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Topic 14: Exhaustion of Rights

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on

IMPLEMENTATION AND USE OF PATENT-RELATED TRIPS FLEXIBILITIES

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TOPIC 14

Exhaustion of Rights: A South African Perspective

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TRIPS FLEXIBILITIES AND PARALLEL IMPORTATIONS

- ❑ In a number of countries (including in South Africa) there have been calls from civil society that barriers to parallel importation of specifically pharmaceuticals should be lessened or removed in order to improve access to pharmaceuticals through price reductions
- ❑ It is proposed that TRIPS Flexibilities should be used in this regard and that exhaustion of rights and parallel importation are TRIPS Flexibilities
- ❑ To consider these aspects one must have regard to:
 - ❖ the underlying principles of the patent system,
 - ❖ the promotion of international trade,
 - ❖ fairness to both the holders of the patent rights and to the consumer of the products and
 - ❖ the factors which drive country economic growth, trade and industry.

WHAT IS THE JUSTIFICATION FOR PATENT RIGHTS?

- the patent system is built on the principle of 'quid pro quo'
 - ❖ in exchange for certain exclusive rights granted by the State, a patent applicant must deliver certain items of value to the public
- the deliverables to be provided by the applicant include –
 - ❖ an invention that is new, that is not obvious, and is useful, i.e. capable of industrial application (TRIPS Art 27.1)
 - ❖ a full and clear disclosure of the invention is to be made, so that a person skilled in the art can carry out the invention
 - ❖ on the understanding that once the patent period expires, the invention and the further use thereof shall fall in the public domain
- the exclusive rights to be provided by the State include –
 - ❖ the right to prevent third parties not having the patent owner's consent from making, using, offering for sale, selling or importing the patented invention (TRIPS Art 28.1)
 - ❖ the right to enforce these exclusive rights and to claim damages when these rights are infringed
 - ❖ on the understanding that the patent owner shall enjoy the full profit and advantage accruing from the patent

THE NATURE AND EFFECT OF PATENT RIGHTS

- **patent rights are territorial rights, i.e. national rights**
 - ❖ a patent owner with patents in different countries owns a bundle of national and territorial rights, with exclusive rights in each country
 - ❖ by manufacturing and selling the patented product in country A, does he exhaust his rights only in country A, or also in all other countries?
 - ❖ in other words, by marketing the product in country A, can the patent owner prohibit a purchaser to import the purchased product into country B?
- **One of the main aims of patent law is to promote technological progress by granting the exclusive rights and full financial benefit derived from the exploitation of such progress for a limited period to a person holding the patent rights in a specific territory over which the patent extends.**

WHAT IS EXHAUSTION OF RIGHTS?

- it is a generally accepted principle of patent law that once the patent owner has exercised his exclusive rights by manufacturing the protected product and releasing it onto the market (i.e. selling it), his right has been exhausted and the purchaser is free to use or resell that article without further restraint from patent law
 - ❖ what is not generally accepted is the extent of the exhaustion (whether it is international, regional, national etc.) (TRIPS Art 6)
 - ❖ exhaustion aims to balance the patentee's interest in obtaining a reasonable reward for its invention on the one hand, and the interests of the general public in the free movement of goods and legal certainty on the other
- TRIPS takes no position on exhaustion (TRIPS Art 6)
 - ❖ it is a matter to be determined by the national laws of individual countries (WTO 2001 Doha Declaration par 5(d))
 - ❖ exhaustion of rights is a TRIPS Flexibility

WHAT IS PARALLEL IMPORTATION?

□ parallel importation is –

- ❖ the importation into (and sale or use in) country A where a patent exists in respect of a product
- ❖ of genuine products covered by the patent but put onto the market by the patent owner (or his licensee) in country B
- ❖ where the patent owner has the exclusive importation right and the importation into country A is not authorised by the patent owner

□ parallel imports are genuine products, not counterfeits

- ❖ however, parallel importations could be infringements
- ❖ this will depend on the exhaustion laws of country A, i.e. whether parallel importation has been legalised or not

□ why would parallel importation take place?

- ❖ generally because the patented product is not available and/or is expensive
- ❖ generally because of price differentials between countries
- ❖ generally because the parallel trader has a profit motive

IS PARALLEL IMPORTATION LEGITIMATE?

