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WASHINGTON COLLEGE OF LAW
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International Law and Policy Supporting Brazil's Patent Reform

Sean Flynn
American University Washington College of Law

Open Letter from Global Academics in Support of Proposal to Amend Brazil's Patent Law to Take Advantage of TRIPS-Compliant Flexibilities

Colleagues:

As many of you may have heard, Brazil has been engaged in a long process of studying patent law reform and in August 2013 (originally scheduled for July 10, 2013) will be issuing a major report and proposed legislative reforms. In sum, as detailed below in (1) an open letter and (2) its attached brief technical review which has the text of the proposed bill as an annex, Brazil is seeking to incorporate lawful TRIPS flexibilities, into its patent law including: eliminating patent term extensions and data exclusivity, restricting patents on new forms and new uses and tightening the the inventive step requirement (following the India example), adopting a government use procedures, and clarifying the role that ANVISA, its drug regulatory agency, plays in the patent examination system.

Brief Technical Review of Brazil's Proposed Patent Law Reforms

Limiting patent terms to 20 years with no extensions is TRIPS compliant:

Article 2 of Bill No. H.R. 5402/2013 limits patents to 20-year terms by revoking Article 40 of Law no. 92790 of 14 May 1996.[1] Article 33 of the TRIPS Agreement merely requires that "The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." There is no requirement in TRIPS that there be patent term extensions to compensate for regulatory delays either in the granting of a patent or in the registration/marketing approval of a medicine. In fact, the term of 20 years was adopted in substantial part to compensate for customary periods of regulatory delay. Accordingly, Article 40 of the current Patent Law, which grants patent protection beyond 20 years whenever the date of granting a patent exceeds 10 years, can properly be revoked.

As explained in the Report, a patent applicant in Brazil has an expectation of eventual patent grant and a right to seek retroactive damages from persons who infringe the pending patent once a patent has been granted. Thus, in a practical sense, patent applicants have de facto exclusive rights even during periods of delay. Admittedly, the Brazilian Patent Office should develop more capacity so that it may reduce its patent application backlog[2] and increase the quality of issued patents, where warranted, on a more reasonable time table.[3] Despite its current delays and stretched capacity, TRIPS does not require patent term extensions such as those in Article 40 of Brazil's Patent Act.

Disallowing patents on new uses or new forms of existing medicines is TRIPS compliant:

Article 3 of Bill No. H.R. 5402/2013, seeks to amend the Patent Law to add Article 10.X and XI in the following way:

> Art. 10. [The following are not considered to be inventions or utility models:]
> X – any new property or new use of a known substance, or the mere use of a known process, unless this known process results in a new product;
> XI – new forms of known substances that do not result in an improvement in the known efficacy of the substance.
>
> For the purposes of this Article, salts, esters, ethers, polymorphs, metabolites, pure form, size of particles, isomers, mixtures of isomers, complexes, combinations and other derivatives of a known substance shall be considered the same substance, unless they significantly differ in terms of properties regarding efficacy.

[1] "The term shall not be less than 10 (ten) years for patents and 7 (seven) years for a utility model, beginning on the date of granting, unless the INPI has been prevented from examining the merits of the application by a proven pending judicial dispute or for reasons of *force majeure*."

[2] The TRIPS Agreement Article 62.2 does require some reasonable degree of timeliness in rendering patent decision:

> Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

[3] It should also be noted that delays can result from applicant behavior, such as aggressive seeking of patents of poor quality, which require lengthy review and narrowing in the application process.

This provision mirrors one that has been in place in India for eight years, and that has been upheld against challenge by the multinational pharmaceutical industry in Indian courts. The stated purpose of these provisions is to prevent the practice of evergreening, the granting of new 20-year patent monopolies on the basis of minor or trivial changes to a known substance or on the basis of easily discovered new uses of existing substances. The "efficacy" standard suggests that there may be an inventive step worth patenting if the product shows significant or dramatic improvement in therapeutic efficacy.[4]

Article 27.1 sets for the basic standards of patentability under TRIPS: "[P]atents 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* (emphasis added)."

The terms new, inventive step and industrial application are not further defined and Members are granted substantial interpretive freedom to adopt loose or strict standards of patentability according to their own needs and circumstances, subject only to meeting the treaty's minimum requirements. Indeed there is substantial variation in precise patenting standards between Europe, the U.S. and other WTO Members, and many countries overtly limit the scope of patentability in various ways. (See, for example, the recent US Supreme Court case, *Association for Molecular Pathology v. Myriad Genetics* (2013), which held that US law forbids patents on genes.). Members' interpretive freedom is expressly set forth in Article 1.1 of the TRIPS Agreement, which states that: "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice." This interpretative freedom is amplified by Articles 7[5] and 8[6], dealing respectively with mutual advantages for owners and users of IP and the right to promote public interest and public health and to prevent abuse of IPRs. These provisions were further amplified by the Doha Declaration on the TRIPS Agreement and Public Health, which confirmed that Members to prioritize public health and access to medicines for all:

> 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. [7]

[4] Whether Brazil intends that this provision incorporates the Indian requirement that there be enhanced therapeutic efficacy in the treatment or prevention of human disease is unclear, but the Novartis v. Government of India decision by the Supreme Court of India has been referenced favorably in the report.

[5]

> 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.

[6]

> 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.

[7] WT/MIN(01)/DEC/2, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

Civil Society Statement in Support of Brazilian Patent Law Reform to Increase Access to Medicines for All

July 15, 2013

This is a joint letter from civil society and advocacy organizations that work on access to medicines, intellectual property and trade policy, human rights, and other social/economic justice issues from around the world. We are writing to support proposed changes to Brazil's patent law outlined in ***Brazil's Patent Reform: Innovation Towards National Competitiveness*** and specified in **Bill no. H.R. 5402/2013**. The public purpose behind the proposed reform is to use flexibilities allowable under the WTO TRIPS Agreement so that Brazil can better meet the rights and needs of its people to have increased access to affordable medicines of assured quality. The reforms should also permit Brazil to become more self-reliant with respect to domestic manufacture of medicines by preventing or overcoming patent and data monopoly barriers and allowing more widespread generic competition. In sum, we think these reforms are essential for Brazil to meet its human rights obligations, including the right to health and the right of access to medicines.

