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DECEMBER 2020
BRIEFS

Traps For The Unwary

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Cannabis Variety Patenting in Canada

With the Supreme Court decision *J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.,* 534 U.S. 124 (2001), plant varieties that are the result of traditional breeding techniques have been ratified as patent eligible subject matter. The court in its 2001 decision affirmed the long standing practice (science 1985) of the USPTO in granting such patents consistent with the Board of Patent appeals decision, Ex parte Hibberd, 227 U.S.P.Q. 443 (Bd. Pat. App. 1985). Canada has recently followed suit by allowing patenting of cells of plant varieties that have arisen through traditional plant breeding. (See patent CA 3052709, Wheat Variety W090489Z1). With Canada being a large and desirable market for Cannabis, this is good news. There are, however some drastic differences in patent rules between the United States and Canada that can result in a breeder unknowingly losing his/her rights, if the breeders assume that the US or even PCT deposit procedures apply.

The crux of any plant variety patent application is the deposit of seed. Deposits allow a patentee to claim self-replicating material, material that would otherwise not be amenable to the description and enablement requirements of 35 U.S.C. §112. This can include inventions relating to material capable of self-replication either directly or indirectly, such as bacteria, fungi (including yeast), algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds.

The United States case law helps those who may be concerned that a deposit in a publicly accessible depository, i.e. an International Depository Authority (IDA) accredited under the Budapest Treaty, may render an invention freely available to the public before a patent is issued. The case of In re Lundak, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir.1985), held that revising an application to include a deposit date of a deposited cell line in the ATCC, after the patent application filing date, did not violate the prohibition against new matter in 35 U.S.C. §132. This has been codified in the deposit rules (37 CFR §§1.801 - 1.809), and US Applicants have made a habit of waiting to make a deposit until there is allowable subject matter in an application.

The PCT and EPO have also followed suit, allowing a PCT or EPO application to be amended to reference a completed deposit as long as the amendment is made prior to publication (16 months after priority).

But what of Canada?

Canada requires that a deposit be **made and acknowledged as accepted** by the depository BEFORE the Canadian filing date (a PCT application designating Canada is considered a Canadian filing date).

How does this play out for the unwary plant breeder/would be patentee? One may file a provisional application in the United States, without having made a deposit, expecting it will be years before a deposit needs to be made, and then file a case in Canada one year later properly claiming priority to the United States application. The priority claim and, if the case was filed in Canada (or designating Canada in a PCT), the entire application will be barred, as no deposit has been made or accepted.

Now more than ever, protecting plant varieties and particularly protecting emerging crops such as Cannabis requires knowledgeable patent counsel and a global patent prosecution strategy as early as nine months after a first filing.

EPA Provides Draft Guidance

Cassie J. Edgar
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For Regulation of Gene Edited Plants

Background

Although the USDA gets the most attention related to the regulation of gene edited plants, in the United States, products of biotechnology are regulated by the USDA, FDA and EPA under the **Coordinated Framework for the Regulation of Biotechnology**, updated most recently in 2017.

Under this framework, the USDA, FDA and EPA each regulate in accordance with their specific laws and regulations.

EPA regulates genetically engineered plants which contain plant incorporated protectants (PIPs). PIPs are defined at 40 CFR § 174.3 as “a pesticidal substance that is intended to be produced and used in a living plant, or in the

produce thereof, and the genetic material necessary for the production of such a pesticidal substance". The term "pesticide" as defined in FIFRA 2(u) means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer. EPA regulates pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA; 7 U.S.C. § 136), and establishes the amount of pesticide residues that may be present in food in accordance with section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA; U.S.C. § 9).

Traditionally, PIPs are thought of as plants expressing a protein which confers pest resistance, such as Bt corn. However, note that pest resistance is broader than insect control and includes disease resistance as well, and that growth regulators and nitrogen stabilizers are also considered PIPs under the statute and supporting regulations. In addition, PIPs can also include traits that result from the loss-of-function of an existing plant gene where, for example, the inactivation of a gene coding for a receptor protein confers disease resistance.

