

IP Protection for Advanced Feedstocks

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Advanced Bioeconomy Feedstocks Conference 2016

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Where's the Value?

- ➢ Human Capital
- Physical Assets
- Contracts, Licenses, Relationships
- Intellectual Property
 - Patents
 - o Utility, Design, Plant
 - Trademarks
 - Copyrights
 - Trade Secrets



• Know How





Patents vs. Trade Secrets

	Utility Patents	Trade Secrets
Applicable Law	Federal	State*
Exclusivity	Yes	No
Government Grant	Yes	No
Requirements	Invention and application to USPTO	Information created, kept secret, and has independent economic value due to secrecy
Novelty	Required	Cannot be generally known or ascertainable
Obviousness	Must be nonobvious	Cannot be generally known or ascertainable
Duration	Generally 20 years	Potentially unlimited
Reverse Engineering	Potential infringement	Defense if properly acquired
Loss of Rights	Public domain – expected	Public domain – unexpected

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What's Happening to IP?

Trade Secrets Legislation

- **Defend Trade Secrets Act** (passed Senate 4/4/2016; passed House 4/27/2016; President signed 5/11/2016)
- Creates federal cause of action for trade secret misappropriation under federal law
- Owner of a misappropriated trade secret can bring a civil action if the trade secret is related to a product or service used in interstate or foreign commerce
 - Misappropriation does not include "reverse engineering, independent derivation, or any other lawful means of acquisition"
- Federal remedies of injunction, damages, and seizure available







Feedstocks: 3 Types of Protection

- Plant Patent Act (asexually propagated plants)
 - 35 U.S.C. §§ 161-164

- Plant Variety Protection Act (seeds and tubers)
 - 7 U.S.C. §§ 2321 et seq.

- Utility Patent to a Plant (any type of plant)
 - 35 U.S.C. §§ 111 (101, 102, 103, 112)
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- 35 U.S.C. § 161 states:
- "Whoever invents or discovers and **asexually** reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor..."
- Plant must be new and distinct from other known varieties and asexually reproduced
- 20 year patent term from date of application filing
- Right to exclude others from making, using, selling, offering for sale and importing the plant, or any of its parts
- Protects a single plant and asexual progeny
- Over 18,000 plant patents
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Plant Patent Act

- If discovered, plant must be found in a cultivated area
 - Plants discovered in the wild are excluded
- Plant patent application includes:
 - Detailed botanical description of plant
 - Plant's breeding history, location developed and identification of original parental lines
 - Comparisons of the new plant with both parental lines and with similar varieties
 - At least one photo showing the unique aspects
 - **Example claim**: "A Petunia plant substantially as described and illustrated in the specification herein."
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Plant Variety Protection (PVP) Act

- Administered by U.S. Department of Agriculture (USDA)
- PVP Office provides protection to breeders of varieties of seed and tuber propagated (sexually reproduced) plants that are:
 - New
 - Distinct
 - Uniform and
 - Stable
- PVP Certificate protects varieties for 20 years from date of grant
 - 25 years for vines and trees
- Exclude others from selling, offering for sale, multiplying, conditioning, importing, exporting and stocking the variety
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- New:
 - Has not been sold or otherwise disposed of for purposes of exploitation for more than one year in the United States, or more than four years in any foreign jurisdiction (six years for trees and vines).
- Distinct:
 - Clearly distinguishable from any other publicly known variety. Distinctness may be based on morphological, physiological, or other characteristics, including commercially valuable characteristics.
- Uniform:
 - Any variations are describable, predictable, and commercially acceptable.
- Stable:
 - The variety, when reproduced, will remain unchanged with regard to its essential and distinctive characteristics within a reasonable degree of commercial reliability.
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- Farmer's exemption:
 - Permits farmers to save seed produced from the feedstock, which was grown from purchased seeds, for the next replanting season on own farm.
 - Farmer is not permitted to sell the saved seed to another farmer.
- Breeder's / research exemption:
 - Breeders are permitted to employ protected plant varieties for plant breeding or other bona fide research toward new plant varieties.



- Technology neutral
 - Available for both sexually and asexually propagated plants
- Not limited to single propagated plant variety / single claim
 - Broader coverage than PVPA certificate and plant patent
- Possible to protect varieties having specific traits, plant parts and methods of producing or using plant varieties
- 20 year protection from date of filing
- Right to exclude others from making, using, selling, offering for sale, and importing the patented invention in the U.S.

