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POST GRANT REVIEW AND INTER PARTES REVIEW AT A GLANCE

Author: R. Scott Johnson

Patent Office reviews known as a Post Grant Review (PGR) or Inter Partes Review (IPR) of issued patents are constitutional, *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1370 (2018), likely to avoid some sovereign immunity challenge, *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322 (Fed. Cir. 2018), and must thoroughly address every claim under review, *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1352–53 (2018). In short, they're here to stay. Almost anyone can institute these proceedings, but only someone with an injury in fact can appeal to the Federal Circuit Court of Appeals. *JTEKT Corp. v. GKN Auto. LTD.*, No. 2017-1828, 2018 WL 3673005, at *2 (Fed. Cir. Aug. 3, 2018). So how will they affect your patent strategy? Each offers the benefit of a lower standard of review than a district court proceeding. Each can potentially save time and expedite a decision versus a district court proceeding. Each is generally less expensive than a full-blown patent infringement action. And each could impact your business strategy in different ways.

PGRs must be filed within nine months from the date a patent[1] issues. This means that in order for any challenge to be placed, you must be actively monitoring competitor owned patents or, preferably competitor owned patent applications. You must monitor these patents or applications to know which ones have potential claim scope that may cause you concern. That concern can arise from a potential to cover your existing products that came to market after the competitor's invention or products you intend to bring to market.

If you find a patent or an application of concern, you must be prepared to evaluate the patent's validity quickly to timely file a PGR. Thankfully, there are several grounds on which you can challenge the patent. These include whether it meets the requirements of section 101 (usefulness and statutory subject matter issues), section 112 (written description), section 102 (novelty or prior public use), or section 103 (obviousness). If instituted, a PGR is typically decided within 12 months. This is often much shorter than the time to judgment in a litigation but check your jurisdiction's typical litigation timeline.

If you do not challenge the patent within the first nine months, you can still challenge a patent through an inter partes review. An IPR is similar to a PGR except your validity challenges are more limited. In an IPR, you can only challenge a patent based on section 102 (novelty) or 103 (obviousness) grounds. Similar to a PGR, decisions are generally expedited, this time by statute. IPRs must be decided generally within 18 months (extendable to 24 for good cause). An IPR is strongly recommended if you are facing a patent threat to your business – i.e. you may be about to be sued and you have a strong invalidity position based on prior art.

Both of these proceedings offer potential benefits to an accused infringer. If instituted, both have high success rates, but both also have potential consequences if unsuccessful. Be sure to consider PGRs and IPRs as part of any patent strategy.

R. Scott Johnson is Chair of the Litigation practice group at McKee, Voorhees & Sease. He has been a member of the Firm for 20 years and specializes in Mechanical patents and IP litigation services.

[1] PGRs can only be filed for patents with an effective filing date of March 16, 2013 or later.

NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD RULES: TIES TO PATENT PROTECTION AND GENE EDITING

Author: Cassie J. Edgar

In 2016, Congress passed an amendment to the Agricultural Marketing Act of 1946 to establish a national bioengineered food disclosure standard. This law was an important milestone in establishing transparency for consumers, ensuring labeling certainty for innovators developing new products, and preventing proliferation of independent state-by-state disclosure laws which would make food packaging unworkable from a compliance perspective.

The question of what will be labeled begins with specifying that the product must be "food" and must be "bioengineered".

What is food?

In the National Bioengineered Food Disclosure Standard, Food is defined as: A food [(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." (per 21 U.S.C. 321(f))] that is intended for human consumption. (7 U.S.C. 1639(2).)

So, yes to that wine from Sonoma County, a green smoothie, and even the beloved frosted brown sugar cinnamon Pop-Tart. No to KeyGene's patented guinea pig, at least in the States.

What is "bioengineering"?

The amended Act defines "bioengineering" as referring to a food "(A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature." 7 U.S.C. 1639(1).