Developers have been awaiting clear guidance from the EPA on what the regulatory approval process may look like for gene edited plants considered to contain plant incorporated protectants (PIPs). The EPA recently released a **pre-publication version** of their proposed rule regarding regulation of gene edited plants which contain PIPs, and provides for an exemption from some requirements under FIFRA if certain criteria apply. Once officially published, the EPA's proposed rule will enter a public comment period for 60 days.

What does the proposed exemption mean?

The proposed exemption does NOT mean that the plants and plant products are not subject to regulation by the EPA; but this new rule would remove some requirements such as a pre-market pesticide approval under FIFRA, and provide a tolerance exemption under the FFDCA, for PIPs which meet the proposed exemption criteria.

Note that if a plant product meets this exemption, developers are still required under FIFRA to meet the adverse effects reporting requirement at 40 CFR § 174.71 and proposed recordkeeping requirements at 40 CFR § 174.73, which include a requirement to maintain documents supporting the determination of exempt status.

Plants with plant incorporated protectants that do not qualify for the exemption under this proposed rule are subject to all the requirements of FIFRA, including permit requirements and a pre-market approval from EPA.

What are the requirements for exemption?

EPA currently exempts PIPs produced through conventional breeding from sexually compatible plants as described in 40 CFR § 174.25. Because the EPA had previously defined sexually compatible plants as including only those plants that create viable progeny through conventional breeding, the current exemption excludes PIPs created through biotechnology, even if they are equivalent to PIPs that could have been developed through conventional breeding.

EPA's proposed rule allows exemption for PIPs created through biotechnology in which the pesticidal substance is found in plants that are sexually compatible with the engineered plant, where specific safety criteria are met. A high-level summary of the two routes are below.

To qualify for the exemption, there are 2 pathways:

1. Pesticidal substance from a plant-incorporated protectant comes from a sexually compatible plant created through conventional breeding.

This is an edit to the existing exemption for plants produced through conventional breeding, to add section (c) which explicitly clarifies that the genetic material is only transferred via conventional breeding. The exemption applies if the following conditions are met:

(a) (Existing) *The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient plant.*

(b) (Existing) *The genetic material has never been derived from a source that is not sexually compatible with the recipient plant.*

(c) (New) *The genetic material is transferred from the source plant to the recipient plant only through conventional breeding.*

In addition, residues of the pesticidal substance from such plants created through conventional breeding are exempt from the requirement of a tolerance, *if the residues of the pesticidal substance are not present in food from the plant at levels that are injurious or deleterious to human health.*

2. Pesticidal substance from a plant-incorporated protectant is based on a sexually compatible plant created through biotechnology.

The pesticidal substance from a plant-incorporated protectant based on a sexually compatible plant created through biotechnology is exempt from certain FIFRA requirements if **all** of the following conditions are met:

(a) *The pesticidal substance is created through biotechnology from either an insertion of new genetic material as discussed in paragraph (a)(1) or a modification of existing genetic material as discussed in paragraph (a)(2).*

(1) *A native gene is engineered into a non-genic location of the recipient plant genome, resulting in a pesticidal substance identical to the pesticidal substance identified in the source plant.*

(2) (i) *The existing native gene in the recipient plant is modified to alter the amount of pesticidal substance produced without altering the identity of the pesticidal substance produced; or*

(ii) *The genetic material that encodes the substance of the existing native gene is modified to result in a pesticidal substance that is identical to the pesticidal substance encoded by a native allele of that gene; or*

(iii) *The existing genetic material is modified pursuant to both (i) and (ii).*

(iv) *The existing native gene in the recipient plant is modified to lose function through the reduction or elimination of the substance encoded by that gene.*

(b) *The pesticidal substance is not expressed at higher levels, in different tissues, or at different developmental stages than identified in a plant that is sexually compatible with the recipient plant.*

For the residues of a pesticidal substances from such a plant produced by biotechnology to be exempt from the requirement of a tolerance, the following requirement also applies:

The residues of the pesticidal substance are present only in tissues and developmental stages identified in a plant that is sexually compatible with the recipient food plant, and do not exceed levels found within that plant, as long as those levels are not injurious or deleterious to human health.

