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YOUR DELAWARE ADVANTAGE

Obtaining and Maintaining Patent Rights in Biotechnology

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Objectives

1. Review – patent and trade secret to protect invention
   - The difference between patents and trade secrets
   - Why choose to patent

2. Getting a patent (focus on US and Europe)
   - Requirements
   - Process and pitfalls
   - Third party interventions

3. Challenges to patents after grant
   - Opposition, post grant review, *inter partes* review
   - Litigation – counterclaims for invalidity or unenforceability

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Intellectual Property – Exclusive Rights

- Patent – the right to keep others from making, using, selling or importing the patented invention or design for a term of 20 years from filing

- Trade secret – the right to keep others from taking or divulging your proprietary information as long as (1) the information gives you an economic advantage and (2) you take reasonable steps to keep it a secret

Patents and Trade Secrets

- To get a patent, the invention must be made public
  - In exchange for 20 years of monopoly on the invention, the patent must provide a written description of the invention that teaches "one of ordinary skill in the art" how to make and use the claimed invention, and that sets forth the "best mode" at the time of filing the patent application.

- Reasons to patent and not to keep invention secret:
  - Secret cannot be kept due to reverse engineering or other reason
  - Someone else can invent independently and get a patent, preventing you from practicing your own invention

- Reasons to keep invention secret and not patent:
  - Difficult to monitor infringement; difficult to enforce patent
  - Technology not easily reverse engineered so secret can be kept

So Why Bother Patenting Your Technology?

Patent Strategy	Competitive Advantage
"Monopoly Protection"	20 yrs of the "exclusive right"
"Capital" for Negotiating	*e.g.* Cross-licensing
Stake a Claim in New Area	Establish Turf in Emerging Technology
Defensive/Deterrent Posture	Avoid Being Boxed Out by Competition
Get Consumers' Attention	*e.g.* Label claims, "Patent Pending"
Get Competitors' Attention	Serve Notice "Take us seriously"
Get Market's Attention	Maximize Value of Intangible Assets
Recouping R&D/Tech. Investment	Spin-offs, Sale/License Unwanted Pats.
Publicity/Vanity	Generate Press

Patents are Powerful *Business Tools*!

Requirements for Obtaining a Patent

United States PTO

1. Patentable subject matter (excludes laws and products of nature, physical phenomena, abstract ideas) (recently – excludes isolated DNA and certain types of diagnostic methods)
2. Utility
3. Novelty
4. Non-obviousness
5. Written description, enablement (specification must disclose full scope of invention and enable skilled person to make and use it)

European Patent Office

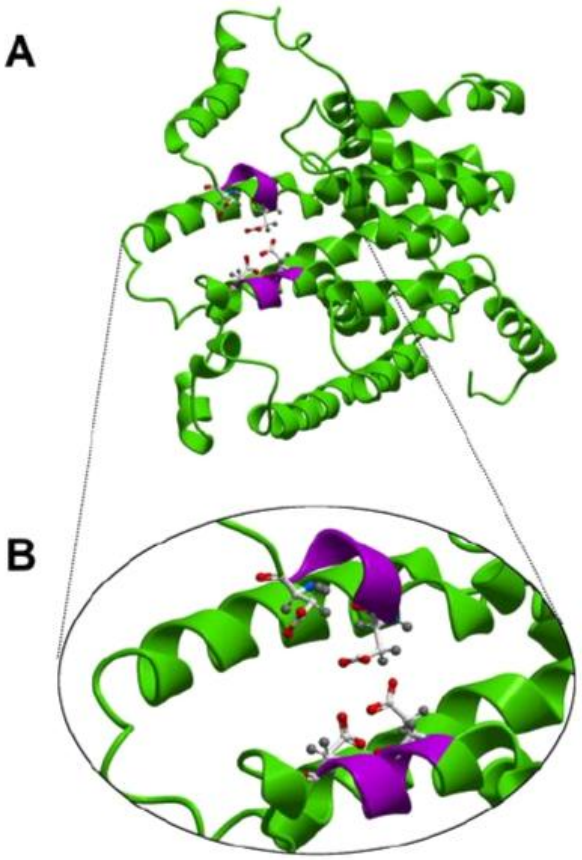
1. Patentable subject matter (excludes plant or animal varieties; essentially biological processes for producing plants or animals; methods for diagnosis or treatment of the human or animal body)
2. Industrial Applicability
3. Novelty
4. Inventive Step
5. Sufficiency of disclosure (specification must disclose the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person)

