be identified as a divisional until after the '740 patent issued but before '271 issued. Acadia indicated an intent to convert the '261 application to a divisional. The question was the proper interpretation of § 121. The competing interpretations are shown below with Acadia's presented first:

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

Acadia argued the bolded portions discuss two types of reference patents - a patent issuing on an application where a restriction requirement was made, or patents issuing on applications filed because of the requirement. The underlined portion describes the challenged patents/applications-divisional applications, and original applications. As such, in Acadia's reading the "filed before the issuance of the patent" requirement applies exclusively to a challenged divisional patent, not a challenged original application.

MSN reads § 121as follows:

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the **other invention is made the subject of a divisional application** which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application **filed as a result of such a requirement**, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, **if the divisional application is filed before the issuance of the patent on the other application.** The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

The MSN argument is simply that the "divisional application" that needs to be filed pre-issuance of the other patent challenged patent, not a reference patent, here '740.

The Court cited Federal Circuit dictum described 35 U.S.C. § 121 as "sheltering from attack 'a divisional application or ... the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application." *Amgen* 580 F.3d 1340 at 1353 (Fed. Cir. 2009). MSN countered with *In re Janssen Biotech, Inc.*, 880 F.3d 1315, 1321 (Fed. Cir. 2018), where the later filed applications invalidated the earlier filed application on ODP. However, as the Court noted in *Janssen* the later filed applications were not designated as a divisional until after they had issued. *Janssen* rejected the later filed applications as being a divisional application because: "For a *challenged* patent to receive safe-harbor protections, the application must be properly designated as a divisional application, at the very latest, by *the time the challenged patent issues on that application*." 880 F.3d at 1323 (emphasis added). Here '271 was amended to claim divisional status of '740 prior to the issuance, which meant that Acadia had complied with the formal requirements for safe harbor.

While having decided that the '740 patent was safe harbored under § 121, the Court went on to consider the impact of *In re Cellect LLC*, 81 F.4th 1216 (Fed. Cir. 2023), and found the '740 patent valid as well since "a patent must be later filed to be available as an OTDP reference, the Court finds that the '271 patent does not qualify as a proper reference against the '740 patent." (*slip Opinion* at 15). Here '271 was amended to be a divisional application of '740, making its effective filing date the same as that of '740.

It is important that an applicant, when filing a new application in response to a restriction requirement, properly designate the application as a divisional preferably at the time of filing to avoid the possibility of failing to claim the divisional status.

NEWSLETTER EDITOR: SAMEER GOKHALE







Oblon | 1940 Duke Street, Alexandria, VA 22314

<u>Unsubscribe managingpartner@oblon.com</u>

<u>Update Profile | Constant Contact Data Notice</u>

Sent by managingpartner@oblon.com powered by

