Chair’s Notes – Suzannah K. Sundby

Buzz Editor – Suzannah K. Sundby
Microsite Master – John Marquardt
Liaisons – James J. Kelley and Suzannah K. Sundby

● Call for Membership – Canadian Bar Association Biotechnology Committee
The Canadian Bar Association (CBA) Biotechnology Committee is seeking to increase its membership and needs you! In particular, the CBA Biotechnology Committee is looking for those interested in and excited about biotechnology in Canada and abroad, including those who want to become more active in identifying, discussing and disseminating information or simply keeping apprised of biotechnological issues. The only requirement to join the CBA Biotechnology Committee is membership in the CBA.

The mandate of the CBA Biotechnology Committee can be found here.

For more information about the CBA Biotechnology Committee and how to join, please contact the Chair, Geoff Mowatt, at gmowatt@dimock.com.

USPTO Relations – Joseph Mallon and Suzannah K. Sundby

● The next USPTO’s Medical Device Customer Partnership Meeting is scheduled for Tuesday, June 2, 2015. The Partnership Meeting will be followed on June 3rd by a Medical Technology Fair. If you would like to present a topic or would like to suggest a topic for discussion, please contact the customer partnership team at Medical_Device_Customer_Partnership_TC3700@uspto.gov.

 IoT Debora Plehn-Dujowich – Reports that for US National Stage Applications, the USPTO now requires an oath/declaration before an RCE can be filed. Click here to find out more information on this requirement that was hidden in the Hague Agreement Concerning International Designs that was published on April 2, 2015.

Vice Chair – Debora Plehn-Dujowich

Services Leader’s Notes – Carla Mouta

Issues Leader’s Notes – Vicki Norton

Biosimilars – Lynn Tyler and Kristin Connann

● Lynn Tyler – Reports on FDA’s denial of Amgen’s Citizen Petition asking FDA to require biosimilars applicants to certify compliance with the BPCIA’s Patent Dance provisions. more

● Kristin Connann - Reports on FDA’s long-awaited Final Guidance Documents on biosimilars. more

Hot Biotech – Noel Courage and Vicki Norton

● Laura Smalley’s – Provided a Hot Biotech report on the Federal Circuit’s grant of Injunction in Amgen v Sandoz, preventing launch of Zarxio® (filgrastim-sndz) until Amgen’s appeal is resolved. more

Community Leader’s Notes – Ling Zhong
Feel free to send comments and recommendations to a Committee Leader using the Leader’s email icon or send an email the Chair, Vice Chair, and all Leaders by clicking here.

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For National Stage Applications, USPTO Now Requires an Oath or Declaration before an RCE can be filed

The final rules for implementation of the Hague Agreement Concerning International Designs were published on April 2, 2015 in the Federal Register (available HERE). Although the Hague Agreement is directed to design patents, some of the new rules will affect utility patents as well. One such rule requires that a National Stage Application be compliant with 35 U.S.C. §371 for RCE practice under 37 C.F.R. §1.114 to be available.

The portion of the final rules for implementation of the Hague Agreement that relates to RCE practice (p.19390 col. 2-3 of the Federal Register Notice, Vol. 80, No. 63) is reproduced below:

Section 1.114: 35 U.S.C. 132(b), which provides for the request for continued examination practice set forth in § 1.114, was added to title 35, United States Code, in section 4403 of the American Inventors Protection Act of 1999 (AIPA). See Public Law 106–113, 113 Stat. 1501, 1501A–561 (1999). With respect to international applications, section 4405(b)(1) of the AIPA provides that 35 U.S.C. 132(b) applies to “applications complying with section 371 of title 35, United States Code, that resulted from international applications filed on or after June 8, 1995.” See 113 Stat. at 1501A–561. The Office recently revised its rules to permit applicants, including applicants in national stage applications under 35 U.S.C. 371, to postpone filing the inventor’s oath or declaration until the application is otherwise in condition for allowance (subject to certain conditions). See Changes to Implement the Inventor’s Oath or Declaration Provisions of the Leahy-Smith America Invents Act, 77 FR 48776 (Aug. 14, 2012) (final rule). An international application, however, does not comply with the requirements of 35 U.S.C. 371 until the application includes the inventor’s oath or declaration. See 35 U.S.C. 371(c)(4); see also 77 FR at 48777, 48780, 48795 (explaining that the inventor’s oath or declaration is still required for a PCT international application to comply with 35 U.S.C. 371, notwithstanding the changes permitting applicants to postpone filing the inventor’s oath or declaration until after a PCT international application enters the national stage).
Thus, the Office is revising § 1.114(e)(3) to clarify that the request for continued examination practice set forth in § 1.114 added in section 4403 of the AIPA does not apply to an international application until the international application complies with 35 U.S.C. 371 (which requires the filing of the inventor’s oath or declaration in the international application, as well as, for example, the basic national fee and an English language translation of the international application if filed in another language). Section 1.114(e) also is amended to provide that a request for continued examination may not be filed in an international design application, as there is no statutory provision to permit the filing of a request for continued examination in an international design application. Section 4405(b)(2) of the AIPA specifically excludes design applications under 35 U.S.C. chapter 16 from the provisions of 35 U.S.C. 132(b), and there is no provision in the AIPA, PLTIA, or other legislative act making 35 U.S.C. 132(b) applicable to international design applications.

