

Report Q202

in the name of the South African Group
by Esmé DU PLESSIS

The impact of public health issues on exclusive patent rights

Questions

I) Analysis of current law and case law

- 1) *Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?*

There is no express provision in the South African Patents Act no. 57 of 1978 (“the Patents Act”) to provide for a research or experimental use exception from infringement. The only indication in the Patents Act that the legislature may have intended to exclude non-commercial use from the definition of infringement is to be found in section 45(1) of the Act. Section 45(1) provides as follows:

“45.(1) The effect of a patent shall be to grant to the patentee in the Republic, subject to the provisions of this Act, for the duration of the patent, the right to exclude other persons from making, using, exercising, disposing or offering to dispose of, or importing the invention, so that he or she shall have and enjoy **the whole profit and advantage accruing by reason of the invention.**” (Emphasis added)

It could be argued that the reference to “the whole profit and advantage” in this provision could be indicative of an intention by the legislature to exclude other persons from carrying out the prohibited acts only insofar as those acts would have prejudicial commercial implications for the patent owner.

However, South Africa courts have not yet considered this aspect to pronounce a clear principle (on the basis of section 45(1) or any other consideration) to the effect that **non-commercial use** of a patented invention (eg for research or experiment) would avoid infringement.

This issue was considered in a somewhat different context by the High Court in the case of *Stauffer Chemicals v Monsanto Company* 1988(1) SA 805(T), and the Court confirmed the interpretation of section 45(1) – in its form then – by finding that it entitled the patent owner to have and enjoy the whole profit and advantage of the invention, but that it does not prohibit the mere possession of an infringing article/product without an intention to use or dispose of it. The Court stated *obiter* that even experimental use of a patented invention will amount to an infringement in that the experiment **uses** the patented invention. In the *Stauffer* case the alleged infringer used the patented invention during the term of the patent to prepare for marketing registration of its own similar product, and the Court found that such activity in fact used the patented invention as a springboard to obtain an improper advantage. This could be viewed as gaining a commercial advantage; such use was found to constitute infringement.

Since the *Stauffer* case, a Bolar-type exception has been introduced by a legislative amendment in 2002 (see question 2) below).

- 2) *Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?*

Section 69A of the Patents Act was introduced by a legislative amendment in 2002 and provides for a Bolar-type exception. Section 69A provides as follows:

“69.A(1) It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.

(2) It shall not be permitted to possess the patented invention made, used, imported or acquired in terms of subsection (1) for any purpose other than for the obtaining, development or submission of information as contemplated in that subsection.”

It will be noted that the exception is not limited to pharmaceutical products; it applies to any invention (in any field of technology) in respect of which any law requires the submission of information for the manufacture, distribution or sale of a product. This would for example cover pharmaceutical and agrochemical products which require marketing authorisation before such products may be put on the market.

The formulation of the provision to apply generally to all patents was specifically intended to comply with TRIPS Art 27.1 which provides that all inventions are to enjoy patent rights without discrimination as to the field of technology.

It will also be noted that stock-piling of products made or imported under section 69A(1) is prohibited by section 69A(2).

- 3) *Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?*

Although this aspect has not specifically been decided by South African courts in respect of medicines or medical devices, it is generally accepted that parallel importation of patented products is not permitted. In general, section 45(1) of the Patents Act (see question 1) above) affords the patent owner the right to exclude others from **importing** the invention to which the patent relates, while section 45(2), which provides for the exhaustion of rights, does not contain any wording which would indicate that international exhaustion would apply; in other words, that parallel importation would be permitted.

Section 45(2) provides as follows:

“45.(2) The disposal of a patented article by or on behalf of a patentee or his licensee shall, subject to other patent rights, give the purchaser the right to use, offer to dispose of and dispose of that article.”

It should be noted that the acts which a purchaser would be permitted to carry out, do **not** include the importation of the patented invention. Accordingly, it is generally accepted that only national exhaustion of rights applies in South Africa, and that parallel importation in general is not permitted **under the Patents Act**.

This aspect was considered by the High Court in the case of *Stauffer Chemical Company v Agricura Ltd* (1979) BP 168. The Judge confirmed that only national exhaustion was intended; he found that he could “read nothing into section 45(2) which would induce (him) to depart from this principle”, namely that a purchaser of an article in a foreign country from a licensee of the patent owner in the foreign country, which article is patented both in the foreign country and in South Africa, would not acquire the right to import the article into, and sell it in, South Africa.

Therefore, the principle of national exhaustion of a patent right was endorsed, so that parallel importation would not be permitted.

However, the **parallel importation of patented medicines** was specifically provided for by a 1997 Amendment Act which amended the South African Medicines and Related Substances Act no. 101 of 1965 to introduce a new section 15C which provides as follows:

- “15C The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may:
- a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act no. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
 - b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;

When section 15C was first published for comment, the initial reaction was that such a provision would enable the Minister to override patent rights and as such could potentially be contrary to TRIPS.

