The ORACLE is a free newsletter *of recent medical device regulatory & computer information that may be of interest to designers, and device Manufactures.*

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NEWSLETTER FROM **DELPHI CONSULTING GROUP** (**DCG**)

An Internet Based Medical Device Regulatory Service, www.delphiconsulting.com

Delphi Consulting Group (DCG), *provides medical device regulatory (FDA) release to market via the 510(k) and PMA pathways. DCG is Internet based to boost efficiency and reduce costs*

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Other events did take place in 2020 here is one

Most of us were too busy grappling with the pandemic to notice that 2020 was also the year we fell into an AI uncanny valley.

GPT-3, an algorithm that can write almost flawless songs, technical manuals, and short fiction in the literary style of your choice, was launched by OpenAI in June; MIT Technology Review called it "shockingly good—and completely mindless." Algorithms, many of them based on GPT-3, can now design avant-garde furniture, create fake movie actors, or talk to people on Reddit for a week without their realizing that there's absolutely no human intelligence behind the façade. Collectively, unwittingly, only half-aware, we're drifting into an era of AI so perfect it's invisible.

What does that mean for you, your business, and the world you live in? That's what EmTech Digital, this March 23-25, is all about.

Now in its ninth year, EmTech Digital is one of the world's top AI conferences not aimed at AI specialists. As always, we've got some of the best AI researchers, the leading business practitioners, and people working on the social and ethical implications of the technology all under one roof.

FDA Selects First Head of Medical Device Cybersecurity

February 17, 2021

The FDA's Center for Devices and Radiological Health has appointed **Kevin Fu** as acting director of its newly created medical device cybersecurity division.

A prominent medical device security researcher at the University of Michigan, Fu has trained hundreds of engineers at medical device companies in cybersecurity engineering.

He will return to his role at the University of Michigan at the end of a one-year term in which he will also serve with the FDA's Digital Health Center of Excellence.

FDA Adds New Regulatory Science Tools for Assessing Medical Devices

FDA has added five tools to its catalog of regulatory science tools to help assess medical devices.

Amanda Pedersen | Jan 24, 2021

FDA recently added five tools to its catalog of regulatory science tools to help assess medical devices, including phantoms and laboratory methods. Here is a brief description of each new tool, along with a reference link for more information. This catalog collates a variety of over 80 regulatory science tools developed by the Office of Science and Engineering Labs (OSEL) in FDA's Center for Devices and Radiological Health. OSEL plans to continue to expand the catalog as new tools become available.

- Phantom for assessing performance of near-infrared hematoma detectors: A modular, polymer phantom approach that enables evaluation of the performance of hematoma detectors using wavelengths close to the 805 nm isosbestic point of hemoglobin. This tool is used for assessing devices in the area of medical imaging and diagnostics. Click here for more information.
- 3D-printed phantom material and design with tissue-relevant Raman signature: A tool for performing Raman spectroscopy measurements on a well-characterized 3D-printed sample that has tissue-simulating optical properties. This tool is also used for assessing devices in the area of medical imaging and diagnostics. Click here for more information.
- Digital models of retinal vasculature based on a clinical fundus camera image: Digital model available on NIH's 3D Print Exchange site that can be used to fabricate tissue simulating phantoms with biomimetic vascular structures derived from a clinical image. Click here and here for more information, or click here for the digital model.
- Multifunctional method for quantitative evaluation of time-dependent eye hazard from laser pointers: A multifunctional test method for quantification of underreported transient fluctuations in critical radiant power characteristics for multiwavelength laser pointers for evaluation of potential eye hazards. Click here for more information.
- Battery of image quality test methods for evaluation of fluorescence imaging systems. Click here for more information.

What the Minerva Supreme Court Decision Could Mean for the Medical Device World and Beyond

Will the "assignee estoppel" doctrine survive future court decisions, or will other patent protections need to be adopted?

Alejandro Menchaca | Feb 25, 2021

In acquiring new medical technologies, the patent rights to that technology often drive the value of the transaction. An evaluation of the commercial product is all well and good, but much of the value arises from exclusive rights to market the technology. After all, the purchasing company will likely be obliged to invest in that technology to streamline it to its other product offerings, get it past any further regulatory hurdles, and dress it up for market. The last thing the purchasing company wants to

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worry about is competition from the company selling the technology.

On the other side, the selling company doesn't want to be limited in its future product development. Perhaps the technology sold is first-generation technology that may be improved in wholly new ways. The last thing the selling company wants to worry about is restrictions on new technologies that may be applied to its next generation of products.

Interestingly, patent law has worked out some of these concerns, or at least had worked some of them out. Some recent legal developments have changed the landscape and altered some long-standing dynamics between purchasing and selling companies.

