



BRIEFS

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THE ROLLERCOASTER RIDE OF GENE THERAPY

Author: Oliver P. Couture, Ph. D.

Gene therapy has had several ups and downs since the idea of editing genes for therapy was first published in 1972. While there have been several instances of successful attempts of treatment in humans, there have also been cases failures which have, at times, temporarily halted clinical studies.

One of the main issues with gene therapy has been the targeting of the molecular machinery to where it is needed and to avoid places it is not. The off-targeting of gene therapy is perhaps the biggest issue that needs to be addressed as it directly relates to patient safety. In the past few years, this issue has been addressed using various nuclease systems, such as Zinc Fingers, TALENS, and CRISPR. These systems have improved not only targeting, but also the efficiency of making changes to chromosomes.

However, these systems also have their drawbacks. For example, the most commonly used CRISPR system can only target about 10% of the genome. It has also been disclosed this year that, contrary to initial studies, CRISPR may have more off-targeting than originally thought. Additionally, a lab in Germany recently has shown that the immune system of most of the healthy volunteers for the study could produce antibodies against the CRISPR nuclease when it was injected. This immunity is likely to run across most forms of the CRISPR nuclease and across multiple species as the nuclease is highly conserved. These studies have shown that the current system has a number of limitations.

These limitations highlight the need of continual innovation in this area. Researchers have already shown some improvements to the nuclease itself. This year a lab at MIT used computation prediction to look for CRISPR nucleases that might be less site restrictive than the most commonly used one. By testing their predictions, they were able to find a nuclease which targets up to half of the genome, five times what the commonly used nuclease can target.

This shows that future innovations may create synthetic nucleases that could target anywhere in the genome by changing how the nuclease interacts with nucleic acid. Additionally, further innovation is needed to decrease the off-targeting of these systems and to hide them from the host's immune system to improve their safety and efficacy for patients.

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LIGHT AT THE END OF THE TUNNEL? EXPANDING CONCEPTS OF WHAT IS PATENTABLE SUBJECT MATTER

Author: [Patricia Sweeney](#)

Justice Warren Burger in the seminal case of *Diamond v. Chakrabarty* found that Congress had intended patentable subject matter to “include anything under the sun that is made by man,” holding that an engineered bacterium used in treating oil spills was patentable. *Diamond v. Chakrabarty*, 447 US 303 (1980). Yet interpretation of subsequent decisions on what is patentable by the US Patent Office has been criticized as overly restricting what can be patented and crimping innovation. Just this year court decisions and actions by the US Patent Office have offered hope for improved predictability and clarity especially as it relates to products of nature and abstract ideas and offers guidance on how to craft claims to avoid a section 101 rejection.

The issue is whether a claim attempts to patent an abstract idea that could be wholly performed in a person’s head or a law or phenomena of nature, which cannot be patented. 35 U.S.C. §101. In *Mayo v. Prometheus Labs*, 566 US 66 (2012) a method for optimizing dosage of drugs by measuring the level of metabolites in blood was found invalid. In *Alice Corp. v. CLS Bank Int’l*, 573 US ____ 134 S. Ct. 2347 (2014) a two-step analysis was presented.

As modified since *Alice* the steps are as follows.

Step 1: are the claims directed to a process, machine, manufacture or composition of matter?

If no, it is not patentable.

If yes, Step 2a asks: is it an abstract idea, law of nature or product of nature? If the answer is yes, Step 2b asks if the claim recites something “significantly different” or “significantly more” than the judicial exception to patentability.

The 2b step is by its nature fraught with subjectivity and faced varying analysis as to whether the standard is met. In 2014 new US Patent Office guidelines presented gunpowder as an example of non-patentable subject matter. Among the organizations calling for legislation to address subject matter eligibility interpretation is the American Bar Association Intellectual Property Law Section (Letter of March 28, 2017), the Intellectual Property Owners group (IPO Daily News, January 2017) and the American Intellectual Property Law Association AIPLA (May 2017).

While these efforts continue, court decisions and recent efforts by the USPTO Director have provided tools to combat such rejections and a hint of relief to come.

