International Intellectual Property

- slides for module 4
- International Patent Law

Venetian Patent Law Of The 19th March 1474

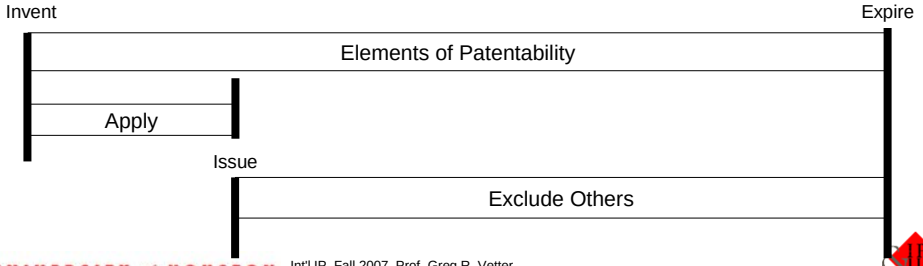
- There are in this city, and also there come temporarily by reason of its greatness and goodness, men from different places and most clever minds, capable of devising and ***inventing all manner of ingenious contrivances***. And should it be provided, that the works and contrivances invented by them, others having seen them could not make them and take their honour, men of such kind would exert their minds, invent and make things which would be of no small utility and benefit to our State.
- Therefore, decision will be passed that, by authority of this Council, each person who will make in this city any ***new and ingenious contrivance, not made heretofore in our dominion, as soon as it is reduced to perfection, so that it can, be used and exercised***, shall give notice of the same to the office of our Provisioners of Common. It being forbidden to any other in any territory and place of ours to make any other contrivance in the form and resemblance thereof, without the consent and license of the author up to ***ten years***.
- And, however, should anybody make it, the aforesaid author and inventor will have the liberty to ***cite him*** before any office of this city, by which office the aforesaid who ***shall infringe be forced to pay*** him the sum of one hundred ducates and the contrivance be immediately destroyed. Being then in liberty of our ***Government at his will to take and use*** in his need any of said contrivances and instruments, with this condition, however, that no others than the authors shall exercise them.

Statute of Monopolies, 21 James I, Ch. 3 (England, 1623)

- I. Whereas your majesty, in the year 1610, published a book declaring that all grants of monopolies, and of the benefit of penal laws, and of the power of dispensing with law, and of compounding penalties, are contrary to law; and whereas your majesty then expressly commanded that no suitor should ever apply for such grants; and whereas, nevertheless, such grants have been applied for and allowed; Therefore to make void all these, and to prevent the like in time to come, may it please your majesty that it be declared and enacted by authority of this present parliament "that ***all monopolies*** and all commissions, grants, licenses, charters, ***and letters-patent***, heretofore made or granted, or hereafter to be made or granted, to any person or persons... whatsoever, of or for the sole buying, selling, making, working, or using of anything, within this realm or the dominions of Wales, or of any other monopolies" and all licenses to do anything contrary to law, or to confer authority on others so to do... "are altogether contrary to the laws of this realm, and so ***are and shall be utterly void***, and of none effect, and in no wise to be put in use or execution."
- . . .
- VI. Provided also, and be it declared and enacted: That any declaration before mentioned ***shall not extend to any letters-patent and grants of privilege, of the term of fourteen years or under***, hereafter to be made, of the ***sole working or making of any manner of new manufactures***, within this realm, to the true and first inventor and inventors of such manufactures, which others, at the time of making such letters-patent and grant, shall not use, so as also they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient; The said fourteen years to be accounted from the date of the first letters-patent or grant of such privilege, hereafter to be made; but that the same shall be of such force as they should be, if this act had never been made and of none other.

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)



Claims

- Claims are the heart of the patent system
- Inventors are those who thought of something covered by the claims, no those who learned it from someone else (may not know who they are until claims are drafted)
- Claims define the scope of coverage of the right to exclude
- Those who operate within the language of the claim are subject to an infringement action

Claim elements/limitations

- In claims using the transition word "comprising," adding more elements/limitations makes the claim more narrow (i.e., there are a smaller number of items that might be covered by the claim)
  - There are other ways to make the claim more narrow, this is not the only way
- For example, arrange these three claims from most to least broad:

Claim 1

- A device for supporting objects, comprising:
- (a) a horizontal support member; and
- (b) three vertical support members each having one end connected to the same face of said horizontal support member.