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- Disease and insect resistance
- Drought and salt tolerance
- Herbicide resistance
- Improvement of fruit and flower quality
- Modification of fatty acid and oil composition
- Increases in amino acids and nutrition
- Improvement of sugars and carbohydrates
- Increases in secondary plant products
- Production of mammalian peptides and vaccines



- Expression cassettes or vectors
- Transgenic plants having a novel phenotype
- Products produced from transgenic plants
- Methods of breeding novel/nonobvious plants using traditional methods
- Methods of molecular plant breeding
- Methods of producing a transgenic plant having a novel phenotype
- Novel plant transformation methods
- Methods of plant cell and tissue culture
- Isolated plant polynucleotides and polypeptides
 - Cannot claim natural products (e.g., new plant found in wild)
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Goldstein Fox Attorneys at Law Utility vs. Plant Patents

	Utility Patent	Plant Patent
Generic claim or protection possible	Yes	No – patent covers a single plant and its clones
Method claims permitted	Yes	No
Number and format of claims limited	No	Yes – one claim of prescribed format
Exclusions	Products of nature	Products of nature, edible tuber-propagated plants
Invention must be novel, nonobvious and distinct	Yes	Yes
Invention must be "enabled"	Yes	No
Deposit of biological material required	May Be Necessary	No
Variety name required	No	Yes



Patent Reform



- Changed from a "first-to-invent" system to "first-inventor-to-file" system
- Provided for prioritized examination
- Introduced new ways to challenge competitor's patents and applications at USPTO
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New Patent Portfolio Options



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The Rise of PTO Litigation (June 2016)

IPR, CBM, and PGR Filings

- Since September
 16, 2012, 4,543 IPR
 petitions, 460 CBM
 petitions, and 28
 PGR petitions have
 been filed.
- Averaged 150
 petitions per month
 in 2015 slightly up
 over 2014. Filings
 are down in 2016.



Inter Partes Review

<u>Who?</u> Any third party

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- <u>What?</u> Petition filed at USPTO asserting one or more claims of a patent are unpatentable (anticipation/obviousness rejections based on prior art patents and printed publications)
- <u>When?</u> For first-to-invent patents (filed before March 16, 2013) any time

For first-to-file patents, available after later of (i) 9 months post-issuance OR (ii) termination of PGR

<u>Standards</u>: "Reasonable likelihood" petitioner will prevail in invalidating at least one claim

Preponderance of evidence

Broadest reasonable claim construction

No presumption of validity

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Goldstein Fox Inter Partes Review Timeline



Source: AIA Implementation, Official Patent Trial Patent Guide

http://www.gpo.gov/fdsys/pkg/FR-2012-08-14/pdf/2012-17908.pdf

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PTAB Institution Outcomes (June 2016)

Tracking the Cumulative Institution Rate



Period	Institution Rate
FY2012-2013	86.8%
1 st Half FY2014	78.5%
2 nd Half FY2014	71.2%
1 st Quarter FY2015	77.7%
2 nd Quarter FY2015	68.8%
3 rd Quarter FY2015	63.6%
4 th Quarter FY2015	62.5%
1 st Quarter FY2016	69.1%
2 nd Quarter FY2016	65.5%
3 rd Quarter FY2016	68.0%
Total	70.9%

• In IPRs, trial has been instituted for 71% of proceedings and 63% of the challenged claims.