Duty of Disclosure (Candor)

United States PTO	EPO
37 CFR §1.56: (a) Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. (b) Information is material to patentability when (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the Office, or (ii) asserting an argument of patentability.	No corresponding requirements

Example – Enzyme and its use in biosynthesis

Phytoene synthase – carotenoid biosynthetic pathway



López-Emparán A, Quezada-Martinez D, Zúñiga-Bustos M, Cifuentes V, Iñiguez-Luy F, et al. (2014) Functional Analysis of the Brassica napus L. Phytoene Synthase (PSY) Gene Family. PLoS ONE 9(12): e114878. doi:10.1371/journal.pone.0114878 http://journals.plos.org/plosone/article?id=info:doi/10.1371/journal.pone.0114878

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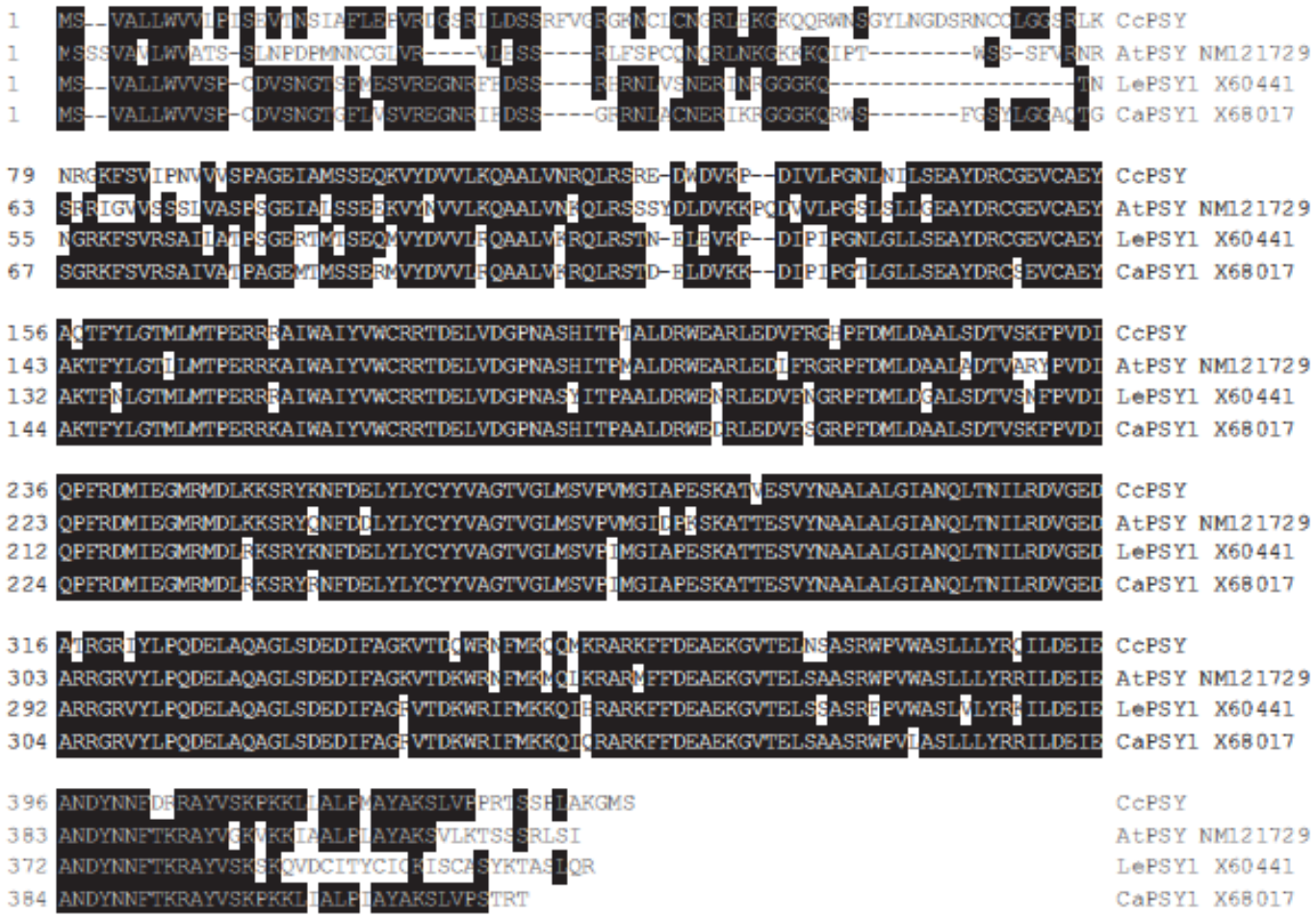
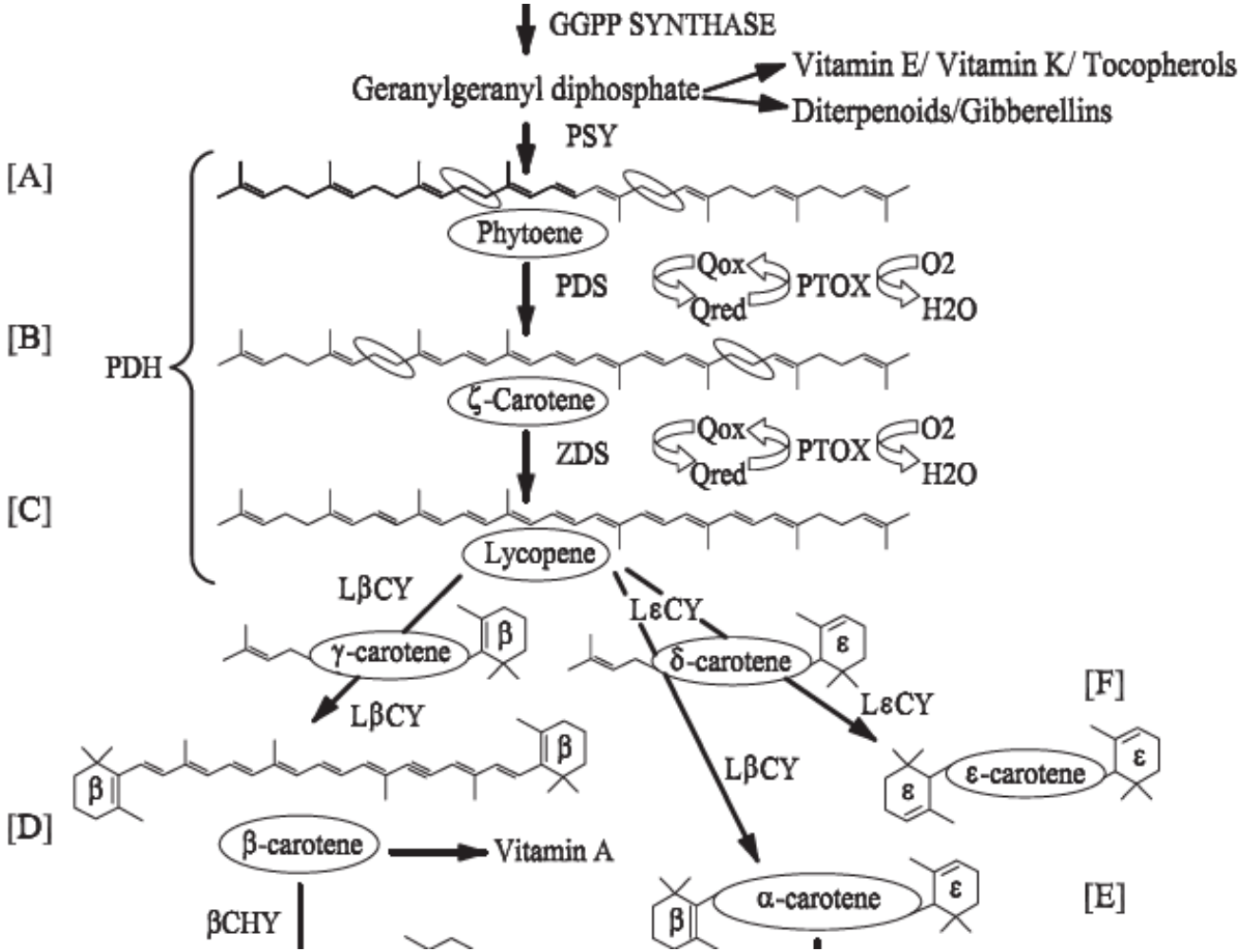