Thus, although the final rules clarify that RCE practice is not available for design patents, they also stress that RCE practice is only available for National Stage Utility Applications that comply with 35 U.S.C. §371 (which requires the filing of the inventor’s oath or declaration in the international application, as well as, for example, the basic national fee and an English language translation of the international application if filed in another language).

The USPTO has not put forth an explicit explanation of how a National Stage Application that has already been filed without an Oath or Declaration will be treated when the Applicant wishes to file an RCE. One possibility that has been suggested is that the USPTO will permit the filing of the Oath or Declaration concurrently with an RCE (see HERE). However, what remains to be seen is the fate of patents that issued from National Stage Applications in which an RCE was filed before an Oath or Declaration was filed (see Carl Oppedahl’s blog post HERE).

The take-home message is to try to get an Oath or Declaration on file as soon as possible for National Stage Applications, to avoid any future problems.

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Debora Plehn-Dujowich
FDA Denies Amgen Citizen’s Petition Seeking Requirement for Biosimilars Applicants to Certify Compliance with Patent Dispute Resolution Procedures

As previously reported, last fall Amgen filed a Citizen’s Petition with the FDA asking the FDA to impose a requirement on biosimilars applicants to certify, before FDA will accept an application for review, that the applicant will comply with 42 U.S.C. § 262(l)(2)(A), added by the Biosimilars Price Competition and Innovation Act (BPCIA), by providing a copy of the application to the holder of the biologics license for the corresponding innovator product.

On March 25, the FDA notified Amgen’s counsel by letter that it denied the petition. After summarizing the BPCIA and Amgen’s Petition, the FDA stated that it denied the petition for several reasons. First, the BPCIA does not impose a certification requirement and does not describe a role for the FDA in enforcing the provisions to provide the application or to engage in the patent dispute resolution process that is part of the same section of the statute.

The FDA also noted that Amgen’s interpretation of the statute to make provision of the application mandatory is the subject of pending litigation. The FDA declined to take the discretionary step of imposing a certification requirement at least while the issue is still pending in the courts.

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FDA Releases Final Guidance Documents on Biosimilars

The US FDA issued three final guidance documents on biosimilars for pharmaceutical manufacturers in late April. These three documents have been in draft form since 2012 include “Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009,” “Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product,” and “Scientific Considerations in Demonstrating Biosimilarity to a Reference Product.”

The Quality Considerations document offers an in-depth view on the analytical studies relevant to assessing whether the proposed biosimilar and reference product are highly similar. The document also considers the manufacturing of biosimilars and the way that sponsors should consider manufacturing changes after completing the initial analytical similarity assessment or after completing clinical studies intended to support a 351(k) application. The guidance provides that analytical similarity studies should include a sufficient number of lots of the proposed biosimilar used in clinical trials, as well as from the proposed commercial process if the process is different from that used to make trial products.

Specifically, the guidance notes “FDA anticipates that more data and information will be needed to establish biosimilarity than would be needed to establish that a manufacturer’s post-manufacturing change product is comparable to the pre-manufacturing change product.”

The Scientific Considerations document remains largely unchanged from the 2012 draft document in terms of substantive information; however, some changes were made for clarity and information was reorganized. The document details the approach that sponsors should take when developing the evidence needed to demonstrate biosimilarity to a reference product, as well as FDA’s “totality-of-the-evidence” approach for reviewing biosimilar applications. The agency continues to stress that sponsors should consult with FDA early and often during the development process because “the type and amount of analyses and testing that will be sufficient to demonstrate biosimilarity will be determined on a product-specific basis.”
The Questions and Answers document presents many of the questions first presented in the draft guidance, while omitting several other questions and also indicating that a few of the questions are in the process of being revised and will be released again for public comment. Significant issues that have been omitted from the Q & A document include those related to interchangeability, biosimilar naming, and standards for indication extrapolation and labeling requirements.

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