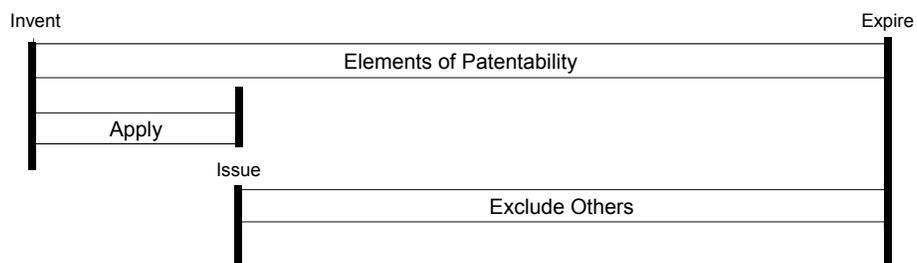


Int'l IP

- Module 3
- Patent Law

The elements of Patentability

- **Patentable subject matter**, i.e., patent eligibility
- **Useful/utility** (operable and provides a tangible benefit)
- **New** (statutory bar, novelty, anticipation)
- **Nonobvious** (not readily within the ordinary skills of a competent artisan at the time the invention was made)
- **Specification requirements** (enablement, written description, best mode, definiteness)



The First Successful U.S. Factory

- What is the interaction between international trade and patents?



Maskus - Lessons from Studying the Int'l Economics of IP Rights

- TRIPS income shifting
- IPRs stimulate international economic activity?
 - Trade
 - FDI
 - Licensing
- IPRs and growth?
- IPRs and “deepening” markets

India Patent Protection – WTO DSU Appellate Body (1997)

- WTO Appellate body reversed panel
 - “disciplines formed under GATT 1947” apply to interpreting TRIPS
 - But, that does not incorporate the “legitimate expectations” principle into a violation complaint
 - Panel misapplied the Vienna Convention
 - The legitimate expectations of the parties are in the treaty itself
 - Must not add or diminish rights – DSU Art. 3.2, 19.2
 - So, a panel must not always take into account legitimate expectations concerning conditions of competition
 - This is in the context of non violation complaints
- Article 70.8
 - “mailbox” system for filing patent applications before TRIPS obligated India to protect patents
- Dispute is over whether India’s mailbox system is in compliance with Art. 70.8

India Patent Protection

- Art. 70.8
 - (a) . . . provide . . . a **means** by which applications for patents for such inventions can be filed;
 - (b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application;
 - (c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term . . .
- A developing country may delay providing patent protection not previously protectable until 1/1/2005. TRIPS Art. 65.
 - But, Art. 70.8 applies without regard to Transitional Arrangements

India Patent Protection

- So, what are the “means”
 - Look to 70.8(b) & (c) for “object and purpose” following Vienna Convention Art. 31 interpretation principles
 - Must allow for the entitlement to file mailbox applications and the allocation of priority and filing dates to them
 - Sound legal basis to preserve novelty and priority
- India
 - We comply by receiving, dating and storing, under administrative instructions
 - They don’t go to an examiner until 1/1/2005
 - India did not provide the text of any of these administrative instructions
 - We are “free” under TRIPS 1.1 to determine the appropriate method to implement
 - Appellate body
 - recounts failed attempt to enact legislation
 - Notes that administrative instructions require India’s PTO to ignore its own patent act’s mandatory referral to examiners

India Patent Protection – WTO Panel

- Municipal law
 - Evidence of facts, state practice, or compliance
 - Here, we must look at the “mixture” of the instructions with India’s patent law to compare it to India’s TRIPS obligations
 - No “rule-making” for these rules
- So, the instructions do not provide a “sound legal basis”
- NOTES
 - Stare decisis
 - GATT acquis

Global Patent Registration?