In a decision this year, the Federal Circuit held that a diagnosing method was patentable in reciting an administration step. The patent in question was to a method of treating schizophrenia patients with iloperidone. The dosage is adjusted to avoid adverse cardiac impact by determining if the patient has lower activity of a gene called CYP23D6. *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int’l*, 887 F.3d 1117 (Fed. Cir. 2018). It distinguished the diagnosis claim of *Mayo*, saying that claim was not directed to a new method of treating a disease but to a diagnostic method. Here, the claims do not “tie up the doctor’s subsequent treatment decision” but recite a dosage regimen. *Id.* at 1135. It also noted that in the *Myriad* decision, which found naturally occurring DNA to be unpatentable products of nature, even if isolated, the Supreme Court was careful to state method claims were not implicated in its decision (citing *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.* 569 U.S. 569, 580 (2012)). Also this year, the Federal Circuit stated that simply because steps are known does not necessarily mean they are conventional. *Exergen Corp. v. Kaz USA, Inc.* 2016-2315, 2016-2341 (Fed Cir. 2018) (nonprecedential).

It upheld a lower court decision that a body temperature detector calculating core temperature by applying an algorithm to temporal artery readings from swiping across the forehead was not eligible. While it applied laws of nature, the Court found the combination to meet the “significantly more” needed to be patentable. Importantly, the Court observed the steps were known but never combined in this matter, adding, “Something is not well-understood, routine and conventional merely because it is disclosed in a prior art reference.” *Id.* at 10. It confirmed its earlier holding in *Bascom* that a method of filtering internet content was not conventional or generic. *Bascom Glob. Internet Srvs.*, 827 F.3d, 1341, 1350 (Fed Cir. 2016). The Court there found unconventional applications of known concepts overcame a finding of subject matter ineligibility.

Further changes are ahead in how patent examiners analyze eligible subject matter issues as revealed by the US Patent Office Director Iancu in September address. He says the Office is working on revised patent eligibility guidelines and his comments reflect he aims to keep subject matter analysis separate from obviousness. Recognizing that there is a need for more predictability, he says the guidelines will list exceptions to patentability and if the claims do not fall within that list, the section 101 analysis ends. His basic concerns are abstract ideas, such as mathematical concepts; methods of organizing human interaction; pure mental processes (such as an observation) and pure discoveries of nature (such as gravity, etc.).

If the claims fall within the exceptions, claims are reviewed to determine if in addition to the exempted matter, claims are directed to “significantly more” and refers to the Berkheimer memo.

This critical 2018 memo from the Office represented a change in what examiners can rely upon when finding that the “significantly more” standard is not met. Previously, an examiner could rely upon his or her own expertise in the art to find the significantly more addition is routine and conventional and fails step 2b. Instead, the Office said evidence may be required from the examiner to support the conclusion and that evidence is limited to: 1) a statement in the application specification or made during prosecution; 2) a court decision; 3) a publication; or 4) by the examiner taking “official notice” of a fact. However, the memo continues, simply finding elements in a single patent or publication is insufficient absent demonstration that such elements are widely prevalent or in common use in the field. Further, if the examiner is challenged on taking official notice, the examiner must present evidence.

New case law, patent office memos and promises of new guidelines hold hope that predictability may return to section 101 analysis. Indeed, in the Berkheimer memo, the Office made note that, “The USPTO recognizes that unless careful consideration is given to the particular contours of subject matter eligibility...it could ‘swallow all of patent law.’” By putting the burden on the examiner to demonstrate a significant addition has not been made, the Patent Office returns to the roots of patent law, that “anything under the sun” made by the hand of man is patentable.

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CAN COMPETITORS USE YOUR TRADEMARKS IN THEIR WEB PAGES OR AS ADWORDS TO DRIVE BUSINESS TO THEIR WEB PAGES?

Author: [Mark D. Hansing](#)

The article below discusses state of the law regarding competitors using your trademarks in their advertising or web pages, or competitors purchasing your trademarks as what are called “AdWords” or “keywords” so that your competitor’s website comes up higher in a search engine search when people use your trademarks as search terms.

