Highlighting the patent law developments you should know in biotech, biologics and pharmaceutical cases, legislation and federal agency actions in December 2019, including:

- The Solicitor General, on behalf of the US, asserts that the Supreme Court's Section 101 precedent creates "substantial uncertainty" requiring clarification
- The Federal Circuit holds that there is no single entity requirement for infringement under section 271(g)
- A district court holds that, under certain circumstances, an anticipatory reference is not necessarily "but-for" material under an inequitable conduct analysis

Happy New Year!

Any Questions?

Please contact **David Manspeizer**

Supreme Court

***Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.*, No. 18817 (S. Ct. Dec. 6, 2019)**

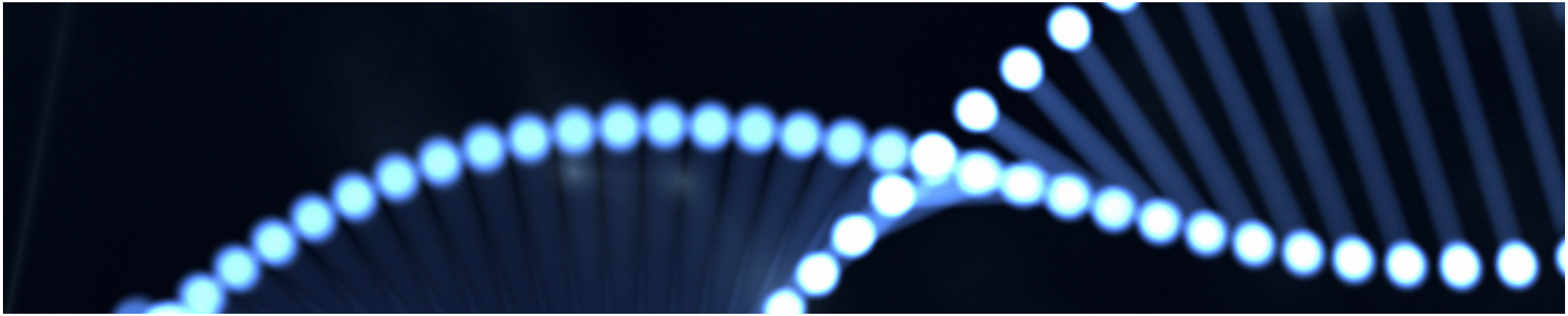
Read the Solicitor General's amicus because the US asserts that the Supreme Court's decisions in *Mayo* and *Bilski* create "substantial uncertainty" and "confusion" requiring a Court review.

On December 6, 2019, the Solicitor General submitted an amicus brief for the US regarding the question of "whether methods of using drugs to treat medical conditions are patent-eligible processes under Section 101." According to the brief, the Federal Circuit correctly decided that method of treatment claims are patent-eligible. However, the US agreed that the Federal Circuit's decision "implicates important and recurring questions on which the Court's recent Section 101 decisions have fostered substantial uncertainty." That uncertainty traces back to the Supreme Court's decisions in *Mayo* and *Bilski*. "The confusion created by this Court's recent Section 101 precedents warrants review in an appropriate case." The brief seems to suggest that *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC.*, No. 19-430 (filed Oct. 1, 2019) might be such a case.

***HP Inc. v. Berkheimer*, No. 18-415 (S. Ct. Dec. 6, 2019)**

Read the Solicitor General's amicus brief if you are a 101 junkie and could not get enough above.

In another December 6, 2019, amicus brief, the Solicitor General also recommended denial of certiorari in a case presenting the question of "whether patent eligibility is a question of law for the court based on the scope of the claims or a question of fact for the jury based on the state of the art at the time of the patent." Harping back to the amicus brief discussed above, the government, again, took the view that the Supreme Court's recent decisions "have fostered uncertainty" concerning the substantive Section 101 standards. Based on that uncertainty, "review to address the logically subsequent, procedural question presented in the petition here is premature."



Federal Circuit

***Amgen, Inc. v. Hospira, Inc.*, Nos. 2019-1067, 1102 (Fed. Cir. Dec. 16, 2019)**

Read the case because the court addresses the application of the Safe Harbor to pre-launch manufacture of commercial batches.

The jury found 14 batches of defendant's biosimilar product infringed one patent and awarded $70 million in damages. The district court denied the parties' post-trial motions. The Federal Circuit first affirmed the district court's claim construction that the method claim at issue was not limited to a particular way of mixing isoforms. After next disposing of other infringement and anticipation arguments, the court turned to the section 271(e)(1) Safe Harbor. Explaining that the relevant inquiry regarding the claimed method of manufacture was "not how Hospira used each batch it manufactured, but whether each act of manufacture was for uses reasonably related to submitting information to the FDA," the court rejected Hospira's jury instruction challenge. Turning to the availability of the Safe Harbor, at issue were 21 batches Hospira's EPO. The jury found seven protected under section 271(e)(1). Substantial evidence supported the jury's finding that the other batches were not protected. While not dispositive, evidence regarding intent to manufacture "commercial inventory" was "probative of whether Hospira's use of Amgen's patented process was reasonably related to seeking FDA approval." The court also disposed of other arguments.

