UNITED STATES

BioPharma Patents

QUICK NEWS & PRACTICE TIPS

2016 Happy New Year!

A. **Subject matter eligibility and "laws of nature."** As reported in our July 2015 newsletter, the Federal Circuit invalidated claims to a method of diagnosing fetal abnormalities without amniocentesis. This precedent—if it stands—will be a challenge for inventors of new diagnostic methods, even where the diagnostic method is acknowledged as a significant advance over the prior art. The patentee petitioned for reconsideration *en banc*, but the petition was denied on 2 December 2015.[1] The Supreme Court could still agree to review this case.

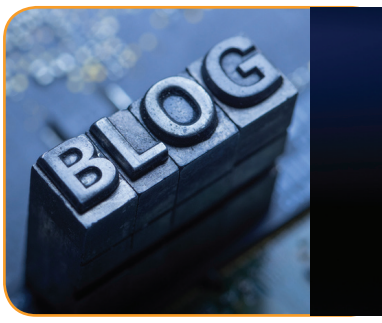
The order denying reconsideration *en banc* includes two very interesting concurrences that suggest that the outcome might have been different:

1. if the claims had been phrased in *Jepson* format ("a diagnostic method for analyzing fetal DNA…, wherein **the improvement comprises**…" emphasis added). (Judge Lourie joined by Judge Moore; or
2. if the claims had been limited to the embodiment that the inventors had **actually reduced to practice**. (Judge Dyk)

Practice tip: Because the basic filing fee includes three independent claims, use the first to write the claim you think you deserve and a second to rephrase that first claim in "wherein the improvement comprises" format. Be sure also to include dependent claims that cover only the exact embodiments that have been reduced to actual practice.

B. **Unhelpful creativity in terminal disclaimers.** The patentee in *Hagenbuch v. Sonrai Systems*[2] found out the hard way that it is better to use the Patent Office's fillable terminal disclaimer forms. While the fillable forms disclaim "the terminal part of any patent granted on **the above-identified application**…" (emphasis added), Hagenbuch submitted a form disclaiming "the terminal part of any patent granted on **the above-identified application** or **any continuation** of it under 35 U.S.C. subsection 120…" (emphases added). As a result, the trial court held that the whole family—including later members in which no terminal disclaimers were filed—expired at the same time as the earlier application in which the terminal disclaimer was filed. **Had the applicant simply filed the USTPO's form, this would not have been the case.**

C. ***Inter partes review* (IPR) of pharma patents.** In December 2015, the Federal Circuit handed down its first appellate decisions following IPR of a pharmaceutical patent. In the twin cases of *Merck v. Gnosis* and *SAMSF v. Gnosis*,[3] the patentee appealed the Patent Trial & Appeals Board's (PTAB) determination that a claimed method of treating homocystinuria was obvious. The Federal Circuit affirmed the PTAB's conclusion that the "preponderance of the evidence" supported a conclusion of obviousness. This is a much lower evidentiary threshold than the "clear and convincing" evidence required to invalidate a claim as obvious in court. **In other words, the *Gnosis* cases show that it is possible to invalidate claims in IPR that would be difficult to invalidate in litigation.** We recommend consulting Harness Dickey's "IPR-PGR Blog" (www.ipr-pgr.com) for tips on how to draft patents that can survive the acid test of validity challenges in IPR.



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[1] *Ariosa Diagnostics v. Sequenom Inc.*, 117 U.S.P.Q.2d 1153 (Fed. Cir. 2015)
[2] 2015 U.S. Dist. LEXIS 39083 (N.D. Ill., Mar. 27, 2015), *rev'd in part on reh'g* 2015 U.S. Dist. LEXIS 120230 (N.D. Ill., Sept. 10, 2015)
[3] CAFC appeals 2014-1778, -1779, -1780, & -1781 (Fed. Cir. Dec. 17, 2015)