Claim 3

- A ***seating apparatus***, comprising:
- (a) a horizontal ***seat***;
- (b) three ***legs*** each having one end connected to the ***bottom*** of said horizontal ***seat***; and
- (c) said connection between said legs and bottom of said horizontal seat being a slim metal piece partially traversing some of said leg and said seat.

Claim 2

- A ***seating apparatus***, comprising:
- (a) a horizontal ***seat***; and
- (b) three ***legs*** each having one end connected to the ***bottom*** of said horizontal ***seat***.

35 USC §101

Whoever invents or discovers any new and useful

process,

machine, manufacture, or composition of matter,

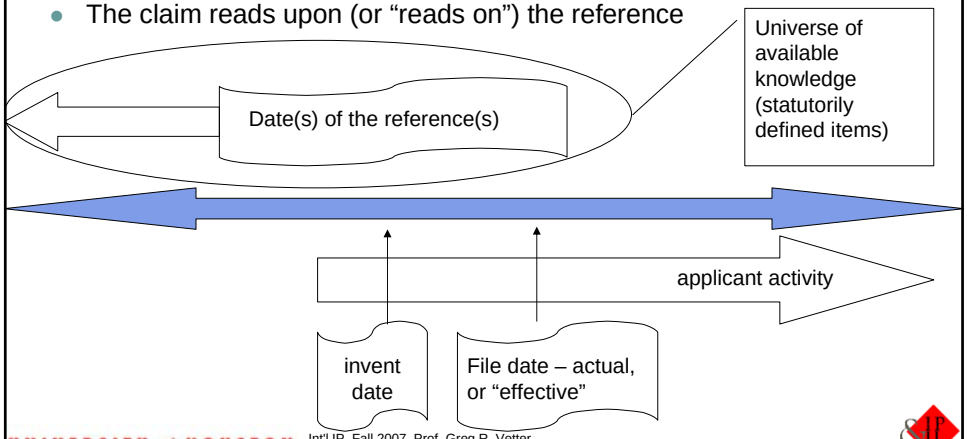
or any new and useful improvement thereof,

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

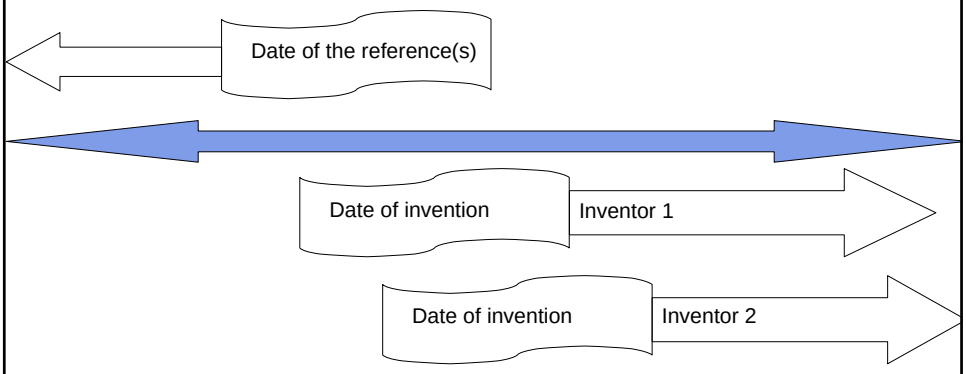
"Product" claims or inventions

Dates of Invention and Prior Art References

- "anticipating" references are Prior Art references that defeat patentability on the novelty element because the reference "anticipates" the claim
- What is an "anticipating" reference? (answered different ways that mean the same thing)
  - The reference "has" all the elements of the claim
  - The claim covers what is disclosed by the reference (the disclosure must be enabled for anticipation purposes)
  - The claim reads upon (or "reads on") the reference



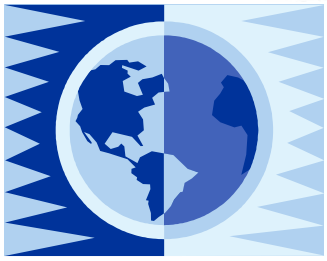
Dates of Invention and Prior Art References



The Development of Int'l Patent Treaties - Kronstein & Till, A Reevaluation of The International Patent Convention (1947)

- Creation period of the Paris Union was 1872 to 1881
- Period was battleground for three competing philosophies:
  - (i) anti-patent;
  - (ii) patents as private property; and
  - (iii) patents as an instrument of public policy.

