The TRIPS agreement and South African legislation: The case of the parallel importation of medicines

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1 INTRODUCTION

The topic of parallel importation and the issues facing South Africa in that regard, are to be dealt with for purposes of this article against the background of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and in the context of the recent South African legislation in the medical field. In this contribution, the objective or end goal is not in the first place to arrive at a solution to a problem, but rather to bring about a thorough understanding of the problem in all its theoretical complexity and practical implications. In this contribution the emphasis will therefore first be on the identification and analysis of the various features of the concept of parallel importation and different related legal principles, and secondly it will focus on the way in which these issues became relevant in the recent medicines legislation.

2 PARALLEL IMPORTATION DEFINED

Parallel importation is generally defined as the unauthorised importation into and sale in a country where an applicable intellectual property right exists, of genuine goods embodying the subject matter of the intellectual property (IP) right and first put onto the market in another country by or with the consent of the right holder.[1]

This may be illustrated by way of example:

Example 1

A patentee P owns a patent in country A in respect of a pharmaceutical X. The pharmaceutical was developed after extensive research work had been done by P's R&D section, and was finally accepted and registered to be marketed after extensive clinical trials had been conducted to the satisfaction of the relevant Medicines Registration Authority. All of this took several years

1 See in general Bennett and Newcomb 1998: 62; Zadra-Symes and Basista:1998: 219; Van Melle 1999: 63; Whybrow 1997: 42; Watts and Treacy 1997: 28; Senior 1996: 26; Grell 1997/1998: 20.

of dedicated work, and cost a substantial amount of money. The patentee P also owns a patent in respect of the same pharmaceutical X in a second country B, where P conducts a manufacturing operation manufacturing the pharmaceutical X. For the sake of the example, assume that manufacture in A is expensive, and in B is cheap. If a trader T should purchase the pharmaceutical X from P in country B and endeavour to import the pharmaceutical into country A, that would amount to parallel importation. An attempt will be made further below to explain why such importation could constitute a problem for the patentee P in country A and could in fact be regarded as an infringement of P's patent rights in country A, so that patentee P may endeavour to prevent such importation.

A number of variations may be introduced into the example without derogating from the principle of parallel importation.

Example 2

Thus, in the second country B, the patentee P may have granted a non-exclusive licence to a licensee L who conducts the manufacturing and marketing operations in return for a royalty paid to P. Should the trader T purchase the pharmaceutical X from the licensee L, the pharmaceutical would still have been put onto the market with the consent of the patentee P so that the goods are genuine; importation thereof into country A by the trader T would amount to parallel importation.

Example 3

In another variation, the patentee P may hold no patent in country C, but may himself put the pharmaceutical X manufactured by him in country A or elsewhere on to the market in country C via a wholesaler W, where it is bought by the trader T. The selling price in country C may be cheaper than in A because of price control in C. Should the trader T endeavour to import the pharmaceutical X into the country A, this would again constitute parallel importation.

Up to now, no view has been expressed on whether or not the parallel importation will constitute an infringement of the patent rights of the patentee P. Good arguments can be advanced in support of either viewpoint.

Example 4

However, the position would be different where in the latter case of country C where no patent exists, a pharmaceutical Y identical or substantially similar to X were to be manufactured and sold to the trader T not by P (or his licensee L), but by an independent third party Q. In this case the pharmaceutical Y is an infringing product, and importation of the pharmaceutical Y into country A would not amount to parallel importation but would constitute an infringement of the patent rights in country A and as such importation could be prohibited by the patentee P.

The series of scenarios sketched above all had to do with patent rights. The parallel importation phenomenon is, of course, not confined to the patent field.

3 WHY PARALLEL IMPORTATION?

The question should be asked, from the African perspective, why parallel trade issues could become relevant to independent countries on the African continent where the principle of free movement of goods as applies in Europe finds no or only limited application. The answer is to be found in the existence of price differentials[2] for example between countries where price regulation or restriction exists in one country and not in the others, [Watts & Treacy 1997: 28 30] or where IP rights exist in one country (leading to price increases for example as a result of royalty payments) and not in the others.