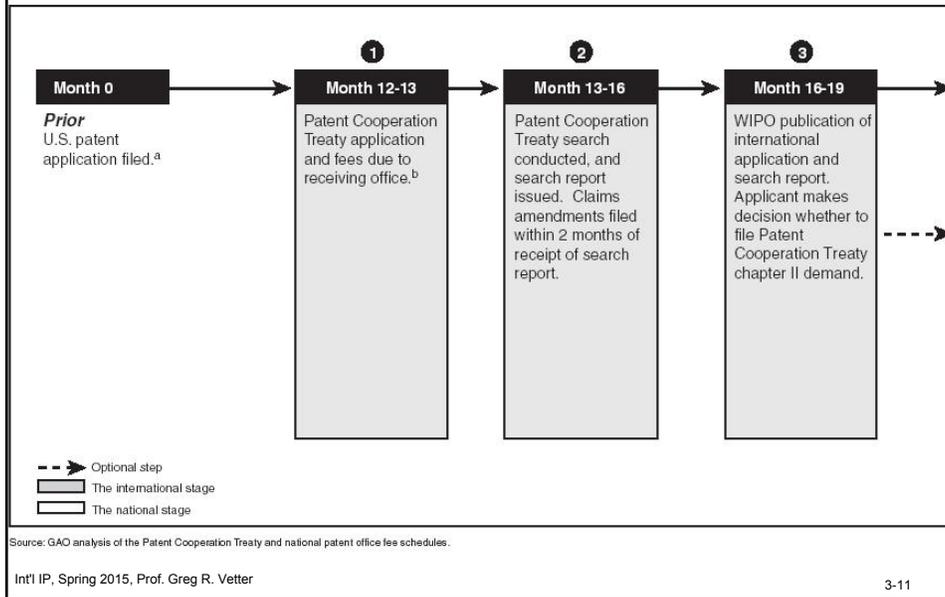
- Substantive harmonization:?
 - 1991 Patent Law Treaty
- Procedural Harmonization?
 - Paris Convention Priority
 - PCT
 - EPO
 - 2000 Patent Law Treaty
- Cost concerns for big and small inventor alike

PCT

- Signed 1970, Entered into force for U.S. in 1978
 - Paris Convention authorized agreement
- International Phase (not a treaty term)
- 4 steps – designated into two “chapters”
 - Single international application designating PCT countries selected by applicant
 - Chapter I
 - File, selected receiving office processes the application
 - Create international search
 - Publish the int'l application, along with search report, communication of these to designated national or regional offices
 - Chapter II
 - Possibility of preliminary (and advisory) patentability examination under criteria of Article 33 and Rule 64.
- National Phase (not a treaty term)
 - Transmission to PCT contracting states for further processing/examination
- Advantages
 - Delay national filing fees
 - Postpone other costs, such as translation fees

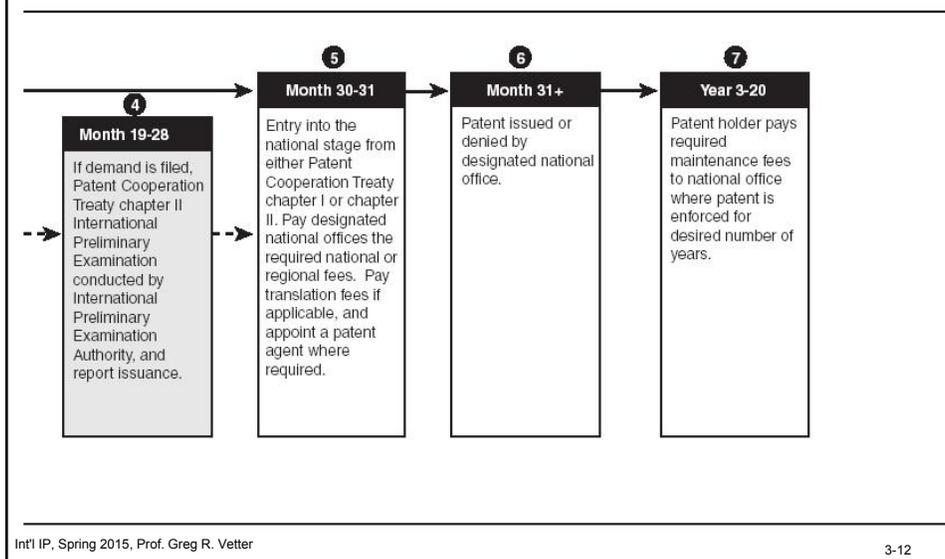
The PCT (1994)