The world can't live half w/ patents and half w/out



- Problems with living "half with & half without"
  - damage to competition because a manufacturer in country w/ patents must pay more for production inputs; thus its goods are less competitive compared to manufacturer where there is no patent covering the same production inputs
  - Patent attracts skilled operatives from one country to another

- US position was to push for
  - No patents for mere importation
  - Patents granted in one country to citizens of another should not be subject to such restrictions as to time and place of manufacture ("working" requirements)
- US view was novel – that in a competitive economy, patents under the control of private owners would not be subject to abuse
- Deadlock between French and US positions resulted in the 1883 Paris Convention to be virtually all procedural, along with national treatment and the right of priority
  - French – no examination and forfeiture for nonworking
  - US – examination and no forfeitures for failure to work

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
  - United States
  - "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

Paris Convention Art. 4

Art. 4	Patents, Utility Models, Industrial Designs, Marks, Inventors' Certificates: Right of Priority
(A)(1)	Any person who has duly filed an application for a patent . . . in one of the countries of the Union, or his successor in title, shall enjoy, ***for the purpose of filing in the other countries***, a right of priority during the periods hereinafter fixed [12 months for patents].
(A)(2) (1883)	Any filing *having the value of a formal* national filing *by virtue of the internal law of each* country of the Union or under *international* treaties concluded *among several* countries of the Union shall be recognized as giving rise to the right of priority.
(A)(2) (current)	Any filing that is equivalent to a regular national filing under the domestic legislation of any country of the Union or under bilateral or multilateral treaties concluded between countries of the Union shall be recognized as giving rise to the right of priority.
(A)(3)	By a regular national filing is meant any filing that is adequate to establish the date on which the application was filed in the country concerned, whatever may be the subsequent fate of the application.

Paris Convention Art. 4

Art. 4	Patents, Utility Models, Industrial Designs, Marks, Inventors' Certificates: Right of Priority
(B) (1883)	Consequently, subsequent filing in one of the other countries of the Union before the expiration of the these Periods shall not be invalidated through any acts accomplished in the interval, as, for instance, another filing, the publication of the invention or the working thereof, by the sale of copies of the design or model, or by the use of the trade mark, and these acts cannot give rise to any right of third-parties or any right of personal possession. The rights acquired by third parties before the date of the first application on which priority is based shall be reserved by the internal legislation of each country of the Union
(B) (current)	Consequently, any subsequent filing in any of the other countries of the Union before the expiration of the periods referred to above shall not be invalidated by reason of any acts accomplished in the interval, in particular, another filing, the publication or exploitation of the invention, the putting on sale of copies of the design, or the use of the mark, and such acts cannot give rise to any third-party right or any right of personal possession. Rights acquired by third parties before the date of the first application that serves as the basis for the right of priority are reserved in accordance with the domestic legislation of each country of the Union

Paris Convention – Art. 5

- Patents as property versus patents as instruments of public and trade policy?

- Original
  - The introduction by the patentee into countries where the patent has been granted, or articles manufactured in any other States of the Union shall not entail forfeiture. The patentee, however, shall be subject to the obligation of working his patent comfortably to the laws of the country into which he has introduced the patented article

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.

Paris Convention – Art. 5 – Revision Conferences

- Looking at the limits of the extent to which national laws may require patentees to exploit their inventions, and types of sanctions allowed to enforce such requirements
- Why do countries care whether a patentee exploits its invention in that country?
- This question of revocation for non-working is the largest single economic impact provision in the Paris Convention
  - Why?

