TRIPS restrictions on exports or imports when there is non-voluntary use of a patented invention

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30. years of TRIPS: Expectations and concerns of developing countries

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Why are limitations on exports or imports important?

Among the benefits of trade are:

Economies of scale. Small markets have difficulty reaching efficient scale.

Comparative advantage. Countries benefit by specializing in producing goods and services they can produce most efficiently, leading to greater overall productivity.

Competition. Increased competition from international trade can drive down prices for consumers, making goods and services more affordable.

Wider range of goods and services. No country can replicate all of the global products, or provide the same quality.

Negotiations over restrictions on exports under compulsory licenses have taken place several times

1995. The original 1995 TRIPS text included in Article 31(f) a requirement that non-voluntary authorizations to use a patented invention predominantly to supply the domestic market. The restriction is waived in paragraph (k) of the same article “where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.”

2000. DS114: Canada — Patent Protection of Pharmaceutical Products. The 222 page panel report was circulated on 17 March 2000. Canada was allowed to import and export patented pharmaceutical products (or inputs) under early working exceptions.

2001. Doha Declaration on TRIPS and Public Health. Paragraph 6 instructed the Council for TRIPS to find an expeditious solution to the difficulties WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement.

2003. Decision of the General Council of 30 August 2003: “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health.” The decision provided a time limited waiver of 31(f), with conditions and restrictions on beneficiaries.

2005. A December 6, 2005 amendment to the TRIPS Agreement replaced the 2003 waiver. The Amendment entered into force on January 23, 2017.

2022. Ministerial Decision on the TRIPS Agreement adopted on 17 June 2022. The Decision clarifies certain TRIPS flexibilities and provided a single time-limited waiver of Article 31(f) to export COVID 19 vaccines. The waiver is limited to developing country members, as both exporters and importers.

Article 31 - Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[7] 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:

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(k) Members are not obliged to apply the conditions set forth in . . . (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive [. . .]

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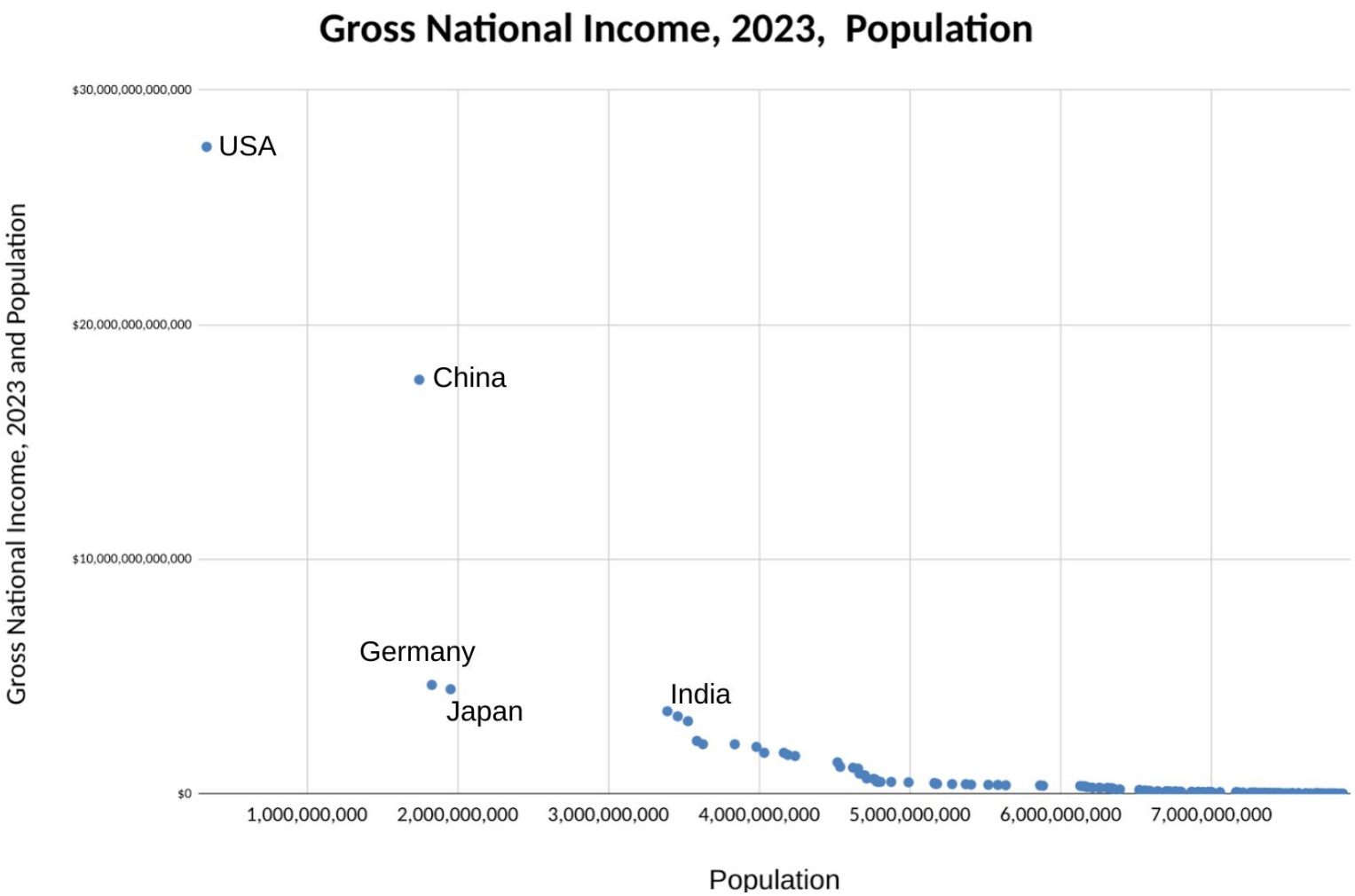
7. "Other use" refers to use other than that allowed under Article 30