On the African continent, but also elsewhere, this is particularly true in the pharmaceutical field. Parallel importation issues have in the past been particularly prevalent in the pharmaceutical industry, and a number of possible reasons have been identified:

- The development and refinement of new pharmaceutical products require substantial research and development expenditure. [Kolker 1997] These expenses have to be recovered, giving rise to higher product pricing in those countries that can afford to carry such pricing.
- Pharmaceuticals are small volume products that can be moved between countries relatively easily. [Watts & Treacy 1997: 30]
- Once the pharmaceutical product has been developed to the marketable stage, it can be copied and reproduced relatively easily and at relatively low cost (when compared to the high cost of the initial research work and subsequent clinical tests).
- The demand for treatment means that specific pharmaceuticals creates a ready market which is sensitive to price differentials, particularly in those countries where funding for health care services is inadequate.
- Because governments in some countries endeavour to reduce expenditure on specific products to enable available health care funds to be spread over a wider area, price controls exists, and resultant price differentials provide an environment conducive to parallel imports.

Generally speaking the latter situation provides the incentive to the parallel trader: price differences in respect of the same product sold in different countries are necessary to create the right scenario for parallel imports. The parallel trader is induced to use the price difference to generate a trading profit.

One should visualise the following chain of trading actions: [Senior 1996: 27]

- ***Conventional trading route:***

  A patentee P owns a patent for a specific pharmaceutical X in the country A where no price controls exist, where manufacturing costs are relatively high, and where P intends to recover his research and development expenditure through sales of the pharmaceutical X. The result is that the pharmaceutical is manufactured by P and sold at say $100 per unit to a wholesaler WA. The wholesaler WA adds his profit and re-sells to the

2 Zadra-Symes and Basista: 219; Whybrow: 42; Senior: 26.

retail pharmacist Q at a unit price of say $120. The pharmacist Q adds his profit percentage and an amount for dispensing, so that the patient pays a unit price of say $140.

- ***Parallel trading route***:

  The patentee P also has a manufacturing operation in country B, where he holds no patent and no price controls exist, but manufacturing costs are low, so that the same pharmaceutical X can be sold to a local wholesaler WB at a unit price of $50. A parallel trader T in turn purchases from WB at a unit price of $60, imports into country A and sells to the wholesaler WC at $80, who can supply the pharmacist Q at a unit price of $100.

  Naturally the competitive situation which has now arisen, in terms of which the patentee P has to compete with his own product which arrived along a parallel trade route, is unacceptable to P; P would like to prevent importation into country A of the pharmaceutical X manufactured by him, P, in country B.

  The position may in fact be aggravated if the parallel trader T and the wholesaler WC, realising that their competitor patentee P in country A cannot sell at under $100 without losing, and wholesaler WA cannot sell under $120, decide to increase the unit price to the pharmacist Y to say $110. This means that a greater share of revenue goes to the parallel trading chain, while the patentee P earns from his manufacturing operator in country B only the lower controlled price. This represents a direct loss of revenue to the patentee P, as well as loss of sales to the wholesaler WA. At the same time, the patient is unlikely to receive any benefit from the potential lower pricing structure.

4 PARALLEL TRADE: MARKET CORRECTION OR MARKET DISTORTION?

The question whether parallel trade serves in practice to correct markets, or has the effect of distorting markets, will elicit different responses, depending upon the interest and position of the respondent. [Senior 1996: 27] In cases of parallel trade, revenue is diverted to the trader, the importing wholesaler, and even to the pharmacist. While revenue is diverted away from the patentee/manufacturer, the benefit does not necessarily reach the patient, nor does any benefit accrue to government health care institutions or funds. The parallel trader who benefits, does so without in any way adding any value to the product or to the service provided to patients.

Two principles are usually relied upon to justify parallel importation. However, it is difficult to understand how a principle such as the free movement of goods, which principle deprives the patentee of the full effect of his territorial patent right, namely to prohibit importation also of genuine goods into a country where he holds a patent, and a principle such as the exhaustion of rights when applied on an international scale, can be relied upon to justify and legalise a parallel trading system in terms of which neither the patentee nor the patient but only the parallel trader reaps the benefit.