Details on each of these components of the definition are to be determined, and the USDA is seeking public comment on this definition including whether, for example, highly refined products such as sugars and oils would contain any modified genetic material.

Interestingly, USDA anticipates that in applying the "found in nature" component of the definition of "bioengineered", they will consider whether a modification has intellectual property protection and was able to meet the patentability criteria of 35 U.S.C. 101, which excludes products of nature from patent protection.

Based on recent U.S. Supreme Court decisions, the U.S. Patent and Trademark Office issued updated guidance to examiners outlining the criteria to determine when inventions are products of nature and therefore not patentable subject matter under 35 U.S.C. 101. *See* for example, U.S. Patent and Trademark Office's 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 FR 74618, 74622-24 (Dec. 16, 2014), and the more recent Memorandum from Deputy Commissioner for Patent Examination Policy to Patent Examining Corps titled "Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant's Response to a Subject Matter Eligibility Rejection" (May 4, 2016).

USDA states that "AMS believes that there are similarities in how a product of nature is interpreted for purposes of patent eligibility and how a modification could be found in nature, for purposes of determining whether a modification is bioengineered". Learn more here.

This is another example illustrating the importance of tying intellectual property and regulatory strategies together, as IP and regulatory agencies review and consider each other's regulations and product-specific documents during the commercialization lifecycle from discovery through post-launch.

Where does that leave products of gene editing?

For products produced by site-directed mutagenesis such as CRISPRs where technology is simply used to "text edit" an existing gene to change a "typo", there is no recombinant DNA technique such as a plasmid insertion involved. Therefore, based on the literal text of the definition, this would not qualify as "bioengineering" as outlined in the Act.

However, once the final rule is implemented, it will become clear whether implementing guidelines expressly exclude products of gene editing or if it will be considered on a case by case basis dependent on the technology as implemented. Issues include whether "recombinant DNA techniques" may include the use of an HDR template and/or guide RNA, and whether products who have met the threshold of patentability under 35 USC 101 by arguing they are not found in nature, even though similar products exist in nature, end up as "bioengineered" in the final rules.

If gene edited products are indeed expressly excluded, does this mean that each state can draft and implement separate legislation regarding labeling for gene edited food products?

This topic was addressed through a section directed to federal preemption, mentioned without discussion in the published rule, noting simply that "Subtitle F addresses Federal preemption of State and local genetic engineering labeling requirements". Subtitle F, below, uses the phrase "genetic engineering" distinct and presumably broader than the strictly defined "bioengineering", but final interpretation is yet to be determined (7 U.S.C. 1639i).

FEDERAL PREEMPTION. - No State or a political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food or seed in interstate commerce any requirement relating to the labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered (which shall include such other similar terms as determined by the Secretary of Agriculture) or was developed or produced using genetic engineering, including any requirement for claims that a food or seed is or contains an ingredient that was developed or produced using genetic engineering.

Further complicating factors include the tie in to the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.), international labeling laws, requirements for importers, and situations where FDA may have voluntary or mandatory labeling requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA).

What will the label look like?

The draft rule proposes options for use of logo and information placement depending on product type and package size, utilizing symbols that display "BE" (bioengineered). There is also allowance for use of an electronic link such as a QR code as proposed by GMA, if accompanied by a telephone number.

What happens next?

On August 31st, the USDA submitted a proposed final rule to the Office of Management and Budget (OMB). OMB will have 90 days to review and then publish a final version. Legal challenges to this rule are anticipated for several reasons such as USDA missing the July 29th statutory deadline to finalize this rule.

Cassie J. Edgar, Patent Attorney and Chair of the Regulatory & Product Development Law practice group, advises clients in product life-cycle management from discovery through post-product launch, including intellectual property, crisis management, compliance, stewardship, regulatory data package generation, lobbying, and obtaining regulatory permits and matters with USDA, FDA, EPA, and FTC. For additional information, please visit MVS or contact Cassie directly via email at cassie.edgar@ipmvs.com.