- **‘parallel importation’ is the importation into a country, without authority of the patent owner, of a patented product released onto the market in another country by the patent owner/licensee**
 - ❖ **the product released onto the market is legitimate; is the importation without the patentee’s authority into another country legitimate?**
 - ❖ **once a patented product has been sold in one country, has the patentee’s right been exhausted only in that country, or also in other countries?**
 - ❖ **there is no consensus amongst countries whether exhaustion of rights should apply only nationally, regionally or internationally**
 - ❖ **if exhaustion applies internationally, parallel importation will be legitimate and will not constitute infringement of patent rights**
 - ❖ **if exhaustion principle applies only nationally, parallel importation will be illegitimate and will constitute infringement**

PARALLEL IMPORTATION EXPLAINED BY SOME EXAMPLES

□ Example 1

- ❖ product X is patented by patentee P in country A
- ❖ product X in country A is more expensive
- ❖ patentee P also has patent in country B, where product is cheaper (for whatever reason; manufacturing costs, availability of raw materials, subsidies etc.)
- ❖ trader T buys product X from patentee P in country B and imports it into country A
 - parallel importation, allowed under international exhaustion, not allowed under national exhaustion

□ Example 2

- ❖ product X is patented by patentee P in country A
- ❖ product X in country A is more expensive
- ❖ patentee P has a licensee L in country B, where product is cheaper
- ❖ trader T buys product X in country B from licensee L and imports it into country A
 - parallel importation, allowed under international exhaustion, not allowed under national exhaustion

PARALLEL IMPORTATION EXPLAINED BY SOME EXAMPLES

□ Example 3

- ❖ pharmaceutical product X is patented by patentee P in country A
- ❖ product X in country A is reasonably priced
- ❖ patentee P markets X to wholesaler W in country C, where the selling price is cheaper because of price controls
- ❖ trader T buys product X from wholesaler W in country C and imports it into country A
 - parallel importation, allowed under international exhaustion, not allowed under national exhaustion

□ Example 4

- ❖ product X is patented by patentee P in country A
- ❖ product X in country A is more expensive
- ❖ third party Q manufactures a similar product Y more cheaply in country C where patentee P has no patent
- ❖ trader T buys product Y from third party Q and imports it into country A
 - not parallel importation
 - infringement of patent rights under both international and national exhaustion

TRIPS DOES NOT PRESCRIBE ON EXHAUSTION/PARALLEL IMPORTATION

□ TRIPS does not dictate a position on exhaustion of rights or the legitimacy of parallel importation

- ❖ Art 28.1 prescribes patent owner's exclusive rights, including importation right but with a footnote stating that such right is subject to Art 6
- ❖ Art 6 states that nothing in TRIPS shall be used to address the issue of exhaustion of IP rights

□ it is therefore a matter for national laws to stipulate the domestic position as regards exhaustion of rights and the legitimacy of parallel importation

- ❖ local laws can legislate to provide for international, regional or national exhaustion
- ❖ local laws can permit or prohibit parallel importation, e.g. of medicines
- ❖ Local laws can have competition law or other provisions to guard against abuse in cases of national exhaustion (*controlled national exhaustion*)

DOES PARALLEL IMPORTATION ENTAIL ADVANTAGES?

- parallel importation could entail advantages
 - ❖ parallel imports are genuine products: for a product to qualify as parallel importation the product must be a genuine product – so, reliable quality
 - ❖ where price differentials exist in different countries for genuine products, parallel importation from a cheaper country may provide a cost benefit in an expensive country – so, cost benefit possible
 - ❖ the end user will derive benefit only if the parallel importer passes the cost benefit on to the end user – so, cost benefit not certain
 - ❖ countries with no manufacturing capacity could acquire genuine products through parallel importation – so, supply facilitated
 - ❖ importation of infringing products (e.g. generic substitutes) constitutes infringement of patent rights – so, cannot be parallel imports
- South Africa in 1997 introduced a parallel importation mechanism via the Medicines Act, 1965

WHICH TYPE OF EXHAUSTION?