5 IMPORTATION AND INTELLECTUAL PROPERTY RIGHTS

The instances of parallel importation exemplified above relate to intellectual property rights and appear to interfere with the exercise by the right holder of his IP right. Parallel importation as a phenomenon can manifest itself in all of the areas traditionally forming part of the field of intellectual property law, namely:

- patent law;[3]
- design law;[4]
- copyright law;[5]
- trade mark law.[6]

The IP rights derived in terms of the abovementioned four "laws" traditionally have a territorial effect:[7] the right holder in each case is given the exclusive right to prohibit others from exploiting the subject matter of his right in the country in which the right was granted. The right to prohibit others from importing goods embodying the subject matter of the right forms, to a greater or lesser degree, part of the exclusive right granted to the right holder, depending on the particular IP right.

For purposes of this article, we will concentrate only on the position in the area of patents.

In South Africa the relevant provisions are the following:

- *Patents Act 57 of 1978*: Section 45(1) (as amended in 1997) provides that the effect of a patent shall be to grant to the patentee the right to exclude other persons from making, using, exercising, disposing or offering to dispose of, *or importing* the invention, so that the patentee shall have and enjoy the whole profit and advantage accruing by reason of the invention.

This is in line with Article 28 of TRIPS.[8] This article provides that a patent shall confer on the owner/patentee the exclusive rights to prevent third parties not having the owner's consent, from the acts of making, using, selling or offering for sale, or importing for these purposes the patented product; or, where the subject matter of the patent is a process, the product obtained by the process. Article 28 has a footnote [9] in terms of which the exclusive right of importation of the patentee is made subject to Article 6 of TRIPS, an aspect to be reverted to further below.

It will be noted that the exclusive right given to the patentee appears to be an absolute right, namely the right to prevent unauthorised importation by others of the protected goods regardless of whether such goods are genuine goods or infringing goods. The comparable provisions in the Copyright and

3 Regulated in South Africa by the Patents Act 57 of 1978.
4 Regulated in South Africa by the Designs Act 195 of 1993.
5 Regulated in South Africa by the Copyright Act 98 of 1978.
6 Regulated in South Africa by the Trade Marks Act 194 of 1993.
7 Section 45 Patents Act; section 20 Designs Act; sections 6–11, 11A and 11B Copyright Act.
8 Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 being one of the package of instruments which constitute the WTO/GATT.
9 Footnote 6 in respect of the term 'importing' in Article 28(1(a).

Trade Marks Acts have not been formulated in such wide and absolute terms.[10] Accordingly, as regards the control of importation, the IP right holder in South Africa in all cases has the right to control (eg to prohibit) the importation of infringing goods. However, it is only in the case of patents and designs that the right holder has a clear right to control (eg to prohibit) parallel importation, that is the importation of genuine goods.

6 IMPORTATION RIGHT AND TERRITORIALITY

It is important to bear in mind that a patent has only territorial effect.[11] Up to now, and despite various efforts to create a so-called world patent, an inventor generally has to acquire separate patents to obtain patent rights in different countries. (It may be mentioned that a number of regional patent systems exist; this does not detract from the relevance of territoriality in the context of parallel importation.) A patentee can therefore enforce his patent rights only within the territory for which the patent has been granted, by preventing exploitation by others of the patented invention within the territorial borders, and by preventing importation by others of the patented product into the territory concerned.

Consequently, taking into account the territoriality of IP laws, and the clear rights afforded the IP right holder at least in the cases of patents and designs, one would expect that a clear principle would apply, namely that the right holder would be entitled to prohibit the importation of goods falling within the scope of his right, regardless of whether the goods were genuine or infringing articles. As we shall see, this is not always the case in practice. In fact, for a variety of reasons as will be considered below, the principle of territoriality and the right to control importation have been eroded.

7 PRINCIPLE OF THE EXHAUSTION OF RIGHTS

The doctrine of the exhaustion of rights,[12] and the question exactly how and to what extent it should find application in IP laws, are not as straightforward as one may expect, and in fact pose some complex questions. On a domestic level, the doctrine is based on the principle that once an IP right holder has manufactured a product in accordance with his IP right and has introduced it into the market by disposing thereof without restriction, such as to a purchaser, that purchaser can deal with the article further as he pleases, for example by re-selling it. The right holder is said to have exhausted his right.