Figure 1: The International and National Stages of the PCT Process



The PCT (1994)

- Chapter II (item 4) – optional preliminary (advisory) examination; then national stage



European Patent

- EPC – regional patent treaty from perspective of PCT
- EPC – special agreement under Paris
- Autonomous, self-supporting intergovernmental organization
 - Munich office
- Relationship to laws of member states?

First to File versus First to Invent

- First to file
 - The rest of the world
 - Arguments for first to file
 - race to the patent office (usually published after 18 months, so competitors have access to the information)
 - increase certainty as to patent ownership
- First to invent
 - U.S. (preAIA)
 - “Venerable traditions and exceptionalism of the US patent system
 - US has a modified first to invent system because of the statutory bars
 - §102(b)
 - Public use
 - On sale

Harmonization of Patent Law (1990) – WIPO Treaty

- First to file

- Opponents say
 - Increase applications, lower quality
 - Unconstitutional
 - Lacks fairness
- Advocates say
 - Certainty
 - First to invent no longer works well for the US because inventions are occurring in foreign countries at a greater rate

- First to invent

- Opponents say
 - Most US filers operate as if the system were first to file to preserve foreign rights
- Advocates say
 - Tradition – 150 years of this system
 - Past studies have not concluded that there is a need for a change

Paris Convention – Art. 5

- Current Art. 5(A)
 - (1) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.
 - (2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.
 - (3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.
 - (4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

Problem 3-7

TRIPS – Art. 27

- 1. Subject to the provisions of
 - paragraphs 2
 - [exclusions for public order or morality, including to protect human, animal or plant life, or avoid serious prejudice to the environment]
 - and 3
 - [methods of treatment for humans or animals; plants & animals, and methods to produce, other than micro-organisms],
- patents shall be available for **any inventions**, whether products or processes, in **all fields of technology**, provided that they are new, involve an inventive step and are capable of industrial application.
- Subject to
 - paragraph 4 of Article 65 [delayed implementation for developing countries],
 - paragraph 8 of Article 70 [even if subject matter not previously patentable in a country, begin protection after TRIPS enters into force] and paragraph 3 of this Article,
- patents shall be available and patent rights enjoyable **without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.**

TRIPS – Other baseline substantive protection

- Eligibility
 - States cannot exclude any field of technology
 - States cannot discriminate as to place of invention
 - Uniform conditions of eligibility [Art. 29]
 - Specified exclusive rights [Art. 28], which must include the right to supply the market w/ imports of the patented products
 - How does this relate to 5A of Paris, the obligation to work patents locally?
- Duration
 - Domestic patent laws must provide uniform 20 year term from date of filing [Art. 33]
- Hierarchy
 - Developing countries
 - Developing countries
 - 5 year implementation delay, 10 for technology areas never covered by patents [Art. 65]
 - Least Developed Countries (LDC)
 - 10 year implementation delay, more on showing of hardship [Art. 66(1)]

TRIPS – Possible counterpoint provisions as compared to Art. 27

- Art. 7
 - The protection and enforcement of intellectual property rights should **contribute to the promotion of technological innovation and to the transfer and dissemination of technology**, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations
- Art. 8
 - 1. Members may, in formulating or amending their laws and regulations, adopt measures **necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development**, provided that such measures are consistent with the provisions of this Agreement.
 - 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to **prevent the abuse of intellectual property rights** by right holders or the **resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology**.