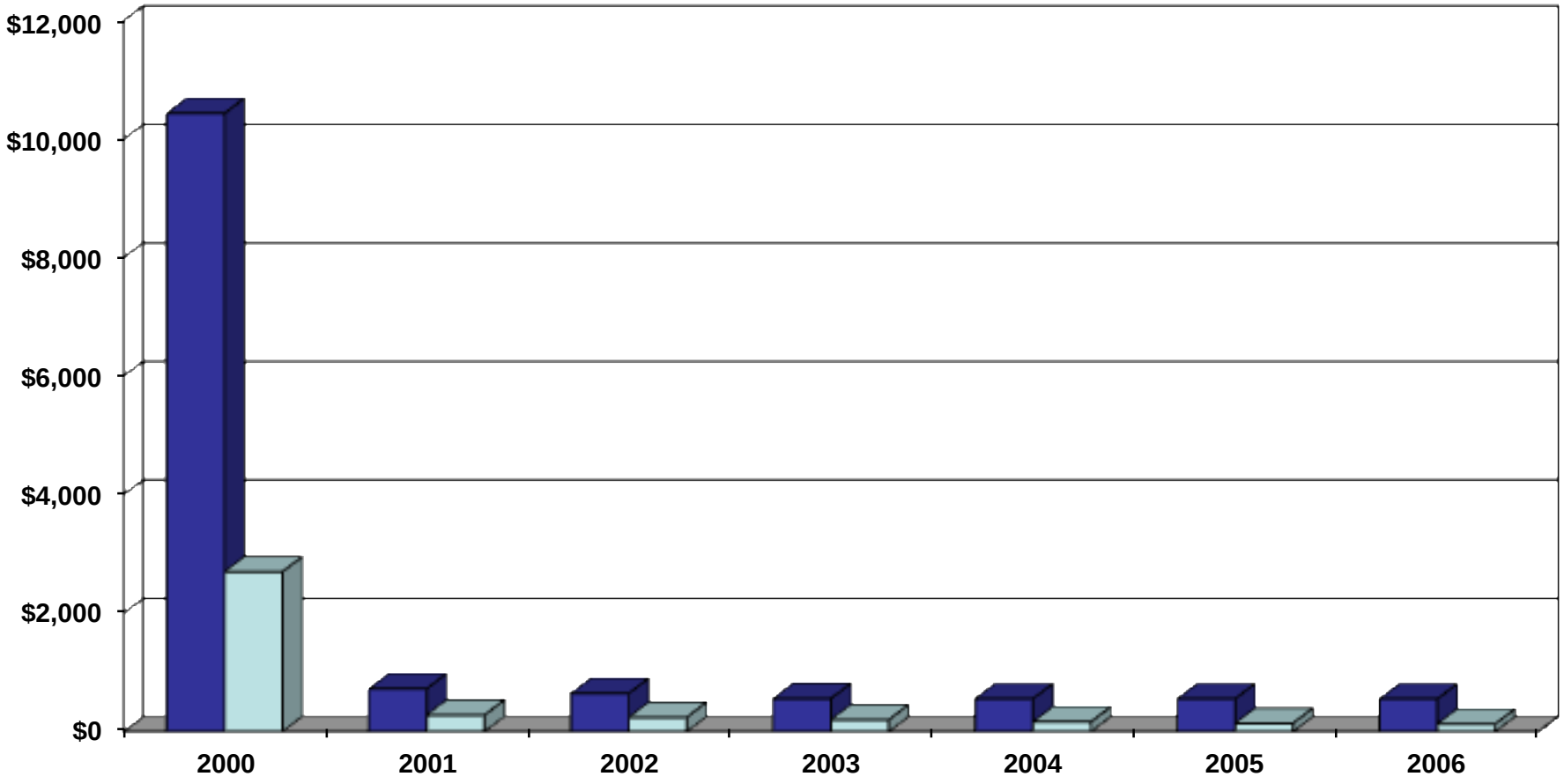
MONOPOLY ECONOMICS

“[T]he ability of patent holders to charge for the use of their patent rights, either in the form of royalties or through end product prices is constrained by the ability of the country granting the patent to pay. Poor countries will inevitably pay proportionately less than wealthy countries for the use of patent rights.”

-Edmund Kitch (1994)

Lowest Price HIC/AIDS Regime, Reported by MSF

Brand Name Price | Generic Price



Source: Médecins Sans Frontières, *Untangling the Web of Price Reductions: a Pricing Guide for the Purchase of ARVs for Developing Countries.* Editions 1-9, published 2001 through 2007.

Price	Volume	Revenue
100	0	
90	10	
80	20	
70	30	
60	40	
50	50	
40	60	
30	70	
20	80	
10	90	
0	100	

Price	Volume	Revenue
100	10	
90	11	
80	12	
70	13	
60	14	
50	15	
40	16	
30	17	
20	18	
10	19	
0	11	

Price	Volume	Revenue
100	0	0
90	10	900
80	20	1600
70	30	2100
60	40	2400
50	50	2500
40	60	2400
30	70	2100
20	80	1600
10	90	900
0	100	0

Price	Volume	Revenue
100	10	
90	11	
80	12	
70	13	
60	14	
50	15	
40	16	
30	17	
20	18	
10	19	
0	11	

Price	Volume	Revenue
100	0	0
90	10	900
80	20	1600
70	30	2100
60	40	2400
50	50	2500
40	60	2400
30	70	2100
20	80	1600
10	90	900
0	100	0