In the context of patent law, the principle of exhaustion can be explained in the following manner: The grant of a patent is a guarantee that the patentee, as a reward for the creative effort in creating a new invention, has the exclusive right to exploit the invention by manufacturing products embodying the inventive concept and putting them into circulation for the

10 See section 23(2)(a) Copyright Act; section 34(2)(d) Trade Marks Act. Section 20(1) of the Designs Act is similar to section 45(1) of the Patents Act.

11 See section 45 Patents Act; Van Melle: 80.

12 See Whybrow 42 following; Van Melle: 64; Zadra-Symes and Basista: 219.

first time, either directly by his own manufacture or indirectly through a licensee (the *quid pro quo* principle). [Whybrow 1997: 43] Once the patentee has had the benefit of placing the product on the market without any restriction on the buyer, his right in respect of that article is said to have been exhausted. This principle is to be found in section 45(2) of the South African Patents Act 57 of 1978, which provides that the sale of a patented article by or on behalf of the patentee or his licensee shall give the purchaser the right to use and dispose of that article.[13]

It would thus be seen as incompatible with the exhaustion principle to allow a patentee to rely on his patent to prevent further dealing with (ie importation) and further sale (ie re-sale) of the product that he had initially marketed, or which had been marketed with his consent. The exhaustion principle has been formulated in substantially similar terms in its application to other IP fields, such as copyright law and trade mark law.

Whereas the exhaustion principle is accepted as good law on the domestic level, it is not clear to what extent it can be said to apply internationally. [Whybrow 1997: 42] In other words, once an IP right holder has placed goods embodying the subject matter of the right, for example the inventive concept covered by the patent, on the market in country A, can it be said that he has exhausted his rights also in country B where he holds a similar IP right? Will a purchaser of the goods in country A be free to import those goods into country B? On the basis of the territorial principle discussed above, such importation should not be permissible, at least not in the case of patents. Furthermore, where a right holder has an IP right in country A, and places goods embodying the subject matter of the right on the market in country C where he holds no IP right, can it be said that his right has been exhausted in country C even though he holds no right there, so that he will be unable to prevent a trader from purchasing the goods in country C and importing the goods into country A? The answer to these questions is not clear, mainly because the principles of territoriality of IP rights and exhaustion of IP rights have been eroded or at least obscured by other considerations related to the globalisation of IP laws, such as the principle of the free movement of goods.[14]

An example of this globalisation effect is to be found in the European Union (EU), where a multi-state regional political organisation has been established within the wider borders of which the principle of the free movement of goods (fundamental to the objectives of the Common Market) is increasingly taking precedence over the principles of IP rights, such as the territorial exhaustion of rights. Reliance on IP rights and the territoriality thereof creates conflict with the free movement of goods principle. Patentees who have tried to rely on their exclusive importation right to prevent parallel imports, have found that the European Court of Justice (ECJ) is increasingly placing reliance on provisions of the EC Treaty (the so-called Treaty of Rome), such as Articles 85 and 30–36, to remove impediments to parallel imports and to promote free movement of goods.

13 Section 20(2) of the Designs Act has a similar provision.

14 Whybrow 42; Watts and Treacy 28.

Another example of the globalisation effect is to be found in TRIPS itself. In the preamble to TRIPS, the desire is expressed to reduce distortions and impediments to international trade, and to ensure that measures and procedures used to enforce intellectual property rights do not themselves become barriers to legitimate trade. TRIPS itself, however, does not address the issue of the exhaustion of intellectual property rights (Article 6). And where provision is made in Article 28 for an importation right to be conferred by a patent, this right is made subject to the exclusionary provision relating to exhaustion.

8 RECENT SOUTH AFRICAN MEDICINES LEGISLATION

Parliament passed, in November 1997, the controversial Medicines and Related Substances Control Amendment Act 90 of 1997.[15] The Amendment Act was controversial for a number of reasons, but from the intellectual property perspective IP practitioners were concerned about an apparent attempt to override IP rights.

