THOMSON REUTERS

Westlaw®

MedTech Update 2020 — Legal and regulatory issues to watch for in the medical technology industry in the new year: IP litigation

By Rubén H. Muñoz, Esq., Melissa R. Gibson, Esq., Matt G. Hartman Esq., and Jason Weil, Esq., *Akin Gump Strauss Hauer & Feld

MARCH 25, 2020

Medical device and diagnostics companies and laboratories should anticipate significant legal, regulatory and market changes in 2020 that will have a lasting impact on the industry. From revisions to how the government regulates value-based care, to shifts in the marketplace for medtech mergers and acquisitions (M&A), 2020 will prove to be another year of evolution.

Based on recent trends and developments, Akin Gump has prepared several articles to provide the medtech industry with a landscape overview of the following issues in the year ahead: FDA regulatory developments; federal health care programs; international trade; intellectual property (IP) litigation; False Claims Act enforcement and health information and privacy and data protection.

We plan to monitor and report on these developments and potential updates as the year unfolds.

IP LITIGATION

Expect possible changes to Section 101 challenges on 'patentable subject matter.'

In recent years, courts have invalidated many patent claims as covering unpatentable subject matter under 35 U.S.C. § 101. Courts have rejected claims covering natural phenomena, laws of nature and abstract ideas, and many stakeholders have increasingly questioned the propriety and application of these decisions.

Over the past 12 months, lawmakers have proposed to eliminate the judicially created exceptions under Section 101. Under their legislative proposal, patent claims would rarely be unpatentable solely because of the type of subject matter they cover.

Instead, useful inventions would be patentable so long as they meet the other requirements of the patent laws, including that the invention be new and nonobvious.

Potential changes to 35 U.S.C. § 101 would affect at least two areas of medical technology — diagnostic tests and computer-associated devices.

- *Diagnostic Tests.* Courts have routinely struck down claims that link genetic or biomarker information to specific human conditions as unpatentable laws of nature. For example, a court invalidated claims to a new maternal blood test that allowed detection of fetal abnormalities in a pregnant mother. Another court invalidated claims to a method of detecting an autoimmune disease in a group of individuals for whom other tests failed. Some industry stakeholders are concerned that such decisions lead to uncertainty in patent rights and a decrease in investment into new technologies. The proposed reforms would eliminate the "law of nature" exception. If enacted, claims to useful, new and nonobvious diagnostic tests would be more likely to withstand a Section 101 challenge.

- *Computer-Associated Medical Devices.* Like most industries, medical device manufacturers routinely integrate software applications, including blockchain, artificial intelligence, wearable devices and telehealth platforms into medical devices. Just as courts have routinely invalidated claims to diagnostic tests as unpatentable laws of nature, courts have invalidated claims to devices that incorporate software applications as covering only abstract ideas. For example, one court recently determined that claims covering a heart rhythm detector that warns an individual of conditions like stroke, heart failure or cardiomyopathy covered an "abstract idea." But similar to the diagnostic test analysis, the proposed 35 U.S.C. § 101 reforms would eliminate the need to determine whether a claim covering a device is actually an "abstract idea," and would focus instead on whether the claimed invention was useful, new and nonobvious.

- *Timing.* Although Senate sponsors had planned to revise their initial proposal and introduce a bill in the summer of 2019, a bill has not yet been proposed. As more medical device companies develop and incorporate these emerging technologies, they can expect the rise in the number of Section 101 challenges to continue into 2020, particularly while awaiting proposed legislative changes to Section 101.

2020 may bring changes to statutory language on 'functional claiming.'

To counterbalance the proposed broader scope of patentable subject matter under Section 101, lawmakers have also proposed narrowing the breadth of functional claiming under 35 U.S.C. § 112(f) by requiring enhanced specificity of the disclosure in the specification.

The proposed legislative change would limit any purely functional patent claim language — regardless of the actual language used — expressly to the structures disclosed in the specification.

We expect that any reform to Section 112(f) would likely be introduced in conjunction with the proposed Section 101 reforms; however, disagreement over the exact statutory language used in Section 112(f) appears to be the holdup of actual introduction of a bill.

PTO trends on inter partes reviews will likely continue in 2020.

Since its inception in 2012, the inter partes review system at the U.S. Patent and Trademark Office (PTO) has been a popular venue for challengers to attack the claims of an issued patent based on prior art patents and printed publications.

In May 2019, the PTO designated as precedential two of its decisions explaining the scope of the Director's discretion to institute review specifically related to follow-on petitions and petitions that challenge the patent based on art or arguments the PTO has otherwise already considered.

By the end of 2019, a large number of patent owner preliminary responses included arguments that the Director should exercise discretion and not institute review. We expect that trend to continue into 2020.

This article first appeared in the March 25, 2020, edition of Westlaw Journal Intellectual property.

ABOUT THE AUTHORS




(L-R) **Rubén H. Muñoz** is a partner at **Akin Gump Strauss Hauer & Feld** and represents public and privately held companies in patent and trade secret litigation involving a wide array of technologies, including medical devices, biotechnology, pharmaceuticals and electronics. He represents clients in federal and state courts, before the International Trade Commission and before the Patent Trial and Appeal Board of the United States Patent Office in inter partes review proceedings. He can be reached at rmunoz@akingump.com. **Melissa R. Gibson** is a senior counsel at Akin Gump, where she focuses on intellectual property law with an emphasis on patent infringement litigation in the life sciences and chemical industries. She also has significant experience representing clients in Hatch-Waxman litigations. She can be reached at mgibson@akingump.com. **Matthew G. Hartman** is a counsel at the firm. He focuses on a variety of patent litigation matters, with an emphasis on biological and chemical technologies. Specifically, he represents clients in patent infringement cases involving antibody and pharmaceutical therapeutics. He can be reached at mhartman@akingump.com. **Jason Weil** is a counsel at the firm whose patent litigation practice encompasses a range of technologies, including monoclonal antibody therapies, biosimilars, DNA diagnostics and medical devices. He can be reached at jweil@akingump.com. All are located in the firm's Philadelphia office. A version of this client alert was first published Jan. 7, 2020, on the firm's website. Republished with permission.