Price	Volume	Revenue
100	10	1000
90	11	990
80	12	960
70	13	910
60	14	840
50	15	750
40	16	640
30	17	510
20	18	360
10	19	190
0	11	0

Figure 1
The shape of the "standard" demand curve

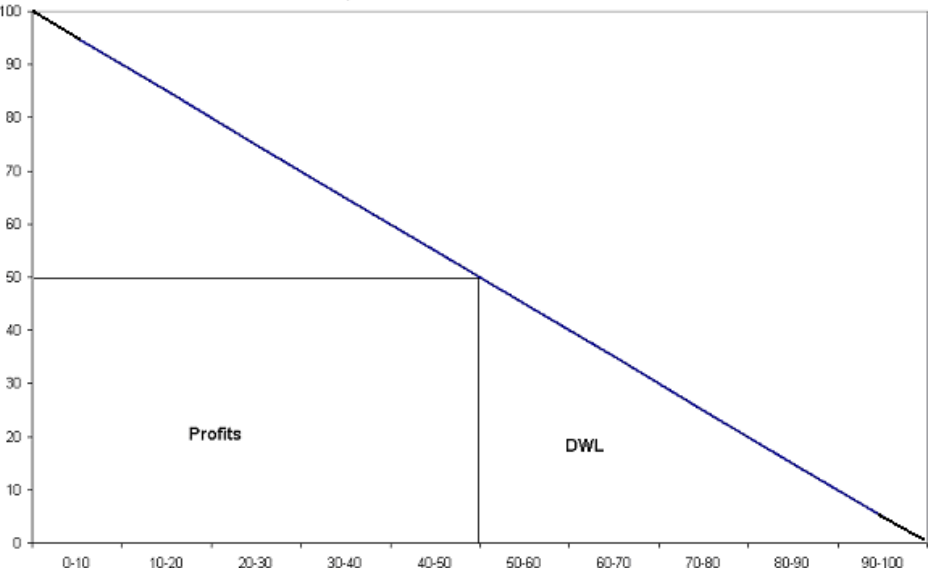
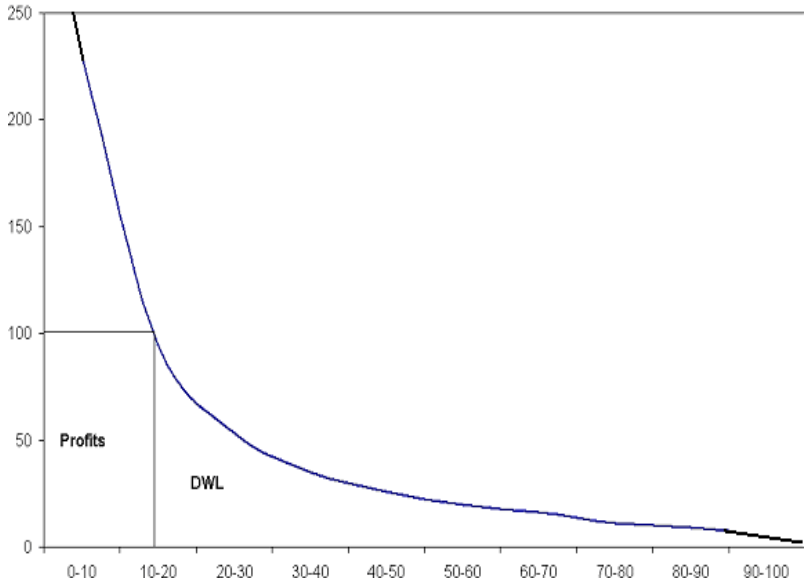
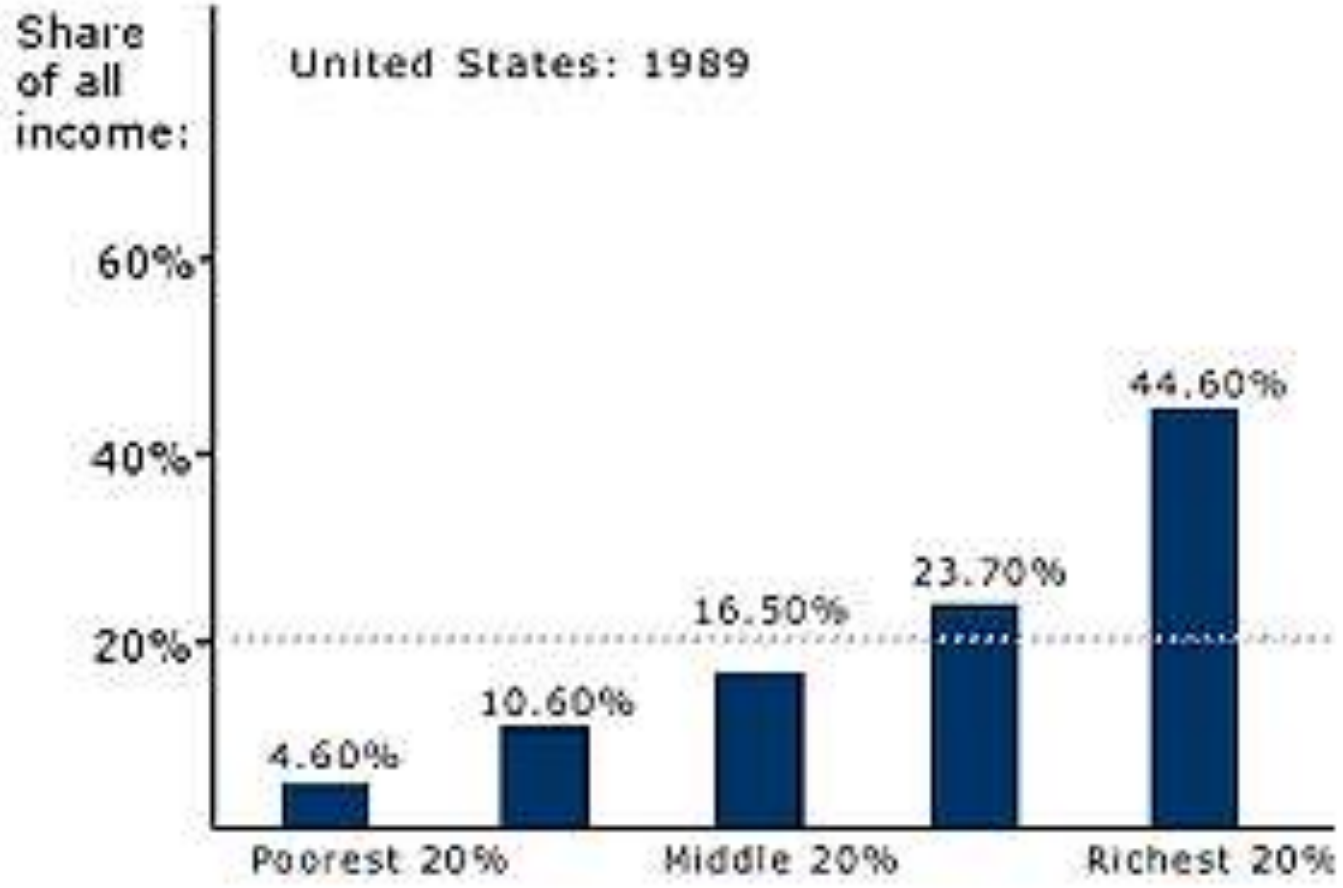
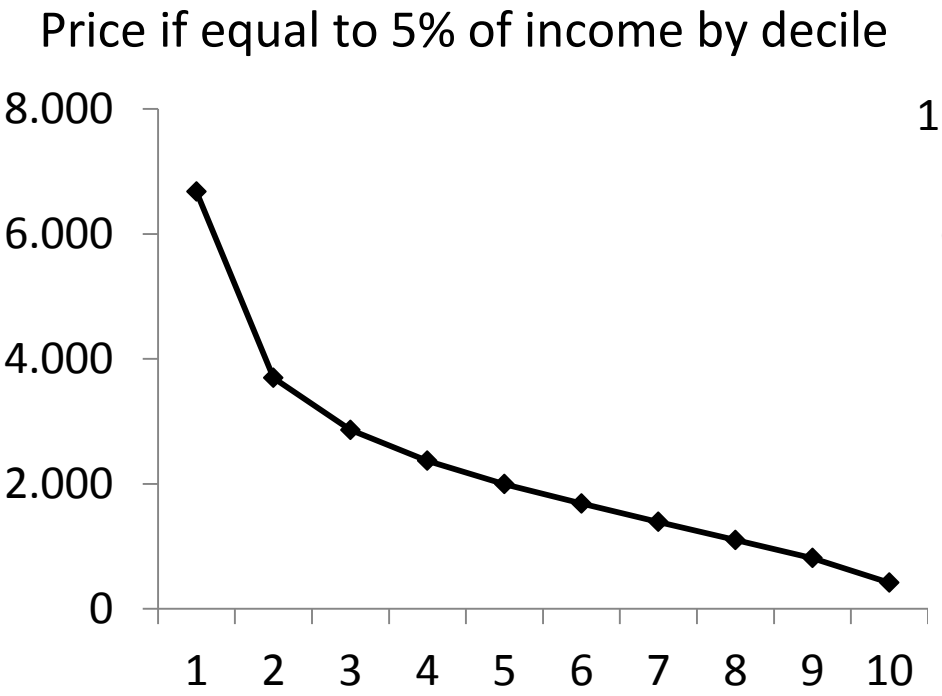