The problem

Many of our clients are rightfully concerned about competitors using their trademarks in the above ways. Shouldn’t this be trademark infringement?

Short answer

The law hesitates to make illegal any use of your trademarks by a competitor. It allows fair, comparative advertising, even when it specifically calls out your trademark. To prevail, you would have to show potential consumers are likely to be confused. This can be difficult if the competitor prominently displays its trademarks and only uses your trademark to discuss a comparison of their products with yours. It can be difficult to convince a judge or jury that confusion is likely when the competitor’s trademark is clear and prominent. One way to prevail is to prove numerous instances of actual confusion -- e.g. witnesses or documents that show your prospective customers thought your competitor was you, based on their use of your trademark. But, again, this is tough if the competitor uses its trademark.

Similarly, Courts have hesitated to stop others from purchasing your trademarks as keywords or AdWords. Although some courts have disagreed, most courts hold this is not trademark infringement. Keywords or AdWords are normally never seen by the public. They are simply auctioned by search engine providers like Google. When people put your trademark into a search request, the owner of purchased AdWords increases their chance for priority placement in the search results (their website comes up higher in the results). Most courts fail to find any likelihood that potential customers would be confused because of it. In fact, some courts have boldly stated that in an Internet-savvy world, we all expect that search results based on our search terms may bring up sites we are not looking for or are competitive with the one we are looking for, and that we are sophisticated enough through self-help to drill deeper to find what we were really looking for. This view seems debatable, but recent commentaries on this issue conclude it is the present status of the law.

So, can you sue and likely win when a competitor either uses your trademark in comparative advertising or purchases search engine AdWords including your trademarks? It is not impossible, but cases usually result in you providing a lot of evidence that consumers are actually confused, and not simply an argument that there is the possibility of confusion.

If you do not have compelling actual confusion evidence, typical techniques of trying to show likelihood of confusion include a professional trademark survey. There are companies that run these. They identify prospective customers for your products and services and present questions designed to probe the potential for confusion based on the competitor’s use of your trademark. These take some time and could cost tens of thousands of dollars. Also, courts like to see at least 10% to 20% potential consumer confusion. Competitors can also run their own surveys and sometimes they come up with different results.

Initial interest confusion

For a while, trademark owners got some courts to agree that even if savvy Internet users eventually figured out the website with the highest ranking was not the one their search was looking for, it was trademark infringement or unfair competition based on what is called “initial interest confusion”. As the term implies, it was considered evidence of actual confusion – for at least some period of time. Essentially the argument was this was a clear, intentional attempted diversion of customers. On the face of it, it seems squarely to fit the test of trademark infringement.

In the case of *1-800 Contacts, Inc. v. Lens.com, Inc.*, 722 F.3d 1229 (10th Cir. 2013), LENS.com showed in court over 1,000 initial interest confusion events after 1-800-Contacts bought Google AdWords with the Lens.com trademarks. Lens.com argued that contact lens purchasers ordering online want to do it quickly and, thus, this is clear actual confusion and economic damage. However, in today’s sophisticated digital world, through computer forensics 1-800-Contacts showed only 25 of those 1000 (1.5%) actively clicked through to their website. The court found that this was insufficient to show meaningful actual confusion and Lens.com lost.

Takeaways

Even with provable evidence of possible confusion because of purchased AdWords, the courts are still skeptical unless a substantial number of click-throughs to the competitor’s site resulted in provable lost business. Therefore, unless the competitor uses your trademark in substitution of theirs (e.g. their trademark never appears on their website, which is rare) without strong high quantity evidence of actual consumer confusion, it is difficult to prevail.

Some commentators go as far as to say that the best course of action is self-help is recommended--that you should bid on as many AdWords as you can so that hopefully you get them and not competitors, or at least it forces the competitor to spend more money to out-bid you.