TRIPS – Possible counterpoint provisions as compared to Art. 27

- Art. 30
 - Members may provide **limited exceptions to the exclusive rights conferred by a patent**, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties
- Art. 66
 - 1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their **need for flexibility to create a viable technological base** [they have a 10 year delayed implementation]
 - 2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

TRIPS – Art. 31

Where the law of a Member allows for other use of the subject matter of a patent **without the authorization** of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made **efforts to obtain authorization from the right holder on reasonable commercial terms** and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be **waived** by a Member in the case of a **national emergency** or other circumstances of extreme urgency or in cases of public non-commercial use.
. . . ;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;**

TRIPS – Art. 31 (cont'd)

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be **terminated if and when the circumstances which led to it cease to exist and are unlikely to recur**. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

- (h) the right holder shall be paid **adequate remuneration** in the circumstances of each case, taking into account the economic value of the authorization;
- (i) . . . judicial review . . . ;
- (j) . . . remuneration . . . judicial review . . . ;
- (k) . . . anti-competitive. . . . ;
- (l) where such use is authorized to permit the exploitation of a patent (“the second patent”) which cannot be exploited without infringing another patent (“the first patent”), the following additional conditions shall apply:
 - (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
 - (ii) . . . to a cross-license . . . ; and
 - (iii) . . . non-assignable

35 USC §101

Whoever invents or discovers any
new and useful
process,

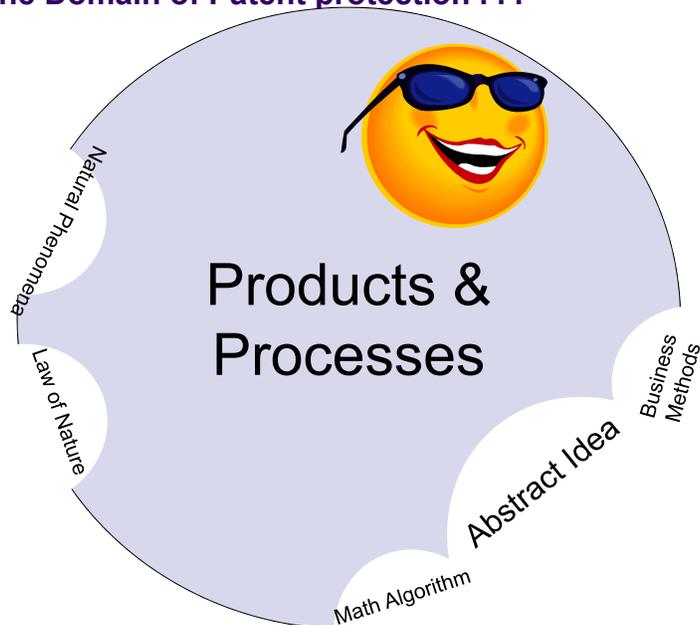
“Product”
claims or
inventions

machine, manufacture, or
composition of matter,

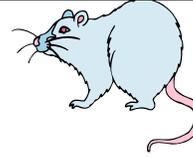
or any new and useful improvement
thereof,

may obtain a patent therefor, subject to the
conditions and requirements of this title

The Domain of Patent protection . . .



Harvard College v. Canada (2002)



- Application – 6/21/1985
- Final action – March 1993
 - Disposition of product versus process claims?
- Result in Federal Appeals Court?