TC1600 Compared to All IPRs

- At Institution Decision:
 - 61% of proceedings instituted in TC1600 and 57% of claims instituted
 - 71% of proceedings instituted and 63% of claims instituted for all IPRs
- When the Board reaches a Final Written Decision and decides whether the Petitioner has met its burden (not counting amended claims, settlements, request for adverse judgment, etc.):
 - The PTAB cancels **54%** of instituted claims in TC1600
 - The PTAB cancels 82% of instituted claims in all IPRs (10,175 cancelled, 2,161 found patentable, USPTO.gov, 4/30/2016).
- 27% of IPRs settle, with a slight majority of settlements coming after the Institution Decision.
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Trial Number	Filing Date	Patent	Title	Patent Owner	Petitioner	Status
IPR2016-00076	10/23/2015	8791049	PLANT TREATMENT COMPOSITIONS PARTICULARLY EFFECTIVE IN THE CONTROL OF HETERANTHERAL LIMOSA ON RICE CROPS, AND METHODS FOR THEIR USE	GOWAN CO.	Aceto Agricultural Chemicals Corp.	Instituted
IPR2015-01016	4/6/2015	8791049	PLANT TREATMENT COMPOSITIONS PARTICULARLY EFFECTIVE IN THE CONTROL OF HETERANTHERAL LIMOSA ON RICE CROPS, AND METHODS FOR THEIR USE	GOWAN CO.	Aceto Agricultural Chemicals Corp.	Institution Denied
IPR2014-01491	9/12/2014	7090873	HOP ACIDS AS A REPLACEMENT FOR ANTIBIOTICS IN ANIMAL FEED	JOHN I. HAAS, INC.	SS Steiner, Inc.	Institution Denied
IPR2014-01490	9/12/2014	8197863	HOP ACIDS AS A REPLACEMENT FOR ANTIBIOTICS IN ANIMAL FEED	JOHN I. HAAS, INC.	SS Steiner, Inc.	Institution Denied
IPR2014-00335	1/8/2014	8028469	AUTOMATED HIGH-THROUGHPUT SEED SAMPLER AND METHODS OF SAMPLING, TESTING AND BULKING SEEDS	MONSANTO TECHNOLOGY LLC	E.I. du Pont de Nemours and Company	Institution Denied
IPR2014-00334	1/8/2014	8245439	AUTOMATED HIGH-THROUGHPUT SEED SAMPLER AND METHODS OF SAMPLING, TESTING AND BULKING SEEDS	MONSANTO TECHNOLOGY LLC	E.I. du Pont de Nemours and Company	Institution Denied
IPR2014-00333	1/8/2014	7832143	HIGH THROUGHPUT METHODS FOR SAMPLING SEEDS	MONSANTO TECHNOLOGY LLC	E.I. du Pont de Nemours and Company	Institution Denied
IPR2014-00332	1/8/2014	8071845	AUTOMATED SEED SAMPLER AND METHODS OF SAMPLING, TESTING AND BULKING SEEDS	MONSANTO TECHNOLOGY LLC	E.I. du Pont de Nemours and Company	Institution Denied
IPR2014-00331	1/8/2014	8312672	METHODS OF SEED BREEDING USING HIGH THROUGHPUT NONDESTRUCTIVE SEED SAMPLING	MONSANTO TECHNOLOGY LLC	E.I. du Pont de Nemours and Company	Institution Denied
IPR2013-00110	1/11/2013	6209259	Seeding Treatments	ENCAP, LLC.	The Scotts Company LLC	Final Written Decision
IPR2013-00023	10/17/2012	6162974	SEED VIGOR BY PRE-HARVEST DEFOLIATION OF MAIZE PLANTS	PIONEER HI-BRED INTERNATIONAL	Monsanto Company	Institution Denied
IPR2013-00022	10/17/2012	5518989	SEED VIGOR BY PRE-HARVEST DEFOLIATION OF MAIZE PLANTS	PIONEER HI-BRED INTERNATIONAL	Monsanto Company	Institution Denied

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- Generally perceived as another recent blow to patent value
- Though not a "death squad," PTO litigation results in:
 - Institution for 63% of challenged claims
 - Cancellation for 83% of claims for which trial is instituted
 - For surviving claims, significant negative PTO litigation history created
- Patent Owner Estoppels:
 - *Practical* estoppel following a negative outcome in PTO litigation
 - *Legal* estoppel:
 - Precluded from taking action inconsistent with an adverse judgment in a PTO litigation proceeding, including obtaining in any patent a claim that is patentably indistinct from a finally refused or cancelled claim
- How does this impact strategic portfolio building and patent prosecution?



- What are best practices for raising obstacles to a would-be IPR petitioner?
 - Create **patent thicket** around product(s):
 - Can serve as an IPR deterrent (increases cost/complexities)
 - Fortress Building additional patents covering the relevant product(s) (e.g., methods of making, methods of using, apparatus, articles of manufacture or combinations)
 - Robust claim sets to avoid necessity of filing motion to amend during IPR (contemplates sacrificing broader claims in order to save patentable dependent claims, with no need to amend)
 - Keep at least one application pending
 - Develop declaration evidence to support technical arguments and secondary considerations



- Other considerations for **Patent Owners**:
 - Conduct **patentability search** prior to drafting application
 - Identify closest prior art
 - Design experiments to show unexpectedly superior properties over the closest prior art
 - **Portfolio Evaluation** Before IPR filed by competitor, consider analyzing important issued patents for possible supplemental examination, reissue or ex-parte reexamination filings
 - Identify and address weaknesses in patent portfolio
 - After IPR filed by competitor, consider expedited prosecution (e.g., Track One) of applications in same family prior to receiving Final Written Decision in an IPR to avoid patent owner estoppel