Importantly, note that any ingredients intentionally added during the development of PIPs created through biotechnology that are specific to the production of the active ingredient (e.g., guide RNA, DNA nuclease) would need to be either be transiently transformed or would need to be removed through segregation of the trait during the breeding process, to meet the exemption criteria.

What is the process for obtaining exemption status?

The proposed rule includes a process for developers of PIPs to submit either a self-determination letter, or request for EPA confirmation that their PIP meets the criteria for exemption. Developers can also submit both the self-determination letter along with a request confirmation from the EPA.

Conclusion

Gene edited plants which are considered PIPs are subject to regulation by the EPA. This newly proposed rule provides a path for exemption from some FIFRA requirements if certain criteria are met: namely, that the plant is produced through conventional breeding, or that biotechnology is used to engineer a native gene into the recipient plant or modify an existing native gene in a particular manner. After implementation, the rule in final form will certainly shape product development and regulatory strategy decisions, as the requirement to seek a full EPA approval comes with substantial time and financial implications.

For information on the interplay between this proposed rule and exemptions for gene edited plants under the new USDA SECURE Rule and Plant Protection Act, or for guidance on specific genetic changes and the potential application of exemptions under this proposed rule and potential regulatory strategy, please reach out to connect.

Expanded Intellectual Property

Glenn Johnson
Practicing in Commercial, Employment and Intellectual Property Law and Litigation

Protection by Design

The legal right granted with the issuance of a patent by the United States Patent and Trademark Office (USPTO) is the ability to exclude others from using or otherwise commercially benefiting from the covered innovation. The burden and cost of enforcing this right of exclusion falls upon the patent owner.

While enforcement presents an expense to the business, it may represent a necessary cost of doing business. Accordingly, what can be done to

enhance the ability to succeed in excluding a competitor on a cost-effective basis? Enter the design patent.

A “utility patent” provides protection often broader in scope as it may cover how a product or component works, is constructed, is a part of a method or process, or the like. Utility patents generally take longer to successfully prosecute to issue before the USPTO and are much more costly.

At the other end of the spectrum is the “design patent.” A design patent is often referred to as an ornamental patent. It can be obtained to protect two-dimensional or three-dimensional appearance of a product, component and/or packaging. In other words, an ornamental feature affixed to or apparent within a particular product may be subject of a design patent without seeking to obtain design protection over the entire product. The entire product or component part may also be the subject of the design patent. Finally, a combination of the configuration of the product or component and distinguishing surface design may also be covered by a design patent as may unique packaging associated with the part or product.

An example of a design patent is found in United States Patent No. D619,962. This covered a servo throttle motor shield shown in Fig. 1. The shield is an aftermarket part to a motorcycle, the use and location as which is shown in Fig. 8.

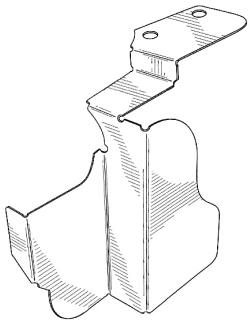

FIG. 1

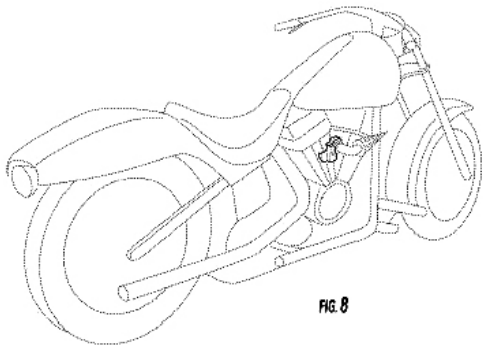

FIG. 8

In 2006, the Federal Circuit, the primary federal circuit court for patent appeals, issued a decision in the case of *Egyptian Goddess v. Swisa* which practically operated to enhance the enforceability of design patents. The net effect of this decision is demonstrated by the upward trend of design patents being pursued. Specifically, data from the USPTO shows that in 2010, 29,059 design patent applications were filed, while in 2019 there were 46,847 applications filed.