The long-standing patent law doctrine at issue is called "assignee estoppel." Assignee estoppel prevents an inventor or selling company from challenging the validity of a patent after the patent has been acquired by a purchasing company. Mainly, the doctrine prevented a selling company from challenging the validity of the patent in a patent infringement lawsuit brought by the purchasing company. The policy behind the doctrine was often stated to be: "an assignor should not be permitted to sell something and later to assert that what was sold is worthless, all to the detriment of the assignee." Importantly, this assignee estoppel applied to only the selling company. Any other person or company could still challenge a patent's validity. Courts noted that "it is the implicit representation by the assignor that the patent rights that he is assigning (presumably for value) are not worthless that sets the assignor apart from the rest of the world and can deprive him of the ability to challenge later the validity of the patent."

Recent developments, however, have substantially weakened the assignee estoppel doctrine. A relatively new procedure to challenge a patent's validity (called inter parties review or IPR) is now available in the Patent Office. One would think that a straight application of the assignee estoppel doctrine would prevent a selling company from availing itself of this IPR procedure to challenge the validity of a patent it previously sold. But the courts have decided otherwise and determined that the doctrine does not control in such IPR proceedings.

A perfect example of these changes arose in a lawsuit between Hologic Inc. and Minerva Surgical Inc. In that case, Hologic owned two patents related to devices for endometrial ablation. The inventor of the patented technology assigned the invention rights to his company, which was later acquired (for $325MM) by Cytc Corporation, Hologic's predecessor. The invention rights matured into two patents and that's how Hologic came to own the two patents in the lawsuit. Years later, the inventor founded a second company, Minerva Surgical Inc. Minerva developed and commercialized its own device for endometrial ablation. Not surprisingly, Hologic sued Minerva for patent infringement of those two patents.

Minerva used the Patent Office IPR procedure to invalidate one of the patents. There was much discussion about whether the doctrine of assignee estoppel could prevent Minerva from availing itself of the IPR procedure to invalidate the Hologic patent. Hologic argued that Minerva, which was the inventor's new company, was estopped from challenging the patent's validity. The courts agreed that the inventor and Minerva should be viewed as one for purposes of assignee estoppel considerations, but ultimately held that the assignee estoppel doctrine is not applicable to IPR proceedings. Minerva successfully invalidated that first patent, notwithstanding the long-standing assignee estoppel doctrine. Minerva successfully invalidated that first patent, notwithstanding the long-standing assignee estoppel doctrine.

The second patent, however, was not subject to an IPR proceeding and continued to trial. The trial court enforced the assignee estoppel doctrine and prevented Minerva from challenging the second patent's validity. Minerva hoped to argue that the second patent was invalid because it was much broader than the original invention rights assigned by the inventor many years earlier. The trial ended with a determination that Minerva infringed the second Hologic patent and owed Hologic $4.7MM.

As one might expect, both Hologic and Minerva felt wronged—Hologic, because assignee estoppel was not enforced in connection with both patents, and Minerva, because assignee estoppel prevented it from showing that the second patent had morphed into an overbroad technology barrier.

The story continues—all the way to the Supreme Court. On January 8, 2021, the Supreme Court agreed to review the application of assignee estoppel in this case. Hologic asked the Supreme Court to review how the courts refused to impose assignee estoppel to prevent Minerva from invalidating the first patent through the Patent Office IPR procedure. The Supreme Court denied that request. Minerva asked the Supreme Court to review how the assignee estoppel doctrine was used to foreclose a validity challenge at trial. The Supreme Court agreed to consider Minerva's question. The Supreme Court's declining Hologic's request but taking on Minerva's suggests that the Court intends to further erode the doctrine of assignee estoppel or perhaps fully undo it. We won't know the Court's decision for another year.

If the Court rules as expected and sharply limits assignee estoppel or abolishes it altogether, what does this mean for the rights of purchasers and sellers of inventions? Sellers will be in the driver's seat. They will be able to profit from sales of those rights and later also challenge those rights and resulting patents should they interfere with future-developed improvements. Purchasers, on the other hand, could find themselves with a lump of coal. But purchasers still hold the purchasing funds—increased future risks may dictate decreased current payments. Purchasers may also wish to explore robust non-compete provisions, but such provisions must be reasonable as to both time and place. Can purchasers extract agreements of no patent challenges? In connection with license agreements, such provisions have been generally found to be unenforceable (but some courts will enforce such provisions if the language is "clear and unambiguous").

The opinions expressed in this article are the opinions of the author and may not reflect the opinions of McAndrews, Held & Malloy, its clients, or any individual attorney. This article is for general information purposes and is not intended to be, and should not be taken as, legal advice.

A DCG housekeeping items

DCG supports ZOOM for conferences and Dropbox for file storage and sharing.

During the end of February, Houston, and all of Texas experienced a very unusual week of very cold weather, with temperatures in the low teens. The result was a large-scale failure of the electric power grid. Days of online activity ware lost, and in DCG case some upset of computers due to power coming on and off. We are pleased to report all is up and running as it should be now.