- Articulate an IP strategy with patent counsel
- Know what differentiates your innovation
 - Patentability search (others are smart)
 - What features are valuable (sought by customers, unique to product)
 - Meet or beat tightened patentability standards
- File early if you are going to file
- Accelerate key patent applications
- Interview examiners
- Consider all options when threatened including patent defenses at USPTO and rapid patent portfolio creation





Contact Information

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Appendix: Biography and Firm Facts

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Peter A. Jackman Director

Mr. Jackman is a director in the Biotechnology/Chemical Group. His practice includes counseling clients in areas such as global patent portfolio procurement, management and enforcement strategies, technology transfer, invalidity, noninfringement, freedom-to-operate and patentability opinions and due diligence investigations. He has significant experience in representing clients in patent reexaminations and inter partes review proceedings and has written and prosecuted patent applications domestically and internationally in areas such as immunology, genomics, molecular and cell biology, recombinant DNA technology, transgenics, bioprocessing, advanced biofuels, bio-based chemicals and enzymes, microbiology, therapeutic methods and food science.

Mr. Jackman is also a member of the firm's CleanTech Industry Group. He frequently lectures and publishes on intellectual property issues surrounding renewable technologies, and he was an Associate Editor for Clean Tech Law & Business, the first peer-reviewed journal devoted exclusively to the pursuit of environmentally sustainable technology. He further serves as a member of the BIO International Convention Program Committee and the BIO World Congress on Industrial Biotechnology Program Committee.

Additionally, Mr. Jackman is a contributing author of <u>Patent Office Litigation</u>, a two-volume set focused on the new contested proceedings under the America Invents Act published in 2012 by Thomson Reuters Westlaw. This book examines how the proceedings interact with other aspects of patent procurement and enforcement, and delivers practical analysis and advice.

J.D., University of Baltimore *magna cum laude* M.S., Microbiology, Thomas Jefferson University B.S., Biology, Villanova University



- Sterne Kessler is an intellectual property law firm located in Washington, DC with 160+ IP and business professionals. More than 60 hold a Ph.D.; most have an advanced technical degree and/or significant industry or academic experience
- Sterne Kessler attorneys are trained to evaluate IP in the context of client business issues and market conditions to ensure alignment with corporate/organizational goals
- We represent a broad range of entities, including emerging and established companies, venture capital firms, universities and select individuals
- For more than 35 years, Sterne Kessler has been at the forefront of a rapidly evolving biotechnology industry
 - One of the largest and most experienced biotechnology practices in the United States
 - Prosecution of U.S. and international patent applications and the development of strategic patent portfolios





Included in the IP Hot List by the *National Law Journal* 2012 – 2015

Named "Patent Prosecution Firm of the Year" 2015 by LMG Life Sciences





Named PTAB "Firm of the Year" 2015 by *Managing Intellectual Property*

Among Top IP Firms & Band 1 in Patent Prosecution – Chambers USA 2015 (13th consecutive year in the rankings)



Ranked "Tier One" nationally for patent prosecution, PTAB litigation & bio/life sciences; ranked a top firm for patent prosecution, litigation & licensing in the Washington D.C. metro area; 13 firm directors honored in Managing Intellectual Property's 2015 "IAM Patent 1000"



Top Ranked

CHAMBERS

10 Directors Recognized as "IP Stars" by *Managing Intellectual Property*



Ranked a "Top Workplace" by The Washington Post 2015 & 2014

One of the "10 Best U.S. Law Firms" for inclusion of racial minority attorneys by Law360 2015





2015 & 2014



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Sterne Kessler Goldstein Fox Art Unit 1600 PTAB Filings by Law Firm (3/2016)

IPR: Top Filing or Defending Firms TC 1600 – Biotechnology/Organic Chemistry	Total	Filed	Defend	# of Clients
Sterne, Kessler, Goldstein & Fox	52	47	5	16
Finnegan	36	6	30	13
Fish & Richardson	32	4	28	9
Goodwin Proctor	27	14	13	9
Wilson, Sonsini, Goodrich & Rosati	25	21	4	5
Cooley	23	0	23	6
Fitzpatrick, Cella, Harper & Scinto	23	6	17	8
Williams & Connolly	22	0	22	6
Foley & Lardner	20	10	10	9





Sterne Kessler published a two-volume set with 1,200 pages focused on the new contested proceedings under the America Invents Act in October, 2012. This book examines how the proceedings interact with other aspects of patent procurement and enforcement, while delivering practical analysis and advice.