Paris Convention – Art. 5 – Revision Conferences

- Brussels, 1897-1900
  - enacted 3 year grace period before revocation for non-working, and only if patentee could not justify inaction
    - But, this does not mean that other sanctions for misuse of monopoly power are barred
- Washington 1911
  - Reservation system proposal failed, just as a restricted union had at Brussels
  - No real changes
- Hague 1925
  - Paragraphs 3 & 4 inserted
    - Compulsory license
    - 3 year grace period
  - Argument that compulsory license clauses are irrational
    - if patentee can work the invention elsewhere, it is because its costs are lower there – so, consumers in target country also benefit (pg 405)
- What type of conditions must attach for a country to implement revocation – i.e., when is the grant of a compulsory license not "sufficient to prevent the said abuses"

Paris Convention – Art. 5 – Revision Conferences

- London 1934
  - Only paragraph 4 was amended
    - compromise that sanction of revocation kept, but only imposable two years after a compulsory license is granted
    - This change also certified that paragraph 3, while unchanged, was more than a mere principle – but that it applied to all members
- Lisbon 1958
  - Variety of "clean-up" changes to all of Art. 5 except its first paragraph
  - As in past conferences, no agreement to abolish non-working forfeiture because lesser developed countries are concerned that local licensees may not be available to implement compulsory licensing
  - Grace period clarified to only apply to non-working and insufficient working, and that primary sanction was compulsory license
  - Do the changes in paragraph 3 allow for imposing the revocation sanction before a license is tried, i.e., a country making a finding that even if a patentee were to try compulsory licensing, it would be insufficient?

Paris Convention – Art. 5 – Revision Conferences

- Working requirements and economic efficiency
  - Economically unsound in any case where efficiencies of scale demand production in one place for international markets
- Intervening Rights and Prior user rights
  - Art. 4(B)
    - Rights acquired by third parties before the date of the first application that serves as the basis for the right of priority are reserved in accordance with the domestic legislation of each country of the Union
- How real is the underlying concern of large entities dominating a local market?
  - How does product substitutability impact this analysis?

Schroeder – 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

Schroeder – Harmonization of Patent Law (1990) – WIPO Treaty

- Grace period
  - Treaty proposes: grace period for inventor against her own publication or anyone who derives information from such publication
- Publishing of applications
  - 18 months after filed

Intervention of Manbeck (US Delegation) - WIPO Treaty

- Various changes requested in US law: first to file, mandatory publication of applications, term measured from filing date, right to prevent importation of patented products, eliminating Hilmer rule, etc.
- Trending away from US interests: oral disclosures anywhere in the world as prior art, issuing patents on obvious differences, inability to include the inventor's name, changes in multiple dependent claim practice, no article on time limits to properly complete examination, continuation practice made optional

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-licence . . .; and

(iii) . . . non-assignable . . ..

TRIPS – Patent Rights

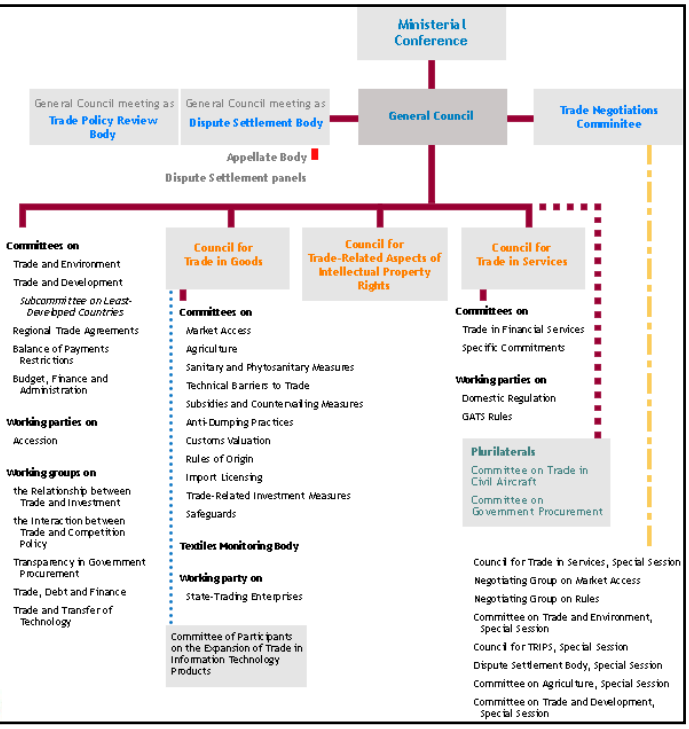
- Early in the Uruguay round of GATT talks that created WTO, Brazil and India submissions said:
  - rigid IP impedes access to latest technology, restricts participation of developing countries in Int'l trade
  - abusive IP distorts Int'l trade
  - what is "trade related" about IP is the restrictive behavior of IP owners
  - patent systems have adverse effects on critical sectors, such as food, poverty and health
  - systems of IP protection are by definition monopolistic, thus, sovereign nations should be able to attune their own systems