Example – Enzyme and its use in biosynthesis

- Phytoene synthase – carotenoid biosynthetic pathway



Example – Enzyme and its use in biosynthesis

Phytoene synthase – *Coffea canephora*

Patent claims:

1. A vector containing a nucleic acid molecule isolated from coffee (Coffea spp.), having a coding sequence that encodes a phytoene synthase, wherein the phytoene synthase has an amino acid sequence at least about 85% identical to SEQ ID NO:13.

6. The vector of claim 1, wherein the coding sequence of the nucleic acid molecule is operably linked to a constitutive promoter, or an inducible promoter, or a tissue-specific promoter.

13. A method of modulating flavor or aroma of coffee beans, comprising increasing production or activity of one or more phytoene synthase enzymes within coffee seeds, wherein the phytoene synthase has an amino acid sequence at least about 85% identical to SEQ ID NO:13, thereby increasing carotenoid production in the coffee beans and modulating the flavor or aroma of the coffee beans.

Patent Office Examination

The claims of a patent application are examined by a patent examiner skilled in the relevant art:

1. Claims are assessed for patentable subject matter

2. Prior art is searched to determine state of the art for
   - Novelty
   - Non-obviousness / inventiveness

3. Specification is examined for
   - Adequate written description
   - Sufficiency / enablement
   - Definiteness / clarity

Right of third parties to weigh in prior to grant

USPTO - Preissuance Submissions by Third Parties:

- 35 U.S.C. 122(e) provides a mechanism for third parties to submit patents, published patent applications, or other printed publications of potential relevance to the examination of a patent application with a concise description of the asserted relevance of each document submitted. Submissions can be anonymous.
- Submissions may be made before (1) the later of (i) 6 months after the date of publication or (ii) the date of a first Office action on the merits rejecting any claims, or (2) before the date of a notice of allowance, if earlier.

EPO – Pre-grant Observations by Third Parties:

- Can be filed at any time after publication while proceedings are in progress before the European Patent Office and should relate to patentability (any ground).
- Any person may file third party observations; but the identity of the party need not be disclosed. The person who filed the observations has no right of participation in the proceedings, but in practice it is possible to follow the prosecution and make repeated observations.

Right of third parties to weigh in after grant

	USPTO			EPO
	***Ex Parte* Reexam (ExPR)**	**Post-Grant Review (PGR)**	***Inter Partes* Review (IPR)**	***Opposition***
Timing	Any time after issuance	For patents filed after 3/16/13, within 9 months of issuance	Any time after issuance (or after PGR period expires if PGR is available)	Within 9 months of grant
Possible Bases for Request	Novelty and obviousness only, based on printed pubs and patents	Novelty, obviousness (any evidence, not just printed pubs and patents), written description, enablement	Novelty and obviousness only, based on printed publications and patents	Essentially all grounds - Novelty, inventive step, industrial applicability, sufficiency of disclosure, claims exceed scope of specification as filed
Requester Anonymity	Can remain anonymous	Real party in interest must be named	Real party in interest must be named	Can remain anonymous
Third Party Right to Participate	Limited to initial request and reply to the patentee's statement	Petitioner may brief issues, submit supporting evidence, and participate in oral hearing	Petitioner may brief issues, submit supporting evidence, and participate in oral hearing	Opponent may file observations, submit supporting evidence, and participate in oral arguments
Estoppel in Later Proceeding	None	Estoppel for claim that was raised or could have been raised by petitioner for any claim that results in a final written decision	Estoppel for claim that was raised or could have been raised by petitioner for any claim that results in a final written decision	None