Figure 2
The shape of the demand curve if based on income distribution




Share of all income:
United States: 1989
60%
40%
20%
4.60%
10.60%
16.50%
23.70%
44.60%
Poorest 20%
Middle 20%
Richest 20%

U.S.


Price if equal to 5% of income by decile
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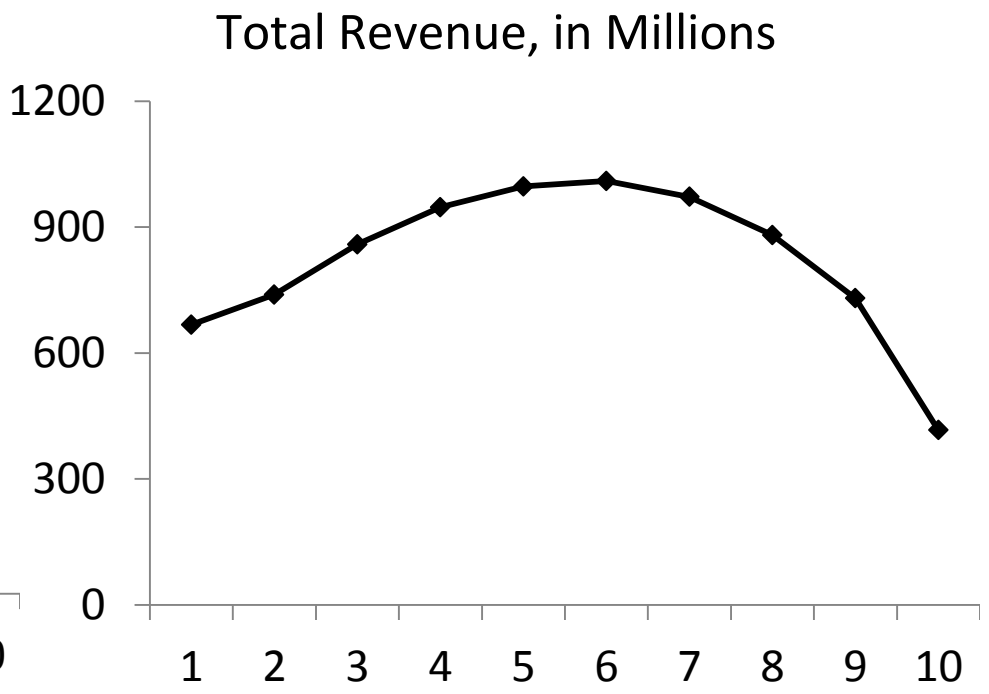
6.000
4.000
2.000
0
1
2
3
4
5
6
7
8
9
10