TRIPS – Patent Rights

- Brazil situation
  - US assertion that TRIPS prohibits discrimination regarding whether products imported or produced locally [Art. 27]
    - thus prohibiting members from instituting local working requirements
  - Backlash and withdrawal?
- South Africa situation – Section 15(c)
  - Ministerial entity granted power to proscribe when rights under a patent will not extend to "acts in respect of" a drug, or importation of generic versions of the drug
  - Backlash & compromise?
  - What is status of 15(c)?
    - Is South Africa out of TRIPS compliance if they are merely administratively forbearing?

TRIPS – Doha Declaration on the TRIPS Agreement & Public Health

- What is it?
- Who promulgated it?
- "The Doha Declaration is a strong political statement that can make it easier for developing countries to adopt measures necessary to ensure access to health care without the fear of being dragged into a legal battle. The Declaration is also a Ministerial decision with legal effects on the Members and on the WTO bodies, particularly the Dispute Settlement Body and the Council for TRIPS"



TRIPS – Doha Declaration on the TRIPS Agreement & Public Health

- What is the Doha conference?
  - Why was the Declaration issued there?
  - Where is Doha, Qatar?
- Is the Declaration rooted in Art. 8?
- How does the Declaration interact with Art. 31 of TRIPS?
- Why was it necessary?
  - What did the US seek?
  - What did the developing and LDC countries seek?

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

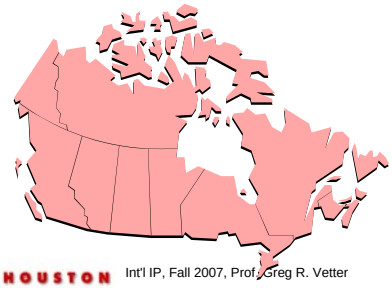
- 5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these ***flexibilities include***:
  - a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read 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.

TRIPS – Canada Patent Protection of Pharmaceutical Products

- WTO Dispute Settlement Panel, March 17, 2000
- Canadian law at issue: Section 55.2 of CPA
  - 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

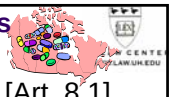
TRIPS – Canada Patent Protection of Pharmaceutical Products

- 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
  - they do not discriminate, or, in the alternative, Art. 27.1 antidiscrimination does not apply to limited exceptions
  - they do not reduce the term

TRIPS – Canada Patent Protection of Pharmaceutical Products

- Europe's case
  - Canada allows violations of Art. 28.1, automatically for anyone in Canada, totally unregulated, no royalties, etc.,
    - applied to both process and product patents
  - Canada is the only country doing this
  - Only two conditions limiting violations
    - Last 6 months for unrestricted violations
    - Unlimited in time for violations for marketing approval submissions
  - Canadian legislative history & regulations & practice limit this to drugs
    - Act inoperative without regulations, and the regulations specified "patented medicines"
    - Allows manufacturing, and phase I-III testing, anywhere in the world, for any jurisdiction
  - Canadian law has a history of compulsory licenses (55.2 is not justifiable as a compulsory license, or as a limited exception)
    - True product patents for pharma compounds first introduced in Canadian coverage in 1993
    - At that time, compulsory licensing eliminated, replaced w/ provisions at issue
  - NAFTA IP provisions include text almost identical to TRIPS Art. 31
    - Canada admitted its compulsory licensing scheme conflicts w/ TRIPS and NAFTA
  - The Canadian law conflict with the normal exploitation of a patent holder and unreasonably prejudice the legitimate interests of the patent owner

TRIPS – Canada Patent Protection of Pharmaceutical Products



- Canada's case
  - These are limited exceptions [Art. 30], for public health [Art. 8.1]
  - They don't unreasonably prejudice legitimate interests of patentee, taking into account legitimate interests of third parties (potential competitors and their position when the patent expired)
  - TRIPS Art. 27.1 antidiscrimination does not apply to limited exceptions
    - Art. 27.1 does not define the rights it applies to, thus it should apply to any rights remaining after Art. 30 limited exceptions are implemented
  - These limited exceptions leave the patentee the full freedom to exploit the invention during the entire term
  - Art. 30 should be judged based on a "commercial exploitation" principle
  - Without these limited exceptions, patentees can exploit time-consuming regulatory review to effectively extend the term of their patent rights