U.S. AND CHINA TRADE WAR AND IP PROTECTION

Author: Xiaohong Liu, Ph.D.

President Trump is continuing to escalate his administration's trade war with China with currently no resolution or end in sight. In July, the United States Trade Representative (USTR) imposed an additional duty of 25% on 818 products of China, worth $34B, under Section 301 of the Trade Act of 1974. Then, USTR imposed additional duties on another 284 products worth $16B. After China retaliated in-kind, the USTR proposed the imposition of an additional 10% tariff on an additional $200B of Chinese imports. Failing to stop China's retaliation and bring China back to the negotiation table, President Trump raised the tariff to 25% on the additional $200B of Chinese imports in late July/early August.

President Trump's reasons to wage this trade war with China include that U.S. exports to China about $130B and China to U.S. about $500B, China unfairly protects its home market and violates U.S.'s companies' IP rights, and China uses its government power to buy or pirate private companies and their technologies. The President believes that this situation has been going on for too long and changes must be made. Because of this, IP rights in China have become a focus point in a lot of Americans' minds.

Why you ask? Because products from China are generally cheap and enrich Americans' lives. American companies' profits have also been improving year after year and stocks generally continue to rise.

According to some in China, more than 40% of its exports are made by foreign companies, most of them American companies. Foreign companies made a lot of money from cheap labor, lax environmental regulations, and weak IP rights in China. It is not hard for every American to notice that every new gadget he/she buys these days most likely is made in China and exported to the United States, but by a U.S. company.

The iPhone is a great example. Apple just became the first $1T company, because Americans' innovation and Chinese manufacturing power. Apple manufactures its products in China and exports to the U.S. and the rest of the world.

China certainly benefits too. China has become the second largest economy next to the United States. China's improved economic standing is evident everywhere. Chinese tourists are in every major U.S. tourist destination, Chinese home buyers with cash are in every hot real estate market, and almost every major American university is paying Chinese students to attend.

The downside of running trade deficits for such a long time becomes more obvious. While Americans bought a lot of cheap stuff that ended in garbage sites, America has lost so many jobs to China and many working Americans have not seen wage increases for a long time.

On the other hand, China is positioning itself to upgrade its industries, to transfer its manufacturing power from producing low-end products to high-tech gadgets, and to surpass the United States in overall manufacture production around 2025. In addition, China's population is aging, the cheap labor force is shrinking, and the cost of production is also rising. More importantly, as the living standard is improving, Chinese people want a better environment and a higher living standard, just like Americans. What China needs now is technology, i.e., Americans' IP, instead of labor intensive and environmentally-destroying factories.

Certainly, Chinese governments at every level have upgraded their policies and incentives to acquire IP themselves or to encourage their domestic industries for doing so. Some IP professionals in the United States have said that China is becoming their preferred place to enforce IP and litigate. Patent applications and trademark registrations are skyrocketing in China. While IP protection is not perfect in China, it is hard to deny that IP protection in China is continuously improving.

No matter how we analyze the cause, motivation, advantages or disadvantages, and potential winners or losers for the United State and China trade practice and the current trade war, IP rights and the protection thereof are the undeniable deciding factor in the future. It is more important than ever for a company to protect its IP rights in China.

Xiaohong Liu, Ph.D., is an Intellectual Property Attorney in the Biotechnology & Chemical Patent Practice Group at McKee, Voorhees & Sease, PLC. He is a native Chinese speaker and would be happy to discuss this topic with you in further detail. For additional information, please visit www.ipmvs.com or contact Xiaohong directly via email at xiaohong.liu@ipmvs.com.

