IAM

Finding stealth prior art before it finds you

Andrew Pinkard, Michael Pomianek and Jason Balich
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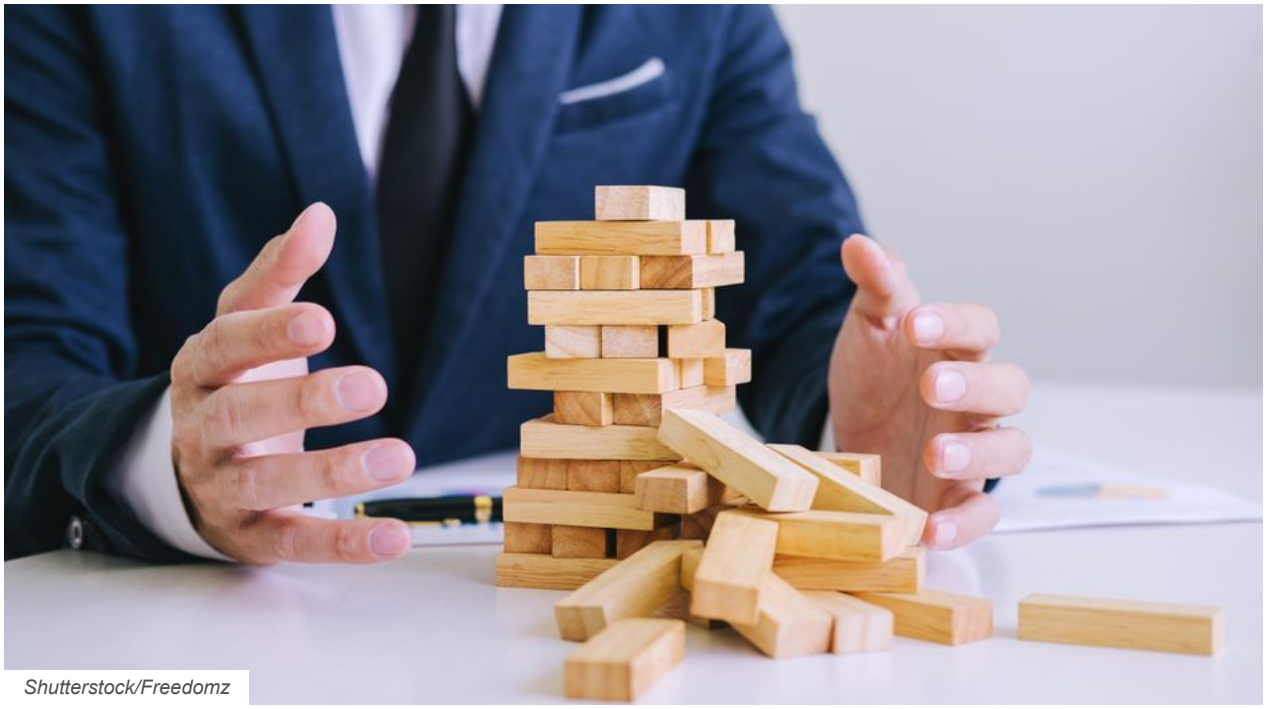

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Last February, Minerva Surgical had its US Patent No. 9,186,208, covering its system for endometrial ablation, invalidated because of stealth prior art that Minerva itself created. Stealth prior art describes activities and disclosures that legally qualified as prior art, but that were often not intended to be a public disclosure by its creator.

Years before filing the application that led to the '208 patent, Minerva displayed an earlier device at an industry conference, and the device happened to meet every limitation of at least one claim of the '208 patent. Unfortunately for Minerva, only the conference attendees knew about the disclosure; no one told the USPTO, nor the lawyers.

Minerva's stealth disclosure was "uncloaked" when Minerva sued Hologic and Cytyc Surgical Products for infringement. Hologic's sleuthy detective work uncovered the disclosure and moved for summary judgment to invalidate the '208 patent. The trial court agreed with Hologic and the Court of Appeals for the Federal Circuit affirmed the trial court's decision. Minerva's loss, however, was both commonplace and preventable.

Whenever inventors (or their employers) publicly disclose innovations prior to filing a patent application, bad things can happen, as illustrated by *Minerva*. In some countries, such disclosure will immediately destroy the ability to obtain a patent on the innovation. In the United States, the consequences may be less dire, but that disclosure starts a one-year clock ticking to either file a patent application to claim that innovation or to forever dedicate the innovation to the public. Below we explain what happened in *Minerva*, we review common circumstances creating stealth prior art, and we explain how to proactively take steps to uncloak it to avoid losing patent protection for your company's technology.