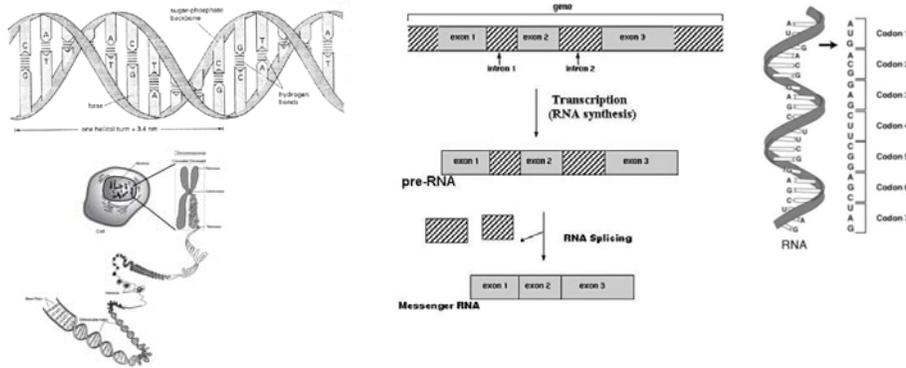
- Compare and contrast by Canada Supreme Court with U.S. Chakrabarty decision
 - Manufacture
 - Composition of Matter

- Implications of self-replication?
- Lower/higher life forms?
 - Impact of treaties?

- Dissent . .

Assn. of Molecular Pathology v. Myriad Genetics, __ U.S. __ (2013)

'252 claim 1: An isolated DNA coding for a BRCA1 polypep-tide, said polypeptide having the amino acid se-quence set forth in SEQ ID NO:2.



- Isolated DNA sequence
- cDNA sequence

cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. As already explained, creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring.

EPC Art. 52

Article 52 - Patentable inventions

(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

- (a) discoveries, scientific theories and mathematical methods;
- (b) aesthetic creations;
- (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- (d) presentations of information.

(3) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

EPO Opposition Revoking European Pat. No. EP-B-0436257

- EU application claiming Paris priority to U.S. filing date of 12/26/1989
- Prior use as prior art?
 - When?
 - Where?
- Effect of this prior use?
 - Europe
 - U.S.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: Irritation may occur through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after use.

FIRST AID
If on skin: Wash off immediately with soap and water. If in eyes: Flush with plenty of water for at least 15 minutes. Seek medical attention.

User Safety Recommendations:
Wash hands before eating, drinking, or using any tools or equipment. Do not use in areas where children or pets play. Do not use in areas where food is stored or prepared. Do not use in areas where food is stored or prepared.

ENVIRONMENTAL HAZARDS
Do not apply directly to water. Do not use near water bodies or in areas of groundwater recharge.

PHYSICAL AND CHEMICAL HAZARDS
Do not use in areas where food is stored or prepared.

KEEP OUT OF REACH OF CHILDREN
CAUTION

See Side Panel for additional PRECAUTIONARY STATEMENTS

Southern Agricultural Insecticides, Inc.
1000 N. W. 10th St., Ft. Lauderdale, FL 33304
Net Contents Liquid: 1 Pint (474liters)

Triple Action Neem Oil

Controls Fungal Diseases Including Black Spot, Blight, Rust, and Scab. Kills Mites and Insects Including Aphids, Spiders, and Scale.

Best Spectrum Fungicide/Insecticide/Miticide For Indoor/Outdoor Use on Ornamental Flowering Plants, Trees, Shrubs, Foliage, Vegetables, Fruit, Nurseries and Home and Residential Landscapes.

Net Contents Liquid: 1 Pint (474liters)

Dyna-Gro Neem Oil



Dyna-Gro Neem Oil is pressed from the seed of the neem tree. Neem oil leaves a natural shine on leaves without clogging stomata that leaves need to take in carbon dioxide and release oxygen and water vapor essential to the basic functioning of the photosynthesis process. Pure Neem Oil is an organic all natural leaf polish that

leaves a natural shine.

preAIA §102(a)

102(a) – if the prior art reference occurred prior to the date of invention of what is claimed, then the claim is not novel if that reference anticipates the claim (has all the limitations/elements of the claim).

	public knowledge or	“Public” is an implied requirement, relates to that segment of the public most interested in the technology, public if no deliberate attempts to keep it secret.
	used by others	One use is sufficient, even if private, remote or widely scattered, public if no deliberate attempts to keep it secret.
	patented or	A grant of exclusive rights, evaluated for what is claimed, accessible to public & not secret
	printed publication	Public accessibility – the document was made available to the extent persons interested and ordinarily skilled in the art, exercising due diligence, could locate it. The test for what is a “patent or printed publication” is the same under 102(a) & (b)).