In the Amendment Act, the objectives are stated to be to amend the Principal Act, that is the Medicines and Related Substances Control Act 101 of 1965,[16] inter alia to make further provision for the prohibition of the sale of medicines which are subject to registration and are not registered; to provide procedures that will expedite the registration of essential medicines, and to provide for the re-evaluation of all medicines after five years; to provide for measures for the supply of more affordable medicines in certain circumstances; to provide for the licensing of certain persons to compound, dispense or manufacture medicines; and to provide for generic substitution of prescribed medicines.

All of these objectives are accepted to be legitimate and in fact necessary in order to provide the necessary machinery to implement government policy, namely to ensure that the entire population should have access to affordable health care and value-for-money medicinal products. However, in creating a legislative and regulatory framework to achieve these objectives, it is important that certain principles should to be adhered to, namely those principles contained in, and recognised and enforced by, national and international intellectual property laws and treaties. It is in this context that serious questions have been raised regarding the Medicines Amendment Act.

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15 Published in the *Government Gazette* 18505 of 12 December 1997.

16 The Amendment Act ie Act 90 of 1997, was subsequently repealed by the South African Medicines Devices Regulatory Authority Act 132 of 1998 (the so-called SAMMDRA Act), with the exception of ten sections, one of which is the controversial section 10 which introduced section 15C into the Principal Act 101 of 1965. The Principal Act itself was also repealed by the SAMMDRA Act, with the exception of seven sections. The SAMMDRA Act was promulgated with effect from 30 April 1999, but its promulgation has been set aside in an appeal heard by the full bench of the Pretoria High Court case A819/99. The previous Act 101 of 1965, as it applied on 29 April 1999, was reinstated. See Government Notice R977 of 13 August 1999 *Government Gazette* 20370.

The most controversial provision was contained in section 10 of the Amendment Act, which sought to insert a new section 15C into the Principal Act, as follows:

"Measures to ensure supply of more affordable medicines

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;

(c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b)."

It will be noted from the introductory part of section 15C, that the authority given to the Minister (of Health) is expressly stated to prescribe conditions for the supply of more affordable medicines in certain circumstances, so as to protect the health of the public.

The provisions of section 15C were interpreted by the pharmaceutical industry as empowering the Minister to be in a position to override patent and trade mark rights at any time by mere administrative action. This was viewed as being contrary to South Africa's international obligations in terms of the TRIPS Agreement, namely that patented inventions in all fields of technology are to be given full patent protection, subject only to the limitations as set out in TRIPS itself.[17]

Article 27 of TRIPS provides that patents shall be available for all inventions, whether products or processes, in all fields of technology, and patent rights shall be enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or produced locally. Article 28 confers on the patentee / owner of the patent the exclusive rights already set out above, including the exclusive right to prevent third parties from importing, using, selling or offering for sale the patented product. These two provisions, when read together, are interpreted as meaning that a curtailment of the exclusive rights in the case of patents in a particular field of technology, as envisaged in section 15C(a), would amount to discrimination as regards the enjoyment of patent rights in contravention of Article 27.

17 See further Du Plessis 1998: 14; Sheppard: 26.

It has to be taken into account that TRIPS itself makes provision for certain exceptions to or limitations on patent rights. For instance, Article 8.1 permits member countries to adopt measures necessary to protect public health, provided such measures are consistent with the provisions of TRIPS. Article 8.2 permits member countries to adopt measures to prevent the abuse of intellectual property rights, provided such measures are consistent with the other provisions of TRIPS. The proviso appearing in Articles 8.1 and 8.2, namely that any measures adopted should be consistent with TRIPS itself, is viewed as an uncompromisable requirement.

Article 30 also expressly states that member countries may provide for limited exceptions to the exclusive rights conferred by a patent, again subject to the proviso that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.

Article 31 sets out in great particularity the principles and directives to be respected where a member country allows for the use of the subject matter of a patent without the authority of the patent owner, including use by the government or third parties authorised by the government. The framework set out in Article 31 is viewed as a fair and workable mechanism inasmuch as a number of checks and balances have been provided for, such as that:

- use by third parties must be considered on individual merit;
- efforts must first be made to obtain authorisation from the patentee on reasonable commercial terms;
- the authorised use will be to supply predominantly the domestic market;
- adequate remuneration is to be paid to the patentee; and
- the legal validity of the decision must be subject to judicial review.