TRIPS – Canada Patent Protection of Pharmaceutical Products

- Object, Purpose & Meaning – Canada's view as it relates to Art. 30
  - (i) Creates limited exceptions
    - Art. 7 – protection of IP should promote innovation and technology dissemination in a manner conducive to social and economic welfare, w/ a balance of rights and obligations
    - Art. 30 implements the requirement for balance; consistent w/ Art. 1.1, members are free to implement
      - Art. 30 is broad because this was a better choice than adopting all the specific proposals for limiting rights brought during negotiations
      - No requirement in Art. 30 to prove that it is a least trade-restrictive measure, or necessary for a particular purpose
    - Art. 30 is more broad than similar copyright and TM provisions
    - Only "sales" allowed were for regulatory review manufacturing, acknowledging the reality of vertical integration; one can only "stockpile" if they are in the information submission process
    - Under prior Canadian law, experimental use exception covered infringement during regulatory period – so comparison of terms under old and new Canadian law is not meaningful
    - Patentee has full right to "work" (manufacture, license, sue most everyone, sue in the case of a generic claiming that it did not infringe, etc.)

TRIPS – Canada Patent Protection of Pharmaceutical Products

- Object, Purpose & Meaning
  - (ii) No conflict w/ normal exploitation of a patent
    - Rights run for patentee to full term
  - (iii) No prejudice to the legitimate interests of the patent owner
    - Consider a patent owner, not a business owner
    - The right is the exclusive right to "work" the invention [pg. 453]
      - ***Does this signal the fundamental theoretical point upon which Canada bases its argument?***
      - ***Is the patent right a right to exploit the invention, or a right to exclude others from operating within the language of the claims?***
  - (iv) Interests of third parties
    - Even if there was a conflict w/ two items above, conflict disappears when interests of third parties are considered
      - society at large, consumers, potential competitors, cost of health care & public health, most members seek to promote generics (WHO).
    - Art. 8.1 & 40 [control of anticompetitive practices] both allow members to take action to prevent abuse of rights; monopolies are bad
  - Implications of Art. 33 [20 year term]
    - Only defines the longevity of the right
    - It would be absurd for it to operate to counteract a reduced scope under Art. 30

TRIPS – Canada Patent Protection of Pharmaceutical Products

- Interpretation & Burden of Proof
  - Interpretation is according to the Vienna Convention
  - Article 31 – interpretative rules
    - Ordinary meaning of terms in light of object and purpose
    - Context for interpretation includes preambles, annexes, and other agreements/instruments under certain conditions in connection with the conclusion of the treaty
    - In addition to context, interpretative meaning comes from subsequent
      - Agreement on interpretation
      - Practice in application
      - Relevant rules of int'l law applicable to the parties' relation
  - Article 32 – supplementary means of interpretation (preparatory work & circumstances) to be used when under Article 31 the meaning is
    - ambiguous, obscure
    - manifestly absurd or unreasonable
- Burden of Proof
  - Europe must present a prima facie case of violation of Arts. 27.1, 28.1 and 33
  - Then, if Europe carries this burden to present evidence, Canada can try to rebut
  - But, Canada has conceded a violation of Art. 28, because it has resorted to Art. 30
  - Thus, Canada bears burden to demonstrate that its law complies with the criteria in Art. 30
  - In essence, under domestic law, this is like proving an Affirmative Defense

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
      - This point maps to both of the last two prongs

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
    - Court 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
    - Text of this third condition (like the second) was drawn from Berne9(2) – exception to copyright holder's right to exclude reproduction w/out permission
      - But, 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 – Canada Patent Protection of Pharmaceutical Products

- Antidiscrimination rule of Art. 27.1
  - Panel concluded that it applied
  - But, Europe did not submit sufficient evidence to counter Canada's formal declaration that the law was not limited to drugs
    - Legally available to every product subject to marketing approval requirements
  - Proof was insufficient for a discrimination claim or adverse effects to a single industry claim
- Notes & Questions
  - Separate proceeding brought by the US
    - Canada's 17 years from date of grant on its patent term for pre-1989 patents is on its face not compliant with Art. 33.

Global Patent Registration?