SUPREME COURT TO DECIDE WHETHER "SECRET SALES" ARE PRIOR ART

Author: Michael C. Gilchrist

Prior art is any publication or activity that can be cited to find a claimed invention invalid as not new or as a merely obvious combination of existing elements. Until recently, the law had been settled that any sale (within the United States) of a product that included claimed features of an invention is prior art, even if the sale did not publicly disclose those claimed features. In other words, patentees were not allowed to extend their exclusive period by making secret sales before filing a patent application. This had the positive effect of encouraging inventors to file patent applications early, rather than withholding the details of their invention from the public. On the downside, it also meant that inventors could, unless they structured the transaction properly, inadvertently create prior art by purchasing their own invention from a fabricator before making the invention public.

The old rule was based on a law that defined prior art as something that was "described in a printed publication in this or a foreign country or in public use or on sale in this country". In 2013, the statutory language was changed to read "described in a printed publication, or in public use, on sale, or otherwise available to the public". The addition of the phrase "or otherwise available to the public" could mean that that the listed categories must make the invention "available to the public" to qualify as prior art. This would exclude secret sales from being prior art.

Old Language

"described in a printed publication in this or a foreign country or in public use or on sale in this country"

New Language

"described in a printed publication or in public use, on sale, or otherwise available to the public"

In the case of Helsinn Healthcare v. Teva Pharmaceuticals USA the Supreme Court agreed to answer the question whether secret sales qualify as prior art under the new law. In *Helsinn*, the patentee agreed to purchase its own drug from a manufacturer before the drug was approved for sale to the public. The agreement was subject to a confidentiality agreement. The Court of Appeals for the Federal Circuit found that the new language in the 2013 Act did not change the meaning of what qualified as being on sale and held the patent invalid in light of the product being on sale before the critical date. Briefing at the Supreme Court will conclude this fall with a decision likely sometime next spring.

Michael C. Gilchrist is a patent attorney in the Mechanical and Litigation practice groups. Mike has been an intellectual property attorney at McKee, Voorhees & Sease for 10 years, serving clients' intellectual property needs.

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REGULATION OF GENE EDITED PLANTS BY THE EPO

Author: Heidi S. Nebel

The gene editing world was dealt a tremendous blow by the European Union in a decision issued July 25, 2018.

This came as a surprise, as all U.S. indicators were that breeders and seed companies were poised to enter a new age of plant breeding and commercial production of specialty crops. These specialty crops are designed to offer consumer, producer and grower traits such as increased omega fatty acids, increased protein content, improved disease resistance, better pest resistance, increased storage time, and the like. The possibilities appeared endless.

It all began with the non-browning mushroom developed at Penn State and the Waxy corn trait from Pioneer/DuPont (now Corteva). Each of these varieties had been created using CRISPR/Cas 9, a gene editing protocol that precisely "edits" a DNA sequence. While CRISPR can insert heterologous genes like traditional genetic engineering (think RoundUp Ready® Soybeans - which have a bacterial herbicide resistance gene inserted), it can also delete sequences in a very precise manner. This means that no heterologous DNA is incorporated into the plant genome. The system simply snips and removes DNA at a specifically designed target. The system is then degraded leaving no foreign DNA while creating a heritable deletion that the plant will pass on to future generations. The non-browning mushroom and waxy corn, each was held to be exempt from GMO regulations by the USDA. Earlier this spring, the USDA went a step further to state that ALL gene edited crops with a deletion would not be subject to GMO regulations.

This success in the U.S. emboldened breeders had hoped the U.S. was setting a precedent for the world to follow. These hopes were dashed as the European Union (EU), which has extremely difficult regulations on GMO crops, announced that it will treat gene edited crops as "genetically modified". The decision was handed down by the Court of Justice of the EU, finding that these crops fall under the 2001 directive. This directive introduced the most restrictive GMO regulations in the world and was aimed at species into which entire heterologous (foreign) genes had been inserted. The directive exempts organisms whose genomes were modified using mutagenesis techniques. These techniques have been used by breeders since the 1920's to induce changes in DNA material in plants. In mutagnenesis breeding, the plant is exposed to a chemical or physical mutagen, such as irradiation, disrupting DNA causing random DNA modifications which are then screened for potential beneficial traits to use in breeding. Think of it as shuffling a deck of cards.