“the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent”

preAIA §102(b)

102(b) – if the applicant does not file within one year of the date of the prior art reference or activity, then the patentee is barred from applying for the patent.

	in public use or	No purposeful hiding of use. Experimental use exception.
	on sale	Commercial offer for sale and invention is ready for patenting
	patented or	same as 102(a).
	printed publication	same as 102(a).

“the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States ”

Geographic dichotomy of 102 in (preAIA) U.S. patent law

This geographic dichotomy is a source of criticism for U.S. law. On one hand, it helps PTO examiners who can search global databases of patents and printed publications. Screening for knowledge or use worldwide is much more difficult. It also means that proving knowledge or use under § 102(a), or public use or an on sale event under § 102(b), is conducted within the U.S. court system with its familiar procedure.

On the other hand, the geographic distinction disadvantages certain types of knowledge in foreign nations. Sometimes called “traditional knowledge,” information in many countries is shared, distributed, improved-upon, and used in an oral tradition. These practices are often associated with indigenous peoples who may have extensive technological information about their local environment, all of which is kept without writings. The classic rhetorical scenario is a U.S. company that discovers indigenous persons in a foreign land who know how to use the leaf of a plant to heal skin abrasions. The U.S. company purifies the substances in the leaf, slightly alters the molecules for use in a salve, and obtains a U.S. patent on the salve. Would the original foreign use of the leaf have rendered the patented salve obvious? Perhaps not, but the use is excluded from the universe of prior art considered in making the obviousness argument due to the geographical distinction in § 102(a)-(b).

Dwyer, BioPiracy . . .

- Examples
- Proposed Solutions
- Self-Help?
 - State powers
 - Local legislation to protect TK and PGR
 - Local research on TK/PGR
 - Better negotiation
- Will local governments protect the interests of those with TK/PGR?



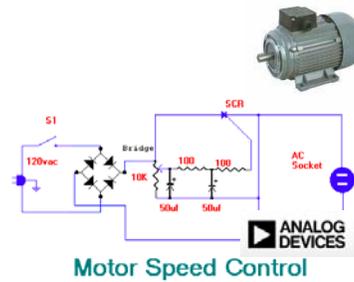
Biopiracy . . .

Int'l IP, Spring 2015, Prof. Greg R. Vetter

3-33

Pellegrini v. Analog Devices (Fed. Cir. 2004)

- Pellegrini's infringement suit
 - Claim: "brushless drive motor circuits"
 - Accused Infringing Device: ?
- What did Analog do?
- Where?
- Infringement claims under 271(a) versus 271(f)
 - Effect of: export statement; HQ in U.S.; injury by P felt in U.S.; . . .



35 U.S.C. 271 Infringement of patent.

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent. . . .

(f)(1) Whoever without authority **supplies or causes to be supplied in or from the United States** all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

Int'l IP, Spring 2015, Prof. Greg R. Vetter

3-34

Microsoft Corp. v. AT&T Corp., 550 U.S. 437 (2007)

- “Infringement occurs only when Windows is installed on a computer, thereby rendering it capable of performing as the patented speech processor.”
- “a copy of Windows, not Windows in the abstract, qualifies as a ‘component’ under § 271(f)”
- Does a single master CD sent abroad with copies made abroad equate to “supplied from the U.S.”?
- Presumption against extraterritoriality
- Dissent . . .



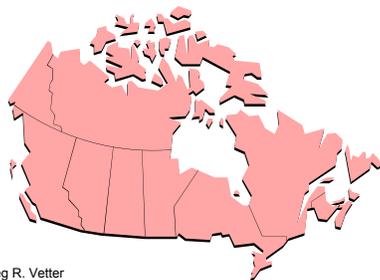
35 U.S.C. 271 Infringement of patent.