Total Revenue, in Millions
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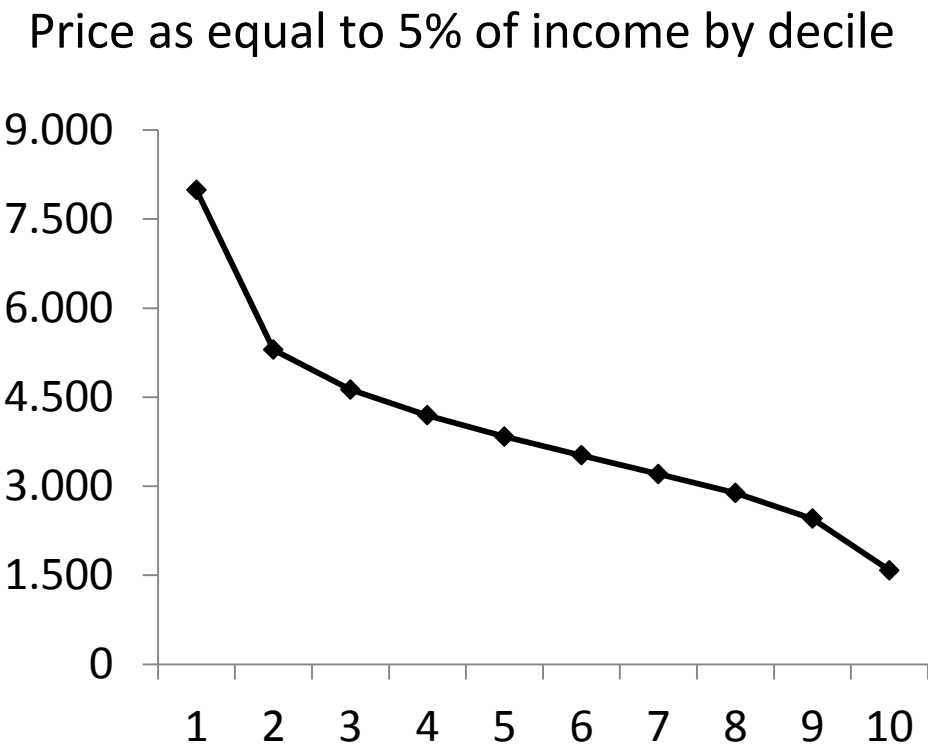
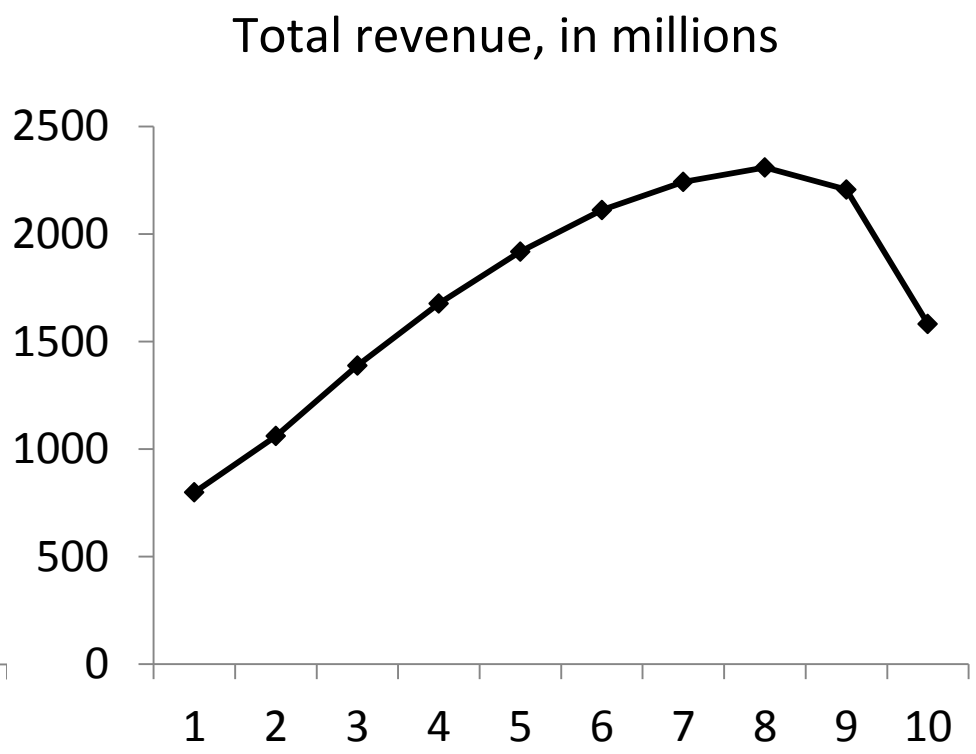
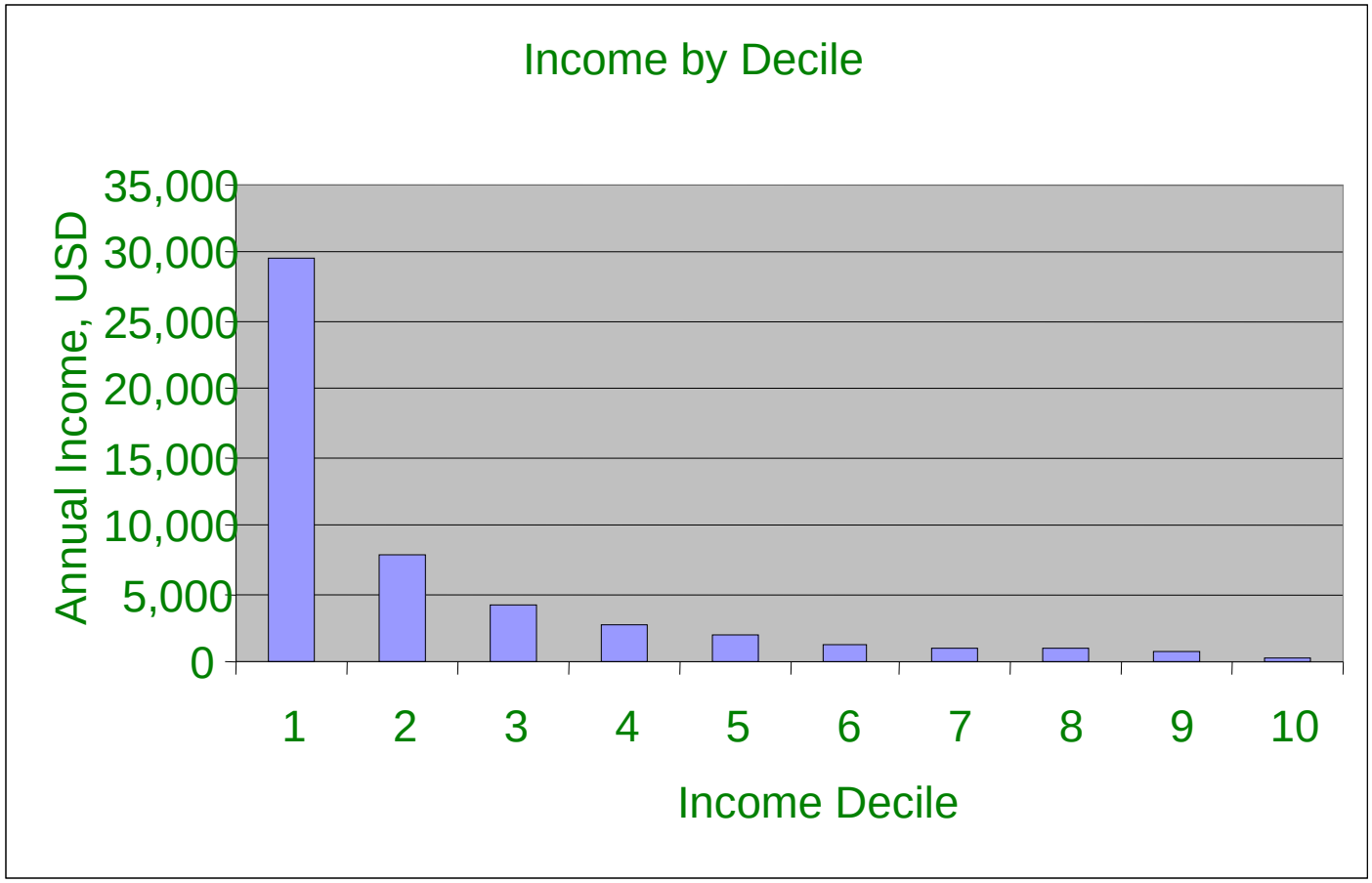
900
600
300
0
1
2
3
4
5
6
7
8
9
10