- ❑ **Complex broader legal and economic issues need consideration when considering what type of exhaustion is most appropriate for a specific country or region**
 - ❖ Exhaustion laws affect all economic sectors and impact a host of issues including beneficiation, imports, exports, trade deficits, research and development investments, manufacturing growth, FDI etc.
 - ❖ Other legal principles such as the relevant contractual laws and competition law principles can play an important roll
- ❑ **Economic arguments in favour of and against the right of parallel importation in patent law are equally convincing**
- ❑ **Also depends on national economic development plans, international relations and foreign policies**

WHICH TYPE OF EXHAUSTION? (CONT.)

- ❑ “It seems apparent that national exhaustion to a large extent carries the possibility of manipulation of the market circumstances to serve the object of the WTO and TRIPS in promoting international trade in a way that is fair both to the holders of the patent rights and the consumer of the products. In contrast, absolute international exhaustion, at the other end of the range, most probably favours the consumer to an unbalanced extent as compared with the rights that exist under a patent. In this regard it should always be borne in mind that the main object of the parallel importer is personal gain while the advantages flowing there from are purely coincidental.” (*Intellectual Property Quarterly*, 2000, 3, 286-294, *The exhaustion of rights in patent law with specific emphasis on the issue of parallel importation*, A Van Der Merwe)
- ❑ “ National exhaustion is more supportive of rights to the extent it ensures the exclusive right to import. It also protects foreign investors against competition arising from parallel imports of their own products made and sold in other countries where production costs are eventually lower. On the other hand, national exhaustion may leave a Member defenceless in the case where an IP owner with a dominant position in the relevant international market abuses its rights with the purpose of partitioning that market and discriminating purchasers in different territories.” (*WIPO Secretariat, CDIP/4/4 REV./STUDY/INF/2, Interface between exhaustion of intellectual property rights and competition law*)
- ❑ The most flexible and convenient solution is possibly a combination of the positive aspects of national exhaustion and competition law or other provisions to temper possible negative consequences or abuse

STAUFFER CHEMICAL COMPANY v. AGRICURA LIMITED (1979) BP CP 168

- ❑ Patents for a herbicide compound and admixture with an antidote (EPTC)
- ❑ Agricultural chemical products regulated in SA and USA
- ❑ Patentee has product registration in SA for product X and in the USA for product X1 (different proportions) – X1 supplied to licensed distributors in the USA subject to territorial restrictions
 - ❖ X1 sold to importer I in the USA,
 - ❖ X1 is imported into SA, diluted to product X proportions and sold in SA by I
- ❑ Position at the time: International exhaustion with exception based on reasonable license restrictions on licensee (*controlled international exhaustion*).

CURRENT POSITION UNDER SOUTH AFRICAN PATENTS ACT

- ❑ section 45(1) of the South African Patents Act, 1978 (as amended after Stauffer) provides that a patent shall grant to the patentee the right to exclude other persons from making, using, exercising, disposing or offering to dispose of, or importing the patented invention
 - ❖ the importation right is now expressly mentioned
- ❑ section 45(2) provides that the disposal of the patented product by or on behalf of the patentee or his licensee shall give the purchaser the right to use or dispose of that product
 - ❖ the purchaser is not granted the right to import/export the product
 - ❖ there is no wording to indicate an intention that the right granted under section 45(2) shall have extraterritorial effect
- ❑ it can be concluded that the patent law position in South Africa provides for national exhaustion
 - ❖ parallel importation into South Africa would constitute infringement

ADDITIONAL MEASURES ADOPTED IN SOUTH AFRICA

- ❑ Medicines and Related Substances Act, 1965, section 15C gives the Minister (of Health) power to prescribe conditions for supply of more affordable medicines to protect public health
 - ❖ the Minister may, notwithstanding anything in the Patents Act, determine that patent rights for medicines shall not cover certain acts once medicine has been put on market → exhaustion of rights
 - ❖ the Minister may prescribe conditions for importation of medicine by persons other than the holder of marketing registration, if that medicine is of identical composition and quality and originates from original site of manufacture → parallel importation
 - ❖ regulations were issued prescribing procedure for obtaining a permit/licence for parallel importation
- ❑ in this context, parallel importation into South Africa of pharmaceutical products has been legalised, provided a permit/licence is obtained
- ❑ In addition competition law applies to instances of abuse



**Thank you for
your attention**

Questions?