The Court had been asked to interpret the 2001 directive in light of newly emerging gene editing technology. It certainly seems that gene editing is more akin to mutagenesis than insertion of entire foreign genes. The ruling held that mutagenesis techniques developed after 2001 did not have a sufficient record of safety to qualify for the exemption granted for mutation breeding. In a small glimmer of hope, the ruling leaves open that possibility that if gene editing techniques could prove as safe as mutagenesis, then they too could earn an exemption. How long will this take? Nonetheless, the immediate chilling effect on Agricultural research in those countries cannot be denied.

Heidi S. Nebel is the Chair of the Biotechnology & Chemical Practice Group at MVS. She serves as the Managing Member of the Firm and has been assisting clients with intellectual property matters for over 25 years.

GET TO KNOW YOUR IP TEAM

Kirk M. Hartung

1. How do you feel IP has changed in the Mechanical/Electrical field since starting out as an IP attorney?
For purely mechanical inventions, not much has changed. However, in many instances today, mechanical inventions also utilize other technologies, and particularly computers and software.

2. What is your greatest IP success story?
It depends on how you define "success". If it is monetary returns to the inventor, a patent is only one piece of the puzzle for a successful commercial product. Commercial success also involves manufacturing at a reasonable cost, distribution networks, marketing, and product life expectancy. Monetary success can also come through licensing revenues for a patented invention. If success means winning a litigation, I have worked on successful litigation for both patent owners and accused infringers. My preferred definition of IP success is developing strong and lasting client relationships where we help the client achieve their goals and objectives, which we do every day at MVS.

3. If you could give one piece of encouraging advice to clients, what would you say?
It normally takes a team to move from a concept or idea addressing a problem, to reduce the idea to a practical solution, to protect the solution through patents and/or trade secrets, and to get the solution to the marketplace so the public can benefit from your innovations. So get the best team members possible, allow each of them to use their expertise, and hopefully there will be a positive, win/win situation for everyone involved.

4. Outside of the office, what are your favorite hobbies?
I believe there are 3 F's which are all important: (1) Family, both immediate family and extended family; (2) Friends, both near and far; (3) Fun, in many forms. Balance these with work, and you'll be happy.

5. Looking ahead to the next decade of your career, what do you want to influence in the world of IP?
I want to continue to promote all aspects of IP to clients and potential clients, since protecting innovation can be a driver of new and growing businesses and job opportunities, and other economic development and prosperity, for individuals and companies of all sizes, at local, state, and national levels. The basis for our IP system has its roots in the U.S. Constitution. Going back more than 200 years, our Founding Fathers understood the importance of incentivizing and protecting creativity to promote progress in science and the arts. That importance is still true today. I have enjoyed being a part of it for the past 36 years, and look forward to many more years of exciting and fun IP work with clients from Iowa and beyond.

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We've Been and We'll Be

June 5 - 7, 2018

Luke T. Mohrhauser and Lars Gunnerson attended the Iowa Association of Business and Industry (ABI) annual conference. MVS was a sponsor of the conference. Luke and Lars were able to network with many Iowa business professionals and leaders.

June 18, 2018

R. Scott Johnson presented at the Iowa Bar Association annual meeting regarding intellectual property litigation. Scott was able to connect with many Iowa attorneys and in-house counsel.

June 21 - 23, 2018

Kirk M. Hartung attended the International Network of Law Firms (LEGUS) summer annual meeting in Copenhagen, Denmark. Kirk is the Chair of the LEGUS Advisory Board (June 2017-June 2019). MVS is the only intellectual property boutique firm in the network that consists of law firms worldwide.