Norway

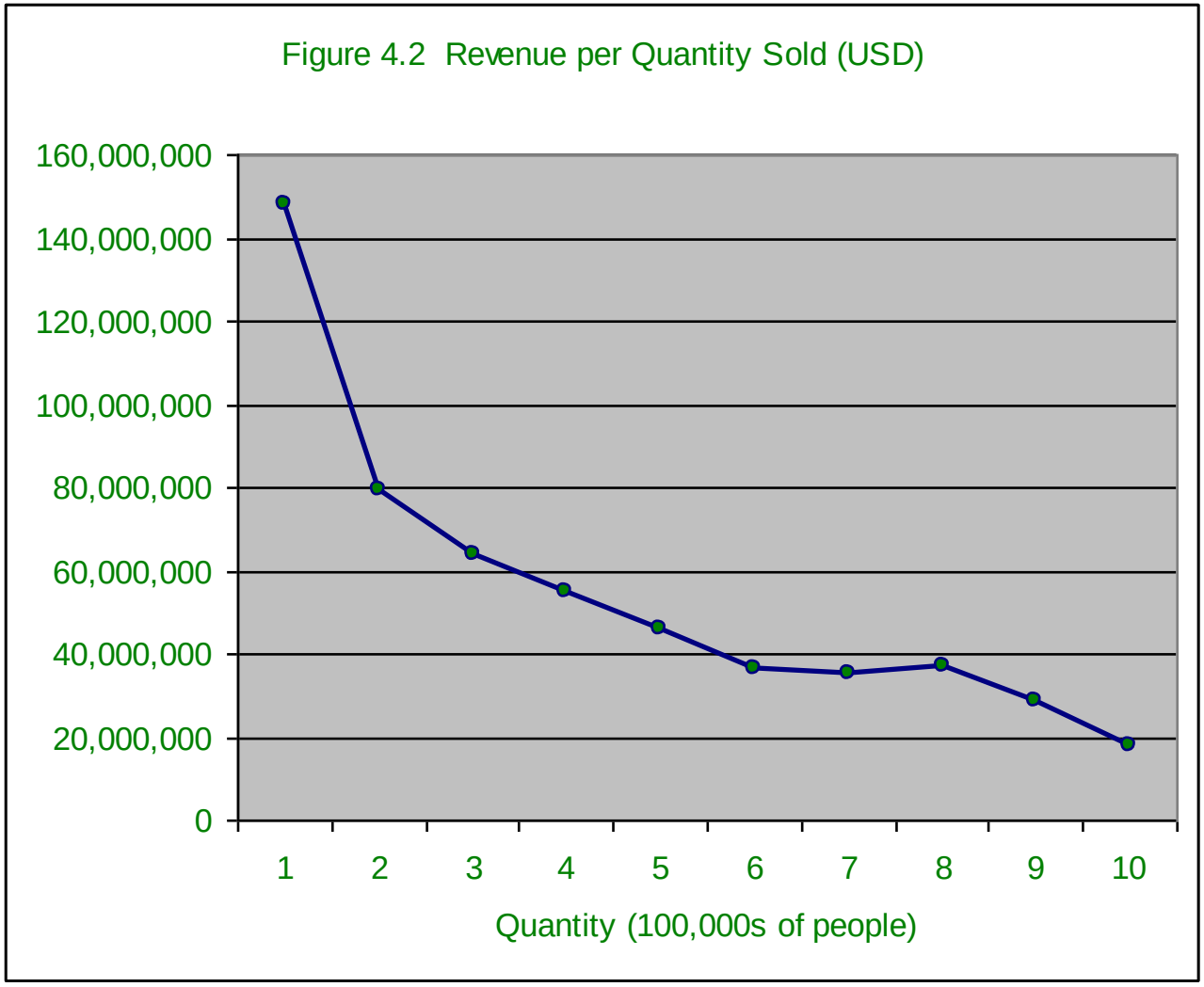

Price as equal to 5% of income by decile
9.000
7.500
6.000
4.500
3.000
1.500
0
1
2
3
4
5
6
7
8
9
10