Gross National Income, 2023, Population
$30,000,000,000,000
$20,000,000,000,000
$10,000,000,000,000
$0
USA
China
Germany
Japan
India
1,000,000,000
2,000,000,000
3,000,000,000
4,000,000,000
5,000,000,000
6,000,000,000
7,000,000,000
Gross National Income, 2023 and Population
Population

Article 30 - Exceptions to Rights Conferred

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.

WT/DS114/R, page 79

(a) The Global Nature of the Pharmaceutical Industry

- Both the brand name and generic pharmaceutical industries were global in nature. Very few countries had fully integrated brand name or generic drug industries within their borders. Even in large countries, generic producers frequently had to obtain ingredients such as fine chemicals from producers in other countries. Many countries had no generic industries at all and had to obtain generic (as well as brand name) products from other countries. Smaller countries that did have generic industries did not have domestic markets sufficiently large to enable those industries to operate on an economic scale. Those industries had to export in order to be able to manufacture in sufficient quantities to achieve economies of scale, so that domestic consumers could receive the benefits of cost-effective generic products.

Article 44 - Injunctions

1. The judicial authorities shall have the authority to order a party to desist from an infringement, inter alia to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

Limitations on remedies - USA

eBay Inc. v. MercExchange, L.L.C.

Large number of cases where judicial authorities permit the non-voluntary use of patents, and where in some cases, all production is for an export market. Many of these are for medical devices, but all sorts of technologies are involved.

FAR 52.227-1 authorization and consent contracts

Thousands of US government contacts have FAR 52.227-1 authorization and consent provisions, including cases where the uses of products are for export markets.

Remedies to anti-competitive practices

Refusals to license patents or otherwise provide access to essential facilities.

Excessive prices (For example, South Africa Competition Act, the Hazel Tau case, India, the Nexavar case).

According to the European Union, Article 102 of the Treaty on the Functioning of the European Union (TFEU) defines an abuse of dominance to include such act as “requiring buyers to purchase all units of a particular product only from the dominant company (exclusive purchasing); setting prices at a loss-making level (predation or predatory pricing); refusing to supply input indispensable for competition in an ancillary market, and charging excessive prices.”

Price fixing

Etc…

Imports and exports on non-voluntary use of patented inventions under different TRIPS articles

TRIPS Article	Restrictions on exports or imports
6	For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.
31(f)	Exports limited to non-predominant share of market
31(k)	No restrictions on imports or exports.
30	No restrictions on imports or exports.
31bis	Restrictions are on importing countries. “Eligible importing Member” means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS. Australia, Canada, the European Communities with, for the purposes of Article 31bis and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States opted out as importers.
June 17, 2022	Only developing country Members are eligible to import or export vaccines under this decision. “Developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision.”
44	No restrictions on imports or exports.