At a minimum, it is good to be aware of this paid search marketplace. To the extent it is possible and economically reasonable to purchase AdWords of your trademarks, it is probably good practice. Otherwise, always watch for and document any events that could be considered actual confusion and evaluate with trademark counsel if it rises to a level to take action.

Mark D. Hansing is a Patent Attorney and Member in the Mechanical Patent Practice Group and has been with MVS since 1981. For more information, please visit the MVS website or contact Mark directly via email at mark.hansing@ipmvs.com.



JONATHAN L. KENNEDY JOINS MEMBERSHIP AT MCKEE, VOORHEES & SEASE PLC



Effective January 1, 2019, Intellectual Property Attorney, Jonathan L. Kennedy will become an official Member of McKee, Voorhees & Sease, PLC (MVS).

Jonathan began his career at MVS in September of 2012. His practice has spanned intellectual property law, including, with transactional and litigation work in patents, trademarks, copyrights, and trade secrets. Since then, Jonathan has focused his practice in patent prosecution and intellectual property litigation. He has represented a wide-variety of clients including Fortune 500 companies, universities, start-ups, and individual inventors. Jonathan's patent practice focuses on inventions related to chemistry, nanotechnology, and materials science. Example industries that he routinely prepares and prosecutes patent applications in include the energy, medical, and cleaning industries.

Adding to his background is a Master's degree in Bioethics where he focused his research and writing on the ethics of technological regulation at the federal level. During law school, Jonathan was Research Editor for Volume 60 of Drake Law Review, served as a junior staff member of Drake Law Review, was Vice President of Drake Law School's Intellectual Property Law Society, was a member of Drake Law School's Intellectual Property Moot Court Team, and was a Research Assistant to Visiting Professor Miguel Schor. He had the honor of publishing his student note addressing a federal circuit split relating to copyright registration timing in Volume 60 of Drake Law Review.

He is the Chair of the Iowa State Bar Association IP Section Council (2017 - 2019) and is Division Chair for the American Chemical Society's Division of Chemistry and the Law (2018). Jonathan has been recognized by Best Lawyers in 2018 and 2019 for his work in the trademark law specialty.

Congratulations, Jonathan!

GET TO KNOW YOUR IP TEAM

Jill N. Link, Pharm. D.



1. How do you feel IP has changed in the chemical patent area since starting out as an IP attorney?

Chemical patent law has not changed as significantly as other areas (i.e. biotechnology, diagnostics and software). In my 10+ years of practice the greatest change has been the implementation of AIA ('patent reform'). However, as a majority of my clients protect international portfolios their filing strategies remain vigilant to timely filing before any public disclosures to protect foreign rights.

2. If you could give one piece of encouraging advice to clients, what would you say?

Protecting IP assets is fun and rewarding. Investments of time and money are required; however, seeing your assets commercialized and realizing profits are exciting! It is like watching your baby grow up (but unlike children we expect this 'baby' to pay us back for our investments!).

3. Outside of the office, what are your favorite hobbies?

I love to experiment in the kitchen – both cooking and baking are hobbies. This makes sense since they involve chemistry, math and physics! I also enjoy spending time with my daughter (Evelyn will turn 1 in January).

4. Looking ahead to the next decade of your career, how do you want to influence the IP world?

My goal for influence is a bit more 'local' in focus. As I highly value my relationships with clients, I strive to be their trusted advisor – for the long term – well beyond the next 10 years!



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We've Been and We'll Be

October 3, 2018

[Luke T. Mohrhauser](#) and [Gregory A. Woods](#) attended the Iowa Association of Business and Industry (ABI) Advanced Manufacturing Conference in Altoona, Iowa. MVS was a sponsor of the conference in support of Iowa businesses. Contact Luke and/or Greg to hear about the latest in manufacturing in Iowa.

October 4, 2018

[Christine Lebron-Dykeman](#) attended The Power of Her Summit, hosted by the Des Moines Downtown Chamber. The conference focused on empowering women in the workplace. MVS was a sponsor of the event. Contact Christine to learn about the Summit.