Minerva v Hologic

Minerva develops and makes devices that treat menorrhagia, a condition of abnormal uterine bleeding affecting over 10 million women in the United States. Minerva's commercial product covered by the '208 patent was FDA approved in 2015, the same year the USPTO issued the '208 patent.

Hologic launched a competing product two years later and Minerva sued for patent infringement. Hologic counterclaimed that the '208 patent was invalid because it was anticipated by Minerva's own device that it demonstrated at the 2009 Global Congress of Minimally Invasive Gynecology, sponsored by the American Association of Gynecologic Laparoscopists (AAGL)—known as the industry's "Super Bowl".

Hologic alleged that Minerva's demonstration at AAGL was public activity that should invalidate the '208 patent. In assessing whether public activity triggers the public use bar, courts assess (1) whether the activity constituted a "public use" and (2) whether the disclosed invention was "ready for patenting". The public use element is met if the invention was "accessible to the public or was commercially exploited". The "ready for patenting" element can be either met by proof of "reduction to practice," which occurs when the invention is shown to work for its intended purpose or by proof that the inventor had "prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention".

In *Minerva*, both elements were met. The 2009 AAGL conference was undisputedly open to the public, including doctors who could understand what the Aurora device had to offer. Indeed, Minerva brought 15 of them to its booth, noting "[l]ots of interested [doctors,] including several potential investigators stopping by...". A researcher on Minerva's Medical Advisory Board gave a presentation demonstrating the device, and Minerva described the device in a brochure that was distributed one day after the conference.

The 2009 conference was more than one year before Minerva filed its provisional application in 2011 to which the '218 application claimed a priority date; thus, the Aurora device invalidated Minerva's patent. But the story could have ended differently had Minerva been more attuned to its own creation of stealth prior art.

Lessons from Minerva – uncloaking stealth prior art

The best way of uncloaking stealth prior art rests not with finding it, but rather, avoiding its creation all together. Filing a patent application ***before*** making any potentially public disclosures is one option to avoid its creation.

Stealth prior art is most often created by uninformed inventors, marketers, and businesspeople who disclose their company's unpatented innovations without informing counsel. A proactive step is to train individuals who work in research, product development, and marketing about the risks of premature disclosures. Such information allows for informed decision making.

Another proactive step is to set up systems that encourage notifying counsel preemptively when a disclosure is planned. For example, implementing an invention disclosure form for innovators that asks not just what their invention is, but also when the first anticipated public disclosure or sale will occur. That date can be turned into a deadline for filing patent applications directed towards the innovation.

Another approach is to have employees clear all potentially public disclosures of new research developments, products, and services with counsel in advance. But above all, implore employees to notify counsel whenever a disclosure has been made (even if it was inadvertent or not cleared ahead of time) so that a patent application can be filed before the statutory bar date.

In addition to relying on reporting by others, counsel should proactively investigate whether any stealth prior art has been or is about to be made by looking out for common forms stealth prior art such as:

- disclosures involving trade shows and industry or scientific conferences, including demonstrations of prototypes, presentations, posters, and handouts (as in *Minerva)*;
- disclosures or specifications of proposed products in contracts, proposals, quotes, joint development agreements, supply agreements, and engineering/manufacturing services agreements;
- grants and grant applications;
- sales of goods embodying an innovation— eg, protypes purchased from a contract manufacturer— or even offers for sale regardless of whether the sale is not consummated and even if the terms of the sale and nature of the product sold are secret;
- marketing materials, such as catalogues, pre-launch publicity materials, and operating manuals;
- investor pitches, meetings with potential development partners, and business plan competitions where no non-disclosure agreement is in place;
- regulatory submissions to federal agencies such as the SEC, FDA, EPA, and others, if the public has the right to access;
- public testing of an invention for marketing and usability purposes (testing for purely experimental purposes may be excluded under very limited circumstances); and
- social media posts on Twitter, LinkedIn, Facebook, Instagram, TikTok, and others.

Before any of the above activity occurs, ask what will be disclosed and file any necessary patent applications, ideally before the disclosure is made. Or, if you only become aware of an occurrence after the fact, ask to see what was disclosed. If the disclosure includes an unprotected innovation, file a patent application as soon as possible within one year of the earliest disclosure.

Proactively taking these steps can go a long way to uncloaking stealth prior art before circumstances similar to those that harmed Minerva threaten your patent rights.

Andrew Pinkard

Author | Patent Agent

Wolf Greenfield

Michael Pomianek

Author | Shareholder

Wolf Greenfield

Jason Balich

Author | Counsel

Wolf Greenfield