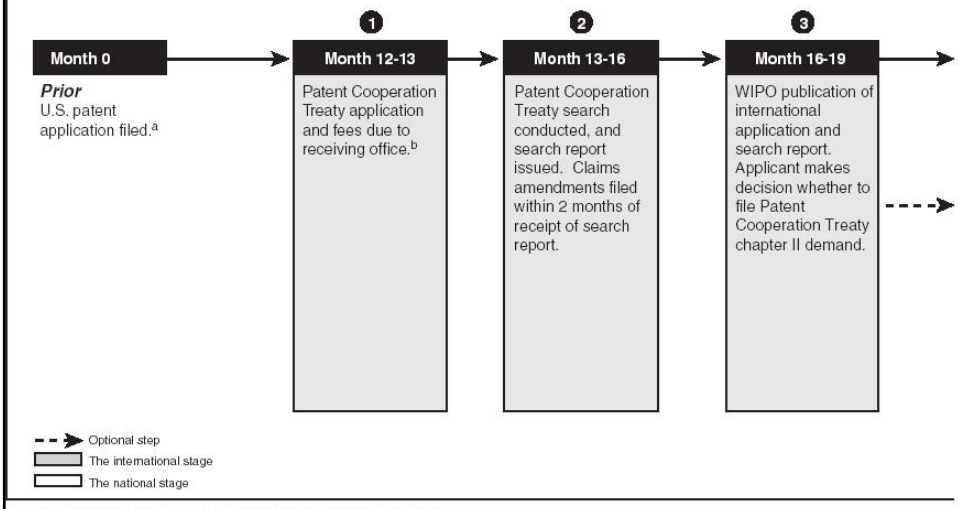
- Substantive harmonization:?
  - 1991 Patent Law Treaty
- Procedural Harmonization?
  - Paris Convention Priority
  - PCT
  - EPO
  - 2000 Patent Law Treaty
- Cost concerns for big and small inventor alike
- Lilly, Int'l Use of Patent Searches (1919)
  - Proposal for Canada to use US patent searches
  - Extent of duplication of patent applications in Canada and US?

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

Cartiglia, The PCT, A Rational Approach (1994)

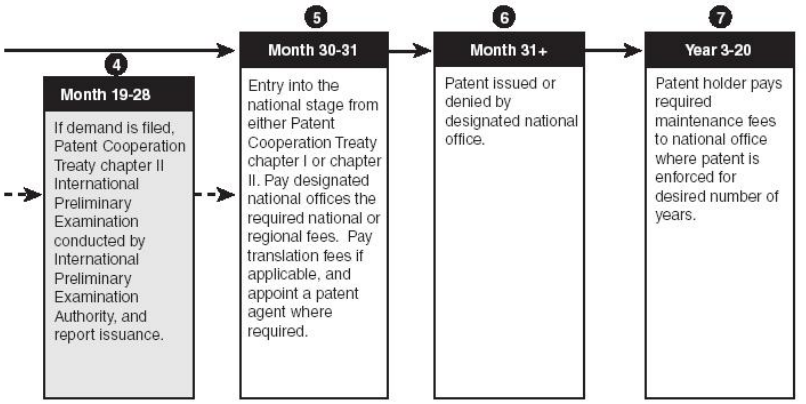
Figure 1: The International and National Stages of the PCT Process



Source: GAO analysis of the Patent Cooperation Treaty and national patent office fee schedules.

Cartiglia, The PCT, A Rational Approach (1994)

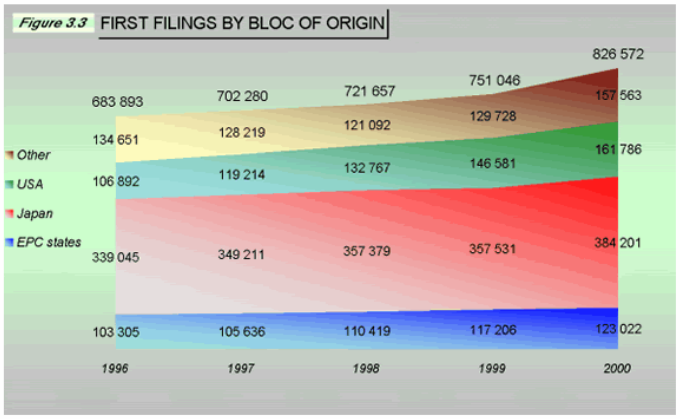
- Chapter II (item 4) – optional preliminary (advisory) examination; then national stage



World wide patent system usage statistics

- Source
- http://www.european-patent-office.org/tws/tsr_2001/ch3/3.2.php

The global total of first filings shows a steadily increasing trend since 1996, growing 10.1% from 1999 to 2000. The highest number of first filings occurs in Japan. In 2000 compared to 1999, first filings in Japan increased by 7.5%, by 10.4% in the USA, and by 5% in the EPC contracting states. For "Others", the number of first filings increased by 21.5% in 2000.