October 11 - 12, 2018

[Heidi S. Nebel](#) and [Patricia A. Sweeney](#) attended the [Association of University Technology Managers \(AUTM\)](#) Western event in Boulder, Colorado. MVS biotechnology & chemical practice group attorneys are actively involved in AUTM association events and conferences. Contact Heidi and/or Pat to learn more about the conference and takeaways.

October 16, 2018

[R. Scott Johnson](#) and [Christine Lebron-Dykeman](#) spoke at the Iowa Association of Corporate Counsel annual conference in Des Moines, Iowa. Scott presented on cybersecurity and post grant review proceedings, and Christine presented on advertising and trademark law. Contact Scott or Christine to learn more about the topics they presented on.

October 16, 2018

MVS sponsored an event hosted by the CRISPRcon Steering Committee. [Cassie J. Edgar](#) is a member of the Steering Committee and hosted a roundtable at the event regarding intellectual property and CRISPR issues on a global scale. The event was held at the Des Moines Downtown Marriott during the World Food Prize conference. Contact Cassie to learn more about CRISPRcon.

October 18, 2018

MVS attorneys attended and sponsored the [Polk County Women Attorneys Association](#) Basket Auction. The event aimed to raise funds for the [Young Women's Resource Center](#). The Resource Center aims to support, educate, and advocate young women ages 10-21.

October 25 - 27, 2018

[Oliver P. Couture, Ph.D.](#), attended the [American Intellectual Property Law Association \(AIPLA\)](#) annual conference in Washington, D.C. Contact Oliver to learn more about the conference.

October 25 - 27, 2018

[Kirk M. Hartung](#) and [Brandon W. Clark](#) attended the [International Network of Law Firms \(LEGUS\)](#) fall meeting in Kansas City, MO. Kirk is the Chair of the Advisory Board and Brandon brought a unique copyright and entertainment perspective to the meeting. Contact Kirk and/or Brandon regarding the meeting summary.

November 1, 2018

[Cassie J. Edgar](#) participated in a webinar for the [Iowa Bio Association](#) titled, "Gene Editing: Regulatory and Intellectual Property Issues". Cassie was joined in presentation by Anya Prince of the University of Iowa and Masha Fedorova of Corteva. The webinar was hosted at the MVS office and several attended online. Learn more about the webinar by contacting Cassie.

November 9, 2018

[Christine Lebron-Dykeman](#) spoke at the [Greater Des Moines Partnership](#) Small Business Success Summit in Ankeny, Iowa. Christine focused her presentation on trademarks and how to protect your brand while not infringing on other brands. Contact Christine to learn more.

November 14, 2018

[Christine Lebron-Dykeman](#) presented a webinar for the Iowa Bar Association regarding Trademark Law updates. Contact Christine for more information or the Iowa Bar for a copy of the webinar recording.

November 16, 2018

MVS sponsored the Greater Des Moines Botanical Garden Champagne and Chocolate event. The MVS litigation team, led by [R. Scott Johnson](#) attended the event in support.

November 28, 2018

[Cassie J. Edgar](#) presented at the [Greater Des Moines Partnership](#) Top 5 Tips for Small Business webinar series. Cassie focused on top 5 intellectual property tips for small business owners. Contact Cassie for more information and a copy of the presentation.

November 30, 2018

[Sarah M. Dickhut](#) and [Brandon W. Clark](#) presented at the 2018 eCommerce and Intellectual Property Law Seminar in Des Moines, Iowa. [Jonathan L. Kennedy](#) moderated the program. Sarah presented on "Protecting IP in the Wake of GDPR, Cybersecurity, and Other Developments", and Brandon presented on "Online Enforcement Procedures: Domain Name Disputes, Take-Down Notices and Other Ways to Protect Your Online Business".

February 10 - 13, 2019

[Patricia A. Sweeney](#), [Heidi S. Nebel](#), [Jill N. Link, Pharm.D.](#) and [Jonathan L. Kennedy](#) will be attending the [AUTM National conference](#) in Austin, Texas. Heidi and Jill are active AUTM members and serve over 35 university and technology transfer clients around the world.

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.