. . .

(f)(1) Whoever without authority **supplies or causes to be supplied in or from the United States** all or a substantial portion of the **components** of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

TRIPS – Canada Patent Protection of Pharmaceutical Products

- WTO Dispute Settlement Panel, March 17, 2000
- Canadian law at issue: Section 55.2 of CPA; paraphrased as follows:
 - no liability for making, using or selling a patented product, or using a patented process “solely for uses reasonably related to the development and submission of information required under any law of Canada” or other countries when such laws are for regulating the manufacture, construction, use of sale of any product
- OR
 - for the manufacture and storage of articles intended for sale after the date the patent expires



TRIPS – Canada Patent Protection of Pharmaceutical Products



- TRIPS Art. 28
 - 1. A patent shall confer on its owner the following exclusive rights:
 - (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
 - (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
 - 2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.
- TRIPS Art. 33
 - The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date

TRIPS – Canada Patent Protection of Pharmaceutical Products



- Europe says
 - by [A] allowing manufacturing and stockpiling 6 months prior to patent expiration and [B] by information submission use for drug marketing approval, Canada violates:
 - TRIPS Art. 28.1 – basic rights to exclude
 - TRIPS Art. 33 – term of 20 years extends to expiration
 - TRIPS Art. 27.1 - patent rights shall be enjoyable w/out discrimination as to the field of technology
- Canada says
 - these are all “limited exceptions” under Art. 30

TRIPS – Canada Patent Protection of Pharmaceutical Products



- Art. 30 - three prong test, all must be satisfied, each prong interpreted in light of the others – so differentiate
 - Limited;
 - not unreasonably conflict with a normal exploitation of the patent; AND
 - not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties
- General interpretive determinations
 - Very existence of Art. 30 signals that Art. 28 rights can be adjusted by members somewhat
 - But, the three limiting conditions signal “strongly that the negotiators . . . did not intend Art. 30 to bring about what would be equivalent to a renegotiation of the basic balance of [TRIPS]”
 - Canada on “limited”
 - “limited” means “confined” or “restricted in scope, extent or amount”
 - Europe on “limited”
 - Narrow, small, minor, insignificant or restricted
 - Court sides w/ Europe – because “limited” is used w/ exceptions, it should have a narrow meaning and coverage
 - AND, measure “limited exceptions” against the extent of curtailment of the exclusive rights, not the “right to work”
 - The following two prongs of the test examine two sets of standards by which such curtailment can be judged economically – meaning that it is correct to evaluate the first prong based on the curtailment of the exclusive rights to exclude

TRIPS – Canada Patent Protection of Pharmaceutical Products



- Application to stockpiling
 - Canada – measure “limited” against the right to commercially exploit
 - Size and extent of economic impact
 - Europe – measure “limited” against the right to exclude
 - 6 months of 20 years, or in effect 8-12 years, is more than insignificant
 - Quantities not limited during these 6 months
 - No royalty fees due, no right for patentee to receive notice
 - During the 6 months it is in effect, the stockpiling completely abrogates the patentees right to exclude competitors under the provision of “making” and “using” the invention
 - With no limitations on quantity, the stockpiling provision completely removes “making” and “using” during the last 6 months
 - This alone is sufficient to run afoul of “limited”
 - Part of the normal expectation of a patentee is that there will be a short post-expiration time period where the patentee will still have an advantage as competitors ramp up
 - Repeated enactment of “such universal” rights with this known effect