Design patents can operate to enhance the protection afforded to a product or packaging of a company, and to facilitate creating a unique and distinct niche within the marketplace. In summarizing the usefulness of design patents and harkening back to an Alka-Selzer commercial of old, “Try it, you’ll like it.”

Branding In The Digital Era

Sarah Luth
Intellectual Property Attorney

USPTO Updates Trademark Specimen Requirements

Since 2019 the U.S. Patent and Trademark Office (USPTO) has been making substantial revisions to its examination rules. From 2016 to 2018 the USPTO issued on average one new examination guide each year. However, in 2019 and 2020 four and three new examination guides were issued, respectively. These changes are made largely to combat fraudulent trademark filings, but also encourage electronic filings and to reflect recent decisions by the courts.

At the beginning of 2019 and early in 2020, the new guidelines addressed trademark applications involving cannabis and cannabis products, applications for "scandalous" marks, and applications for Generic.com terms, among other things. Further, new regulations included a requirement to have an online account to complete filings electronically and a requirement that all foreign applicants designate a U.S. attorney as an agent. However, the bulk of the new guidelines addressed changes to specimen requirements.

With respect to the use of screenshots of websites, it needs to show the full URL of the web page on which the goods or services are offered for sale or advertised/described, along with the date that the screenshot was taken. Additionally, product packaging specimen are required to include a description or image of the product itself, either on the packaging or in addition to the packaging itself. Relatedly, as of 2019, trademark applicants cannot simply submit labels as such. Rather, tags and labels must be shown as affixed to the relevant goods.

Most recently, the October 2020 update guide addresses further guidance for digital specimen. A digital specimen is identified as such when the specimen depicted appears to be electronically created or altered, and "the mark appears to float over the product or container" or "the mark appears superimposed onto signage or other advertising or marketing materials for service." When such specimen are submitted, the Applicant should provide further information enabling the USPTO to assess the authenticity of the specimen, such as proof of sales or the source of the image submitted as a specimen of use.

The USPTO clarified that their Examiners may also conduct internet searches for extrinsic evidence when the submitted specimen appears suspicious. For example, if an examining attorney believes the submitted specimen includes a mark that was superimposed on another party's image, the Examiner can use free image searches, such as a reverse image search on Google. If the Examiner were to find the original image and it appears to support a specimen refusal, the results of that internet search may be entered into the prosecution record and used to support a final refusal.

For trademark applicants needing to submit specimen, particularly those submitting digital specimen, there are a few general guidelines that will minimize the risk of refusal. Webpages submitted should always have the relevant mark, the full URL and date accessed. The content of such webpages should include, if possible, a "cart" function, showing the ability to purchase goods or services directly through the website. The goods or services depicted

should closely match those described in the trademark application.

In terms of photos of goods sold, the mark should ideally be affixed directly to the goods. For goods sold with branded packaging or tags, include photos showing the tags or packaging together with the goods. Finally, for non-traditional goods or services for which submission of a specimen is challenging or impractical, be prepared to provide supplemental evidence of actual use in commerce (such as sales invoices with the mark) and be prepared to submit a further statement explaining the circumstances as part of the application materials.

Since at least early 2019, USPTO rules regarding specimens have become increasingly stringent. However, these updated regulations need not be overly burdensome for trademark applicants. Rather, applicants should prepare evidence of their use in advance of trademark filing and discuss proper evidence with their attorney to ensure a smooth filing experience.

WIPO Standard ST.26

Brian D. Keppler
Patent Agent

Future Changes to Sequence Listings

Patent applications containing nucleic acid or protein sequences are currently required to submit the sequence data in a standardized electronic format in accordance with World Intellectual Property Organization (WIPO) Standard ST.25. This standard went into effect in 1998 and has not been revised since. Now changes are coming soon—WIPO member states have agreed that all sequence listings must be compliant with the new WIPO Standard ST.26 beginning January 1, 2022.