However, article 8 of TRIPS allows a member state, in formulating or amending its laws and regulations, to adopt measures necessary to protect public health and nutrition, provided that such measures are consistent with the provisions of TRIPS. Accordingly, provided that section 15C could be implemented by the Minister in a fashion which is in accordance with TRIPS, a strong argument could be made out that section 15C would not be contravening TRIPS.

It should be noted that paragraph (b) of section 15C, which deals with the importation of an “identical” medicine does not refer to importation by persons other than the **patent owner**, but to importation by persons other than the holder of the “**registration certificate**” in respect of the medicine – presumably the certificate authorising the marketing of the medicines. This discrepancy created some uncertainty in the patent context.

In regulation 7 of the Regulations issued by the Minister in terms of section 15C, there is a clear reference to the importation of a patented medicine sold outside South Africa with the **consent of the patent holder**, ie by the patent holder or a voluntary licensee. This is interpreted as an indication that parallel importation was in fact contemplated and legalised by the legislature in respect of patented medicines, provided the required importation permit is required.

Unfortunately, however, some doubt remained because the term “parallel importation” (which is defined in the definitions part of the Regulations as the “importation into the Republic of a

medicine protected under patent and/or registered in the Republic that has been put onto the market outside the Republic by or with the consent of such patent holder”) has not been used in Regulation 7 itself. However, the Guidelines issued in respect of the Regulations appear to support the contention that parallel importation is indeed what is contemplated in Regulation 7, and that Regulation 7 should be interpreted and applied in this sense, namely to refer to the importation of branded products obtained outside South Africa from the patentee or its authorised licensees.

Regulation 7 sets out the requirements and conditions to be met in order to obtain an importation permit:

- The medicine must have been sold outside South Africa with the consent of the patent holder. This means that the medicines may be obtained from a licensee under a voluntary licence but not under a compulsory licence.
- The medicine must be imported from a person licensed (for marketing) by a regulatory authority recognised by the South African Medicines Control Council.
- The medicine must be registered (for marketing in South Africa) in terms of the South African Medicines Act.
- The medicine so imported may only be sold to the State or to a person authorised to sell medicines in terms of South African legislation.
- An importation permit is valid for a period of two years.

4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

No such exception is recognised in South Africa.

5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee’s exclusive rights?*

Methods of medical treatment are not patentable in South Africa.

6) *Are compulsory licences available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licences granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.*

The Patents Act provides for compulsory licences to be obtained in two circumstances: section 56 provides for a compulsory licence to be granted in cases of “abuse of patent rights”, and section 55 in the case of a so-called “dependent patent”.

In addition, the Act provides in section 4 for a Minister of State to acquire the right to use a patented invention “for public purposes”. This is referred to in more detail under question 8) below.

Compulsory licences for abuse of patent rights

Section 56 identifies four scenarios in which patent rights shall be deemed to be abused:

- a) where the patented invention is not being worked in South Africa on a commercial scale or to an adequate extent, within certain time periods;
- b) where the demand for the patented product in South Africa is not being met to an adequate extent and on reasonable terms;

- c) where trade or industry in South Africa is being prejudiced by reason of the refusal of the patent holder to grant a voluntary licence on reasonable terms, and it is in the public interest that a licence be granted;
- d) where the demand in South Africa for the patented product is being met by importation and the price charged by the patent holder is excessive in relation to the price charged in other countries.

The applicant has to apply to the Court of the Commissioner of Patents for a compulsory licence; the procedure is a judicial one. Section 56 is substantially compliant with TRIPS Art 31.

Compulsory licences for a dependent patent

Section 55 provides for a compulsory licence to be granted in the case where a "dependent" patent cannot be worked without infringement of a "prior" patent. Again application must be made to the Court of the Commissioner of Patents (ie a judicial procedure), and it is required that the dependent patent must involve an important technical advance of considerable economic benefit.

Section 55 is substantially compliant with TRIPS Art 31(l).

Compulsory licences for State use

See question 8) below.

- 7) *Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003? Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.*

Article 31bis of TRIPS has not yet been ratified or implemented in South Africa. No other legislation has been passed to implement the WTO decision of 30 August 2003.

Four cases have been decided by the South African courts under section 56 on compulsory licences. None of these related to pharmaceutical products.

Licences for the manufacture, importation and exportation of pharmaceutical products were granted in 2003 as a result of an intervention by the Competition Commission. In 2003 the provisions of the South African Competition Act no. 89 of 1993 were invoked when an NGO known as the Treatment Action Campaign (TAC) laid a complaint against two pharmaceutical companies, namely Boehringer Ingelheim and GlaxoSmithKline.