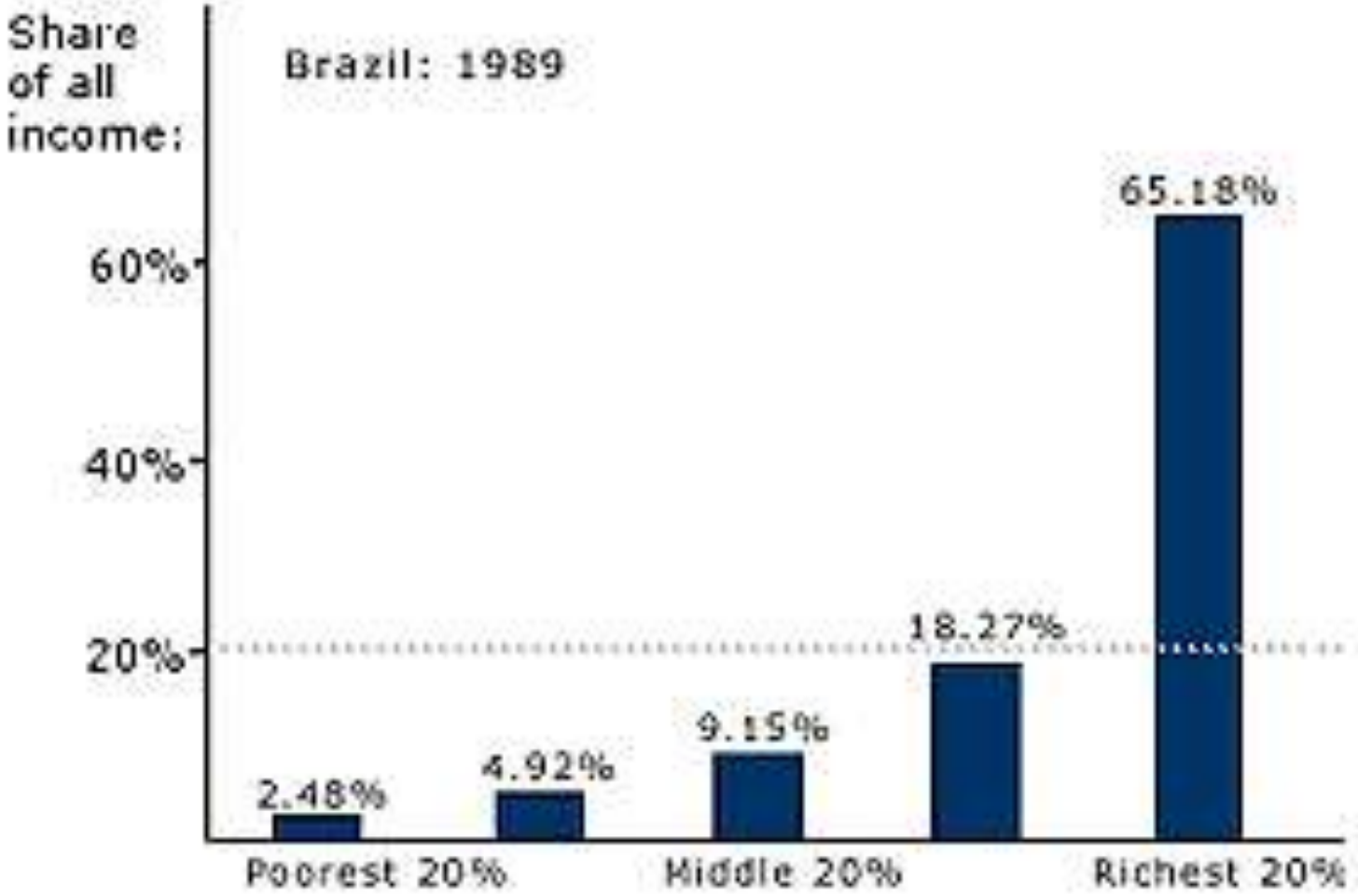

Total revenue, in millions
2500
2000
1500
1000
500
0
1
2
3
4
5
6
7
8
9
10

South Africa



Profit Maximizing SA

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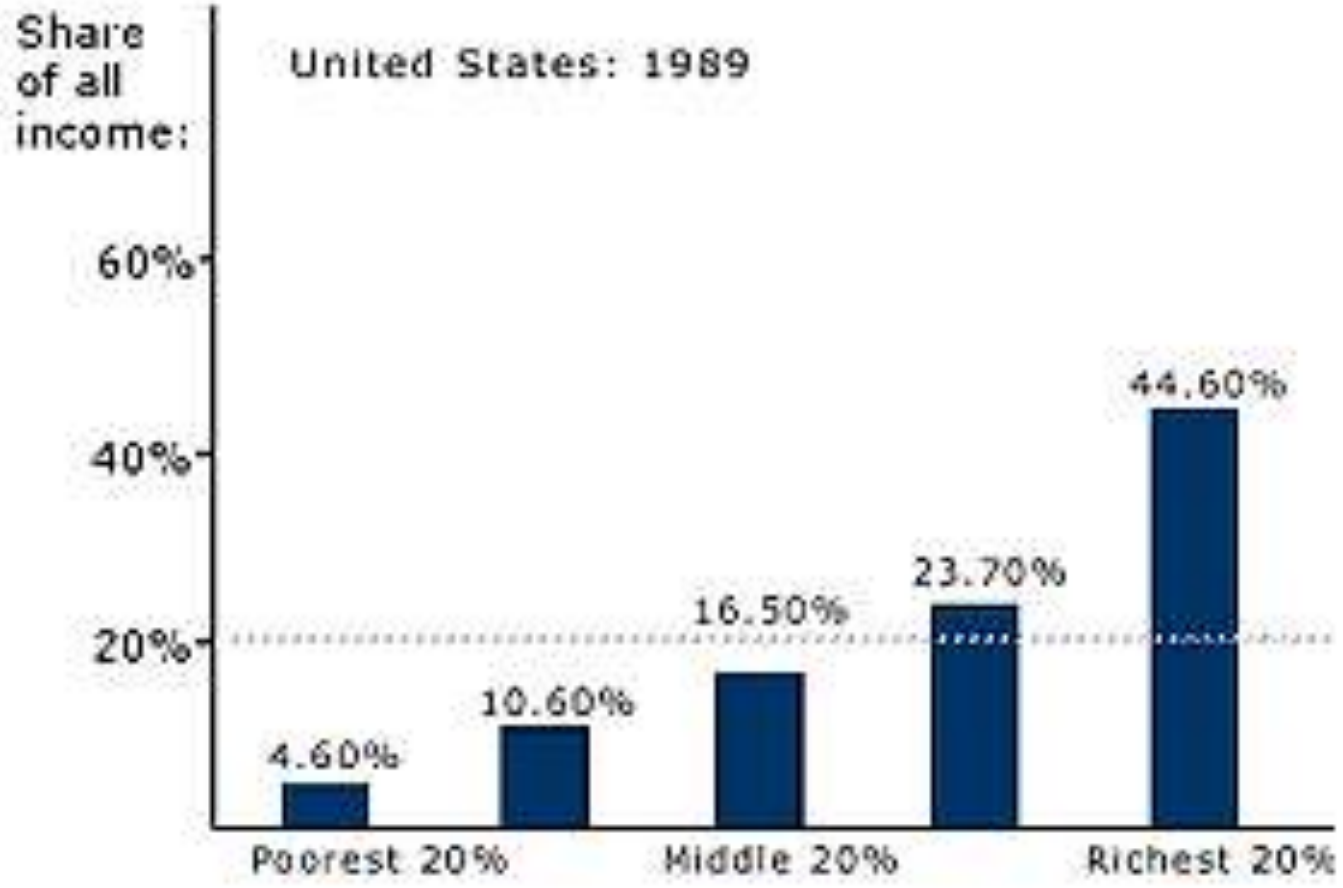
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TRIPS

Territorial Period

1st Globalization 1880s

2nd Globalization 1950s+

3rd Globalization 1984+

Brazil Reform Proposal

- No patent extensions
- New forms and uses
- Inventive step
- Avoiding data exclusivity
- Pre-grant opposition
- ANVISA approval
- Govt Use license

TRIPS

- Art 33. 20 year patent
- Art. 27. Three Step
- Art. 1, 8, 27
- Art. 39.3. “commercial use”
- Art. 41.2. fair & equitable
- Art.1; 27 “discrimination”
- Art. 31

Article 1.1: “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”

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.

Doha Agreement on TRIPS and Public Health

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. 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.

Brazil Reform Proposal

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TRIPS

- "[P]atents 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* (emphasis added).

The Question of Patent Eligible Subject Matter and Evergreening Practices

Posted by Burcu Kilic and Luigi Palombi on July 27, 2013

Add comments

Burcu Kilic and Luigi Palombi

Over the past few years, patent-eligible subject matter has become one of the hotly debated areas of patent law in several countries. Even in the U.S., the Supreme Court is beginning to express concerns about overly inclusive patent rules that stifle both competition and follow-on innovation. However, significant confusion persists over the difference between patent eligible subject matter and patentability requirements. Patent eligibility tests have proven quite difficult to apply, often leading to inconsistent and unpredictable results.

An inquiry into the patent examination begins with determining whether a claim is eligible for patenting and falls into one or more categories listed under patent eligible subject matter. The term patent eligibility denotes limitations on the categories of subject matter that may be considered for patent protection. This inquiry is different from and always precedes the question of whether the subject matter meets the patentability criteria of novelty, industrial application and inventive step.

Brazil Reform Proposal

- The granting of patents for pharmaceutical products and processes shall depend on the prior consent from the National Sanitary Agency - ANVISA, that shall examine the object subject to the patent application in light of public health.

TRIPS

- Art 27. “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.”
- *Canada Pharmaceuticals*

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References

U.S. and Brazil income distribution slides:

PBS, Commanding Heights, Educators Guide, Examining Income Distribution, http://www.pbs.org/wgbh/commandingheights/lo/educators/ed_u1_distrib_exercise.html