The change has been a long time coming—the European Patent Office (EPO) first proposed a new sequence listing standard back in 2010. One of the most notable differences is a change in format from ASCII text to XML (eXtensible Markup Language). The current format and the new XML format are shown below for the same 44 amino acid sequence for comparison:

```
<210>  1
<211>  44
<212>  PRT
<213>  Homo sapiens

<400>  1

Phe Thr Gly Ile Arg Asp Arg Lys Lys Lys Asn Lys Ala Arg Ser Gly
1               5                   10                  15


Glu Asn Pro Tyr Ala Ser Ile Asp Ile Ser Lys Gly Glu Asn Asn Pro
            20                  25                  30


Gly Phe Gln Asn Thr Asp Asp Val Gln Thr Ser Phe
        35                  40
```

WIPO Standard ST.25

```
<SequenceData sequenceIDNumber="1">
        <INSDSeq>
                <INSDSeq_length>44</INSDSeq_length>
                <INSDSeq_moltype>AA</INSDSeq_moltype>
                <INSDSeq_division>PAT</INSDSeq_division>
                <INSDSeq_feature-table>
                        <INSDFeature>
                                <INSDFeature_key>SOURCE</INSDFeature_key>
                                <INSDFeature_location>1..44</INSDFeature_location>
                                <INSDFeature_quals>
                                        <INSDQualifier>
                                                <INSDQualifier_name>MOL_TYPE</INSDQualifier_name>
                                                <INSDQualifier_value>protein</INSDQualifier_value>
                                        </INSDQualifier>
                                        <INSDQualifier>
                                                <INSDQualifier_name>ORGANISM</INSDQualifier_name>
                                                <INSDQualifier_value>Homo sapiens</INSDQualifier_value>
                                        </INSDQualifier>
                                </INSDFeature_quals>
                        </INSDFeature>
                </INSDSeq_feature-table>
                <INSDSeq_sequence>FTGIRDRKKKNKARSGENPYASIDISKGENNPGFQNTDDVQTSF</INSDSeq_sequence>
        </INSDSeq>
</SequenceData>
```

WIPO Standard ST.26

Although the new format looks more complicated at first glance, it is expected to enhance sequence listing accuracy, offer uniformity across all patent offices, and improve compatibility with other sequence database providers.

Other than the change to XML format, there are also some additional tweaks to be aware of. For example, currently sequences with fewer than 10 nucleotides or 4 amino acids are not required to be presented in a sequence listing whereas WIPO Standard ST.26 explicitly prohibits the inclusion of such sequences. There are also some changes to the requirements for including sequences with D-amino acids or modified amino acids as well as sequences with gaps or branches.

Along with the new standard comes new software tools for preparation of sequence listings in the new format. The first stable release of "WIPO Sequence" was recently launched on November 4, 2020. In addition, "BiSSAP" (Biological Sequence Submission Application for Patents) from the EPO can create sequence listings in both ST.25 and ST.26 format, as well as convert from one standard to the other. The USPTO has not yet announced if they also intend to create their own software or update their "PatentIn" software for the new format.

Specific details regarding implementation of the new standard at the USPTO and revised USPTO national regulations are not yet available. MVS will continue to monitor guidance from the USPTO in the coming year to ensure compliance with any updated sequence rules as the transition to the new standard occurs.

We've been and will be

September 22, 2020

Jill N. Link, Pharm.D., Patent Attorney and Chair of the **MVS Licensing Practice Group** attended the AgTech NEXT! Virtual Conference session on "The Future of Protein" that discussed the cutting edge work on non-animal meat proteins and food technologies.

October 2, 2020

Jill N. Link, Pharm.D., Patent Attorney and Chair of the **MVS Licensing Practice Group** attended the Drake University Law School Board of Counselors meeting. The Drake Law School Board of Counselors is an association of distinguished alumni and attorneys who meet at least three times during the academic year to discuss issues related to the Law School and serve as advisers to the dean. They seek to advance the cause of legal education and promote the interests of Drake Law School. This is Jill's third year on the board and she is a 2007 graduate of the Drake Law School and she also received her Pharm.D. degree from the university.