June 21, 2018

MVS was a sponsor of the James Arthur Albert Foundation annual fundraiser to help raise funds for children in Belize. The funds go to help building schools and supplying the children with tuition and school supplies. To date, the organization has awarded 1,700+ scholarships, provided over $250,000 in textbooks and school supplies and have donated over $167,000 to build classrooms. Brandon W. Clark is on the planning committee for the annual fundraiser.

July 6, 2018

R. Scott Johnson and Christine Lebron-Dykeman presented at the Association of Corporate Counsel (ACC) Wisconsin annual conference. Scott and Christine discussed the potential pitfalls in enforcing trademarks. MVS was a sponsor of the conference.

July 9 - 11, 2018

Heidi S. Nebel, Pat A. Sweeney, Jonathan L. Kennedy, and Lars Gunnerson attended the Association of University Technology Managers (AUTM) Central meeting in Minneapolis, MN. The meeting centered around hot topics in technology transfer and how universities and research foundations are addressing issues. MVS was a sponsor of the conference.

July 19, 2018

Jill N. Link, Pharm.D., and Nick J. Krob presented a webinar for the Iowa Bar Association regarding IP licensing, and monetizing and enforcing patents.

July 25 - 26, 2018

Patent & Regulatory attorney, Cassie J. Edgar, and Patent Agent, Brian D. Keppler, attended the Iowa Biotech Association Animal Health in the Heartland conference. The conference focused on regulatory practice, gene-editing, USDA updates, and much more.

August 9, 2018

MVS was the presenting sponsor of the Business Record Women of Influence Awards. Heidi S. Nebel spoke on behalf of the firm in support of the outstanding women in our community making a difference every day.

August 16, 2018

Cassie J. Edgar presented a webinar for the Iowa Bar Association regarding gene editing with consideration to intellectual property and regulatory law.

August 19 - 23, 2018

Jonathan L. Kennedy and Xiaohong Liu, Ph.D. attended the American Chemical Society (ACS) fall meeting in Boston, MA. The conference, *Nanoscience, Nanotechnology & Beyond*, focused on the latest news and information in the chemical industry.

August 28 - 30, 2018

MVS sponsored the Iowa AgriTech Accelerator booth at the Farm Progress Show in Boone, Iowa. This is the Nation's largest outdoor farm event and many agricultural clients attend. Luke T. Mohrhauser and Cassie J. Edgar are both mentors for the Iowa AgriTech Accelerator mentorship program for agricultural startup companies.

September 10 - 12, 2018

Heidi S. Nebel, Jill N. Link, Pharm.D., and Cassie J. Edgar attended the Ag Innovation Showcase in St. Louis, MO. The conference will explore data-driven innovation in novel plant-based foods and nutrition.

September 12 - 13, 2018

Heidi S. Nebel and Jill N. Link, Pharm.D. are attending the Association of University Technology Managers (AUTM) Crop Productivity Partnering Forum in St. Louis, MO. The forum will touch on topics such as growth/yield, precision agriculture, pest control, biologics, chemicals, and genetics/breeding.

September 28, 2018

Many MVS attorneys will be present at the Drake University Clark 150 Celebration Banquet. The Celebration marks the 150th anniversary of the Iowa Supreme Court decision in Clark v. Board of Directors. MVS is a sponsor of the banquet.

September 27 - 28, 2018

Heidi S. Nebel will be attending and speaking at the Association of University Technology Managers (AUTM) 2018 The Conversation: A Leadership Forum. The Forum will consist solely of panels to encourage a high-level conversation regarding technology transfer. Heidi will sit on a panel with Sandra Coufal from Sibling Capital, LLC, Laura Johnson from DexCom, Inc., and Paul Michel, Former Chief Justice, United States Court of Appeals for the Federal Circuit. MVS is also a sponsor of the Forum.

If you're interested to learn about what our MVS attorneys attend and learn, please contact them through www.ipmvs.com or by calling 515-288-3667.