***Syngenta Crop Protection, LLC v. Willowood, LLC*, Nos. 2018-1614, 2044 (Fed. Cir. Dec. 18, 2019)**

Read it because on an issue of first impression, the Federal Circuit holds there is no single entity requirement for infringement under section 271(g).

In a multi-issue appeal, including an interesting discussion regarding pre-emption of copyright claims by insecticide labeling laws, on an issue of "first-impression," the court held that infringement under section 271(g) (import, sales or use of a product made by a process patenting in the US) does not require "a single entity." The "statutory language as a whole is clear that practicing a patented process abroad cannot create liability under § 271(g), whether that process is practiced by a single entity is immaterial to the infringement analysis under that section." The court declined to import the "single-entity" requirement of direct infringement under section 271(a). Infringement under section 271(g) is "not predicated on practicing the claimed process." The context of the "statutory scheme as a whole, and the legislative history" also supported the court's conclusion.

District Court

***Eagle Pharmaceuticals, Inc. v. Hospira*, Civ. Action No. 18-1074 (CFC) (D. Del. Dec. 16, 2019)**

Read the case (subscription required) because the "disclosure-dedication" rule can bar application of the doctrine of equivalents for disclosed, but unclaimed, alternatives.

The defendant moved to dismiss the action for failure to state a claim of infringement. The district court denied the motion as to one patent, and granted it as to eight others. Regarding one patent, the defendant's argument that its product could not meet a "non-aqeuous" limitation was a claim construction dispute not suitable for resolution on a motion to dismiss. Concerning eight other patents, dismissal was appropriate because the plaintiffs' claims of infringement under the doctrine of equivalents are barred by the "disclosure-dedication" rule. The specifications of those patents identified ethanol as an alternative to the claimed propylene glycol, either directly or by incorporation by reference. The court rejected the plaintiff's argument that not every disclosed embodiment listed ethanol as an alternative: "the rule is triggered by any disclosure in the written description that is not claimed." The disclosure of the entire accused product is not required – the issue is "whether the patent discloses the element of the invention that is alleged to be equivalent."

***Quest Integrity USA, LLC v. Cokebusters USA, Inc.*, Civ. Action No. 14-1483 (RGA) (D. Del. Dec. 20, 2019)**

Read the case (subscription required) because, according to the court, under certain circumstances, an anticipatory reference is not necessarily "but-for" material under an inequitable conduct analysis.

The district court held that although a reference had been found to anticipate, as to an inequitable conduct inquiry, such a reference might not be "but-for" material if other anticipatory references were also disclosed and the "PTO erred in not finding other references in the file to have also" anticipated. Thus, to prove "but-for" materiality, the defendant must show that the admittedly anticipatory reference is not cumulative – "it has to prove that other references before the PTO do not disclose similar information."

Legislation

The "Elijah E. Cummings Lower Drug Costs Now Act"

Read the bill because drug price control efforts remain a significant legislative priority in the US.

On December 12, 2019, the House of Representatives passed H.R. 3. The bill requires the Centers for Medicare and Medicaid Services (CMS) to negotiate maximum prices for insulin products and for at least 25 single source, brand-name drugs that do not have generic competition and that are among the 125 drugs that account for the greatest national spending or the 125 drugs that account for the greatest spending under the Medicare prescription drug benefit and Medicare Advantage (MA). The negotiated prices must be offered under Medicare and MA, and may also be offered under private health insurance unless the insurer opts out. The negotiated maximum price may not exceed (1) 120% of the average price in Australia, Canada, France, Germany, Japan and the UK; or (2) if such information is not available, 85% of the US average manufacturer price. Drug manufacturers that fail to comply with the bill's negotiation requirements are subject to civil and tax penalties.

Letter from Congress Regarding the Patent Term Extension Application

Read the letter because patent term extension is one of the foundations of the Hatch-Waxman bargain.

On December 12, 2019, members of Congress, including 11 Senators, requested that the USPTO "conducts a thorough review" of a company's conduct "in order to determine if the company has been candid and acted in good faith with regards to its request for PTEs." The request is based on underlying third-party allegations that the company "deliberately delayed development" of safer drugs to maximize profits. Read *The Washington Post*'s story regarding the underlying allegations.

Executive Actions

Importation of Drugs

Read the notice because importation from Canada and potentially other countries just got more real.

On December 23, 2019, the Department of Health and Human Services, acting through the Food and Drug Administration (FDA), published a Notice of Proposed Rulemaking regarding the importation of certain prescription drugs from Canada in the Federal Register. HHS also issued a draft guidance, setting out a route that would permit manufacturers to import FDA-approved prescription drugs that were originally manufactured and intended to be marketed for sale in a foreign country into the US. Drugs offered under an ANDA would not be eligible for importation under the draft guidance.