October 10, 2020

Several MVS Attorneys attended the **Iowa Intellectual Property Law Association (IIPLA) Annual Conference**.

October 20-21, 2020

Cassie J. Edgar, Patent Attorney and Chair of the **MVS Regulatory Law Practice Group** attended the Iowa State University Gene Editing in Agriculture and Food: Social Concerns, Public Engagement and Governance Virtual Conference.

October 21, 2020

Luke T. Mohrhauser, Patent Attorney and Co-Chair, **Mechanical**-**Electrical** Practice Groups attended the Ag Startup Engine Investor Virtual Meeting. MVS is the first Gold Sponsor of the **Ag Startup Engine** at the Iowa State University (ISU) Research Park.

October 21, 2020

Luke T. Mohrhauser, Patent Attorney and Co-Chair, **Mechanical**-**Electrical** Practice Groups attended the **Ag Startup Engine (AES)** and Agricultural Entrepreneurship Initiative (AGE) Unconference.

October 26-30, 2020

Jill N. Link, Pharm.D., Patent Attorney and Chair of the **MVS Licensing Practice Group** attended **The Women, Influence & Power in Law (WIPL) Virtual Summit**. This is the premier global forum designed to provide strategies and practical solutions for attendees and their organization.

October 28, 2020
Cassie J. Edgar, Patent Attorney and Chair of the **MVS Regulatory Law Practice Group** attended the Startup Community Way: Iowa Startup Ecosystem Virtual Event.

November 2, 2020
MVS was a sponsor of the of the **NUtech Ventures Annual Innovators Celebration**. This event featured keynote presentations from Andrei Iancu, USPTO director, and Molly Kocialski, USPTO Rocky Mountain regional director, who discussed the importance of university innovation and its impact on U.S. patents, as well as other priorities for the USPTO.

November 4-6, 2020
Jill N. Link, Pharm.D., Patent Attorney and Chair of the **MVS Licensing Practice Group** attended the **ChIPs Virtual Global Summit** with a slate of topics and speakers that delve into some of the most controversial and current topics impacting attendees in tech, law and policy.

November 5-8, 2020
Tina G. Yin-Sowatzke, Pharm.D., Intellectual Property Attorney in the MVS **Biotechnology** & **Chemical** Practice Groups attended the American Society for Pharmacy Law (ASPL) Virtual Fall Meeting from 11/5-11/8. ASPL holds a Developments in Pharmacy Law Seminar annually that provides for discussions on current legal topics for both pharmacists and lawyers.

November 9, 2020
Tina G. Yin-Sowatzke, Pharm.D., Intellectual Property Attorney in the MVS **Biotechnology** & **Chemical** Practice Groups was a panelist at the Legus International 2020 Fall Zoom Meeting for the Leadership and Young Lawyers portion of the meeting.

November 12, 2020
Sarah M.D. Luth, Intellectual Property Attorney in the MVS **Biotechnology** & **Chemical** Practice Groups hosted the FemCity Beer & Branding Virtual Social event. This event included a virtual beer tasting from three local Des Moines breweries along with a brief presentation by Sarah on the different ways of obtaining legal protection for businesses' identity, products, and services. **FemCity** is a networking group for women in the Des Moines, Iowa area.

December 7-9, 2020
Heidi S. Nebel, Managing Member and Chair, **Biotechnology** & **Chemical** Practice Groups to attend the **American Seed Trade Association (ASTA) CSS & Seed Expo Virtual event**.

December 10, 2020
Heidi S. Nebel, Managing Member and Chair, **Biotechnology** & **Chemical** Practice Groups and **Christine Lebrón-Dykeman**, Intellectual Property Attorney and Chair, **Trademark Practice Group** will be presenting at a webinar hosted by the Seed Innovation & Protection Alliance (SIPA). The webinar will discuss procuring and enforcing Plant Variety Protection (PVP) rights in the U.S.

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