TRIPS – Canada Patent Protection of Pharmaceutical Products



- Application to regulatory review
 - First prong, limited, satisfied
 - Second prong - unreasonably conflict with a **normal** exploitation of the patent
 - Normal is to exclude all forms of competition that could significantly detract from economic returns
 - Panel does not believe that some post-expiration market advantage is not normal – except for regulatory review, which most patent owners do not face
 - Thus, the regulatory review provision does not unreasonably conflict w/ normal exploitation
 - Third prong - not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties
 - As an example of “legitimate interests” consider the experimental use exception available in some countries – a country has a legitimate interest in using the patent disclosure to advance science and technology
 - TRIPS Art. 30 added “interests of third parties” - this signals that “legitimate interests” goes to more than mere legal interests
 - Europe’s argument that the pioneer drug companies get a 40-60% shortened term fails because this is not a compelling or widespread “legitimate interest” (other governments are still divided on the point)
 - Thus, Canada satisfies all 3 prongs

TRIPS – Art. 31

Where the law of a Member allows for other use of the subject matter of a patent **without the authorization** of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made **efforts to obtain authorization from the right holder on reasonable commercial terms** and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be **waived** by a Member in the case of a **national emergency** or other circumstances of extreme urgency or in cases of public non-commercial use.
... ;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) **any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;**

TRIPS – Art. 31 (cont'd)

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be **terminated if and when the circumstances which led to it cease to exist and are unlikely to recur**. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid **adequate remuneration** in the circumstances of each case, taking into account the economic value of the authorization;

(i) . . . judicial review . . . ;

(j) . . . remuneration . . . judicial review . . . ;

(k) . . . anti-competitive. . . . ;

(l) where such use is authorized to permit the exploitation of a patent (“the second patent”) which cannot be exploited without infringing another patent (“the first patent”), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) . . . to a cross-license . . . ; and

(iii) . . . non-assignable

Brazil Measures Affecting Patent Protection

Art. 68.

The titleholder shall be subject to having the patent licensed on a compulsory basis if he exercises his rights derived therefrom in an abusive manner, or by means thereof engages in abuse of economic power, proven pursuant to law in an administrative or judicial decision.

(1) The following also shall occasion a compulsory license:

I. non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process, except cases where this is not economically feasible, when importation shall be permitted; or

II. commercialization that does not satisfy the needs of the market.

(2) A license may be requested only by a person having a legitimate interest and having technical and economic capacity to effectively exploit the object of the patent, that shall be destined predominantly for the domestic market, in which case the exception contained in Item I of the previous Paragraph shall be extinguished.

(3) In the case that a compulsory license is granted on the grounds of abuse of economic power, the licensee who proposes local manufacture shall be assured a period, limited to the provisions of Article 74, to import the object of the license, provided that it was introduced onto the market directly by the titleholder or with his consent.

(4) In the case of importation to exploit a patent and in the case of importation as provided for in the preceding Paragraph, third parties shall also be allowed to import a product manufactured according to a process or product patent, provided that it has been introduced onto the market by the titleholder or with his consent.

(5) The compulsory license that is the subject of Paragraph 1 shall only be required when 3 (three) years have elapsed since the patent was granted.

TRIPS – Doha Declaration on the TRIPS Agreement & Public Health

- 1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
- 2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
- 3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
- 4. We **agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.** Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement **can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health** and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, **to the full**, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

TRIPS – Doha Declaration on the TRIPS Agreement & Public Health

- 5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these **flexibilities include**:
 - a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
 - b. Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
 - c. Each member has the right to determine what constitutes a **national emergency or other circumstances of extreme urgency**, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and **other epidemics**, can represent a national emergency or other circumstances of extreme urgency.
 - d. The effect of the provisions in the TRIPS Agreement that are relevant to the **exhaustion** of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

TRIPS – Doha Declaration on the TRIPS Agreement & Public Health

- 6. We recognize that **WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing** under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
- 7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Doha Implementation Decision

- Eligible importing member – any LDC, and . . .
- Limited waiver of TRIPS Art. 31(f)
 - Importing Member Notification
 - Quantities / Distinguishing features of the pills
 - Exporting Member Notification
- “ensure availability of effective legal means to prevent” diversion
- Work toward an amendment in TRIPS