Options for parties sued for patent infringement

- US Patents – Counterclaim for invalidity or unenforceability
  - Invalidity is determined on a claim-by-claim basis
  - Validity can be challenged in court on any ground
    - Lack of novelty, obviousness, lack of written description, enablement, lack of patentable subject matter . . .
  - Unenforceability extends to the entire patent and can extend to other patents within a family (see next slide)

- EP National Patents – Counterclaim for invalidity
  - Patent infringement suits are brought in the courts of the countries in which the EP patent has been validated
  - Laws differ, but generally validity can be challenged on any ground
  - Unenforceability for acts during prosecution is not an issue (see next slide)

USPTO duty of disclosure and enforceability of patents

- Inequitable conduct can be found for:
  - –Failure to disclose information material to patentability
    - •Failure to disclose material prior art
    - •Failure to disclose negative data
  - –Providing false or misleading information on a subject material to patentability, including
    - •False or misleading data
    - •False representation of the state of the art
- Result – unenforceability of the patent and any related patents "tainted" by the inequitable conduct

Lack of candor – effect on European national patents

- In the EPO there is no equivalent to the US duty of candor.
- However, there is an expression in the UK that "he who seeks equity must come with clean hands".
  - In this regard, if the Courts can see that a patentee has acted in an inequitable way, they are likely to treat that patentee differently to one who has acted equitably. For example, the ability to amend patent claims during proceedings is at the discretion of the Courts and the Courts would be more likely to exercise their discretion if the patentee has acted equitably.

- If misleading or false information is included in a European patent, this on its own would not give rise to a valid ground of opposition.
- But if an opponent can prove that the information is misleading or false, it is likely in the EPO that this would have a bearing on whether the description provides sufficient information to enable a skilled person to repeat the claimed invention.

Back to Example – hypothetical scenario

Phytoene synthase – *Coffea canephora*

Patent claim:

13. A method of modulating flavor or aroma of coffee beans, comprising increasing production or activity of one or more phytoene synthase enzymes within coffee seeds, wherein the phytoene synthase has an amino acid sequence at least about 85% identical to SEQ ID NO:13, thereby increasing carotenoid production in the coffee beans and modulating the flavor or aroma of the coffee beans.

- *At the time of filing, no experiments had been done to prove the above will work, but scientific rationale exists and is explained in the patent specification.*
- *During prosecution of claim 13, inventors performed experiment and found out that increasing production of PSY in Coffea cells did not lead to increased carotenoid production. Inventors failed to disclose this to USPTO or EPO.*
- *Additionally, during prosecution, patent attorney discovered a prior art patent that disclosed overexpression of PSY in Arabidopsis resulted in increased production of β-carotene, but neglected to disclose to USPTO or EPO.*
- *A patent covering claim 13 is issued by USPTO and is granted by EPO.*

Summary

1. There are good reasons to apply for patents (as opposed to maintaining trade secrets), but challenges in obtaining and keeping them

2. Patent applications must meet several requirements before they are accepted for grant – these requirements are similar but not identical between the USPTO and the EPO

3. Patent applications are examined in respective patent offices by technically qualified examiners; third parties can weigh in during pendency and after grant

4. Conduct during the application process can have direct and indirect effects on the ability to maintain a patent after issuance

    - USPTO – duty of candor; failure can lead to unenforceability

    - EPO – no duty of candor, but “unclean hands” can weigh against the patentee in national courts, and may provide indirect grounds for revocation in EPO opposition.

Questions? Comments?

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