The basis of the complaint was that these companies, in refusing to grant voluntary licences under their patents in respect of first-line ARVs, had engaged in prohibited anti-competitive acts, namely

- denied a competitor access to an essential facility;
- engaged in excessive pricing;
- engaged in an exclusionary act.

Settlement agreements were concluded as a result of the investigation by the Competition Commission, in terms of which one of these companies agreed to issue four licences, and the other three, under their patents for the ARVs to generic manufacturers. The licences were to permit the manufacture in, and importation into, South Africa of the ARVs. The agreements also allowed for the exportation of any ARVs manufactured in South Africa to all sub-Saharan African countries. More specifically, where the licensees did not have manufacturing capabilities in South Africa, the licensor permitted the importation of the drugs for distribution

in South Africa; and the licensees were permitted to combine the relevant ARV with other ARVs and were charged royalties of no more than 5% of the nett sales of the relevant ARVs.

- 8) *Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?*

The Patents Act contains two provisions which give special powers to the State and which could be used as a basis for "crown use" of a patented invention.

Section 4 provides that a Minister of State may use a patented invention "for public purposes" on such conditions as may be agreed upon with the patent owner, or failing agreement, on such conditions as one determined by the Court of the Commissioner of Patents. In essence this would amount to a compulsory licence mechanism. This provision, which is **not** limited to pharmaceutical products, has not yet been invoked.

Section 78 provides that the Minister (of Trade and Industry) may, on behalf of the State, acquire any patented invention on such terms and conditions as may be agreed upon. In essence this merely enables the State to acquire patents in the normal course of business, by agreement with a patent owner.

- 9) *Is the government allowed to expropriate a patent and, if so, under which conditions?*

The acquisition mechanism provided for in section 78 of the Patents Act (see question 8) above) is not an expropriation. Moreover, section 25(1) of the Constitution of South Africa (Act no. 108 of 1996) provides that "no one may be deprived of property except in terms of a law of general application, and no law may permit arbitrary deprivation of property". Although section 25(2) of the Constitution provides specifically that property may be expropriated, under specified circumstances, for a public purpose, no attempt has been made to create a law of general application which would enable the State to expropriate patents.

- 10) *If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.*

The specific legislative initiative for facilitating access to medicines and medical products was introduced by way of the 1997 Amendment of the Medicines and Related Substances Act no. 101 of 1965 (see question 3) above).

II) Proposals for adoption of uniform rules

- 1) *Should patent law provide for*

- *research and experimental use exception;*
- *Bolar exception;*
- *parallel import of patented medicines;*
- *individual prescriptions exception;*
- *medical treatment defence;*
- *compulsory licensing;*
- *expropriation;*
- *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*

If so, under what circumstances? If not, why not?

It is important to accept that access to affordable medicines, particularly for poor populations in developing and least-developed countries, is a critical issue, and that measures to facilitate such access must be high on the priority list of AIPPI and individual countries.

It is also important to recognise that access to affordable medicines is not the only critical factor for ensuring effective treatment to poor people suffering from pandemic and endemic illnesses. Effective and accessible health care systems, improved living (sanitary and dietary) conditions, better education all play an important part.

In adopting and promoting a workable and sustainable basket of principles for addressing the current public health demands, a balanced solution must be found, which would be based on a balanced recognition of the importance of patent and other IP rights as an incentive while facilitating access to medicines and health care.

Unduly eroding the effective term and ambit of the protection afforded by patent rights on its own will not necessarily provide a solution.

To achieve such a balanced solution, a uniform set of rules in regard to appropriate and reasonable limitations or exceptions on patent rights would be a step in the right direction (inter alia to discourage inappropriate and unreasonable interferences).

- 2) *Do you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

Some further initiatives should also be considered within the context of patent law, eg:

- providing for incentives to encourage relevant R&D (eg innovation prize models)
- supporting relevant innovative activities, eg projects at universities, research on the basis of traditional remedies, etc
- promoting effective and sustainable technology transfer.

More specifically it is recommended that AIPPI should make a study of the work of the WHO's Intergovernmental Working Group (IGWG), and its draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property; and, furthermore, that AIPPI should participate in this initiative by preparing and submitting comments and suggestions.

- 3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?*

Harmonisation would be good. A variety of different dispensations applicable in different countries open the door for price and quality differentials which would not be in the public interest, and could indeed be abused.

Summary

Although research or experimental use is not recognised as non-infringing activities, and although Art 39bis of TRIPS has not yet been implemented, the South African legal system provides for a number of different mechanisms to enable or facilitate access to patented medicines, including a Bolar-type early use exception; compulsory licences in the case of the abuse of the patent rights (eg when the demand for the patented product is not being met to an adequate extent and on reasonable terms); and parallel importation in terms of a permit issued under the Medicines and Related Substances Act, 1965.