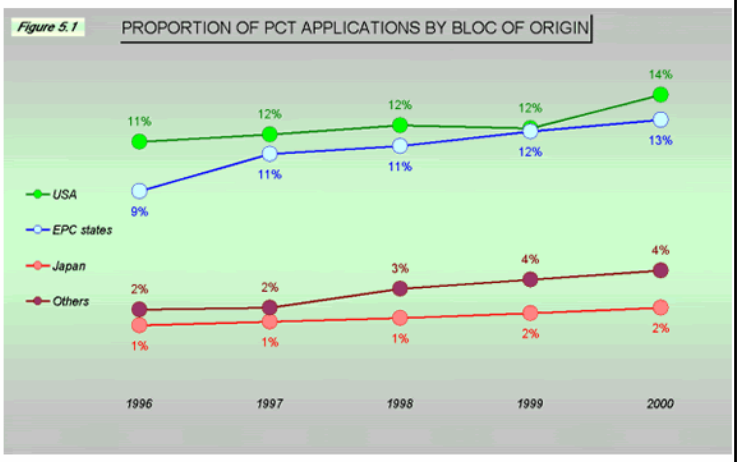


The number of first filings in 1999 was 751 046. From these first filings, one year later (2000) 431 274 subsequent filings were registered. Thus on average one invention, from which a first patent filing was made, led to 0.57 subsequent applications. The same exercise carried out by considering the demand for patent rights generated from first filings shows that one first filing led to 11.7 subsequent applications for patent rights. Three years ago, the rate was at a lower level of 5.5. This shows the ongoing internationalisation of the patent system.

PCT usage statistics

- Source
- http://www.european-patent-office.org/tws/tsr_2001/ch5/5.1.php

Figure 5.1 shows, for each bloc, the proportions of all patent applications filed (as given in the Chapter 3) that are PCT international applications. Applications are counted in the year of filing.



There has been an increase in the use of the PCT as a route for filing patent applications. The EPO experienced a significant increase from 1996 to 1997 of 2.1%. The JPO has shown a small but consistent growth over the years. Levels at the USPTO have increased but there was a very slight decrease in 1999.

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?

Lenzing AG's European Patent (1997)

- Lenzing (Austrian co.) alleges that an EPO opposition board (BofA) wrongly ordered revocation of its EPC patent.
  - UK marked the patent as revoked as well
- Also, Lenzing has sued Courtaulds for infringement in UK court system
  - They defend, seeking dismissal due to revocation
- Lenzing's EPC patent is a "European Patent (UK)"
  - If two patents for same invention, EPC patent prevails, national patent revoked
- Opposition procedure
  - Announcement after oral hearing

Lenzing AG's European Patent (1997)

- Lenzing alleges procedural irregularities as foundation for a collateral attack
  - Agency law idea – EPO did not operate in accordance with the EPC, so UK property right should not be impinged
    - Or, is the opposition only a part of the original, EPO controlled granting process?
      - It must be in the first 9 months after issuance.
  - Counter-argument is that all the UK requires is certification or proof from the EPO as to the issuance or revocation of an EPC patent
    - But, what if the grant or revocation at the EPO is a breach of principles of "natural justice" (due process)
  - From a TRIPS perspective, there is a review available for the revocation
    - UK act calls the BofA a "court"
- Does Lenzing have a remedy on an ex-ante basis?

Lenzing AG's European Patent (1997) - notes

- Beyond opposition, no centralized nullification proceeding
- Bundle of national patent rights once issued
- Various organs within EPO (pg. 996)
  - 3 examiners
- Elements for a filing date
  - Seeking European patent
  - Designate at least one contracting state
  - Identify the applicant
  - Description of the invention and at least one claim in an allowable language
- Costs, flow of funding, central attack in opposition