The framework contemplated in Article 31 is generally accepted to be embodied in a system of compulsory licences, as provided for in section 56 of the Patents Act 1978.

The question then remains to be answered: was there an alternative route available to the Minister of Health to achieve the stated objective of more affordable medicine?

It is submitted that the mechanism of compulsory licences, already recognised in the Patents Act, could have been modified to apply in the situation concerned.

The South African Patents Act already contains provisions in section 56 for the granting of compulsory licences in circumstances where patent rights are abused. These provisions provide a useful framework for a mechanism which could have been used to achieve the curtailment of patent rights as apparently envisaged by section 15C(a). The compulsory licence mechanism of section 56 is generally in conformity with the provisions of Article 31 of TRIPS, where the requirements for use of the subject matter of a patent without the authority of the right holder, including use by government or third parties authorised by government, are set out.

The granting of a compulsory licence in terms of section 56 of the Patents Act takes place by way of judicial process, before the Commissioner of Patents. A judicial process is not only transparent, but it affords the patentee whose rights are to be curtailed, an opportunity to be heard.

International norms generally favour a judicial process or a subordinate legislative process to be used when patent rights are to be curtailed.

Section 56 contains provisions setting out when patent rights will deem to be abused, if for example:

- the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms;
- by reason of the refusal of the patentee to grant a licence on reasonable terms the trade of any class of persons is being prejudiced, and it is in the public interest that a licence should be granted;
- the demand for the patented article / product is being met by importation and the price charged by the patentee is excessive in relation to the price charged in other countries where the product is manufactured by the patentee.

It is known that the pharmaceutical industry initiated court proceedings against the Minister of Health and others, and that the Amendment Act has not been implemented. It is not unlikely that it will fall away altogether, in view of other draft legislation published recently.

9 PARALLEL TRADING ISSUES FACING AFRICA

It is my firm conviction that parallel importation issues will become increasingly relevant to the countries of Africa. In my view this will happen for several reasons:

African countries are emerging as new destinations for technology, which means that the intellectual property rights relating to the technology will require protection. As more countries on the African continent join multiple-filing systems such as the Patent Co-operation Treaty, the protection of IP in African countries will become easier and therefore more attractive.

That does not mean to say, however, that the IP owners will necessarily put up manufacturing operations in all countries where they hold rights. It is more than likely that the local demand in individual countries will be met by importation. This is entirely in line with TRIPS provisions.

This means that the scene will be set for parallel traders to see an opportunity of profit. Particularly in the field of pharmaceuticals, and taking into account the enormous need for health care in Africa, this phenomenon is likely to occur. Many hold the view that this might ultimately be to the benefit of African countries, as a mechanism to suppress elevated price structures.

If parallel importation of pharmaceuticals is to be used to benefit the people of Africa, it is essential that an accurate and reliable study should be made of all of the aspects outlined above, with particular relevance to the countries of Africa. A debate amongst African countries needs to commence. Much can be learnt from recent decisions by the European Court of Justice

in regard to parallel imports of pharmaceuticals in European countries, and from the writings of learned authors on that subject, but the fundamental differences between the situation in African countries and that of European Community Member States (with the fundamental principle of the free movement of goods) should not be overlooked.

It is suggested that the following aspects need to be taken into account in the course of such an African debate:

- The importance should be recognised of intellectual property rights and their appropriate protection, as a means of encouraging innovation and creative activity on the African continent, and to encourage foreign technology to be introduced into Africa.
- The need should be accepted for African countries to endeavour to bring their IP laws in compliance with TRIPS, so that IP owners will be assured of the necessary minimum levels of protection and enforcement of rights, and so that the playing fields will be levelled.
- Unfortunately, TRIPS itself does not provide a solution, nor even clear guidelines, to the issue of parallel importation and the doctrine of the exhaustion of rights. These aspects will have to be assessed, not only from an academic point of view but also in practical terms, and workable yet fair solutions found.
- Efforts should be made to encourage pharmaceutical companies to set up manufacturing operations in Africa. In the absence of local manufacture on the continent, African countries will continue to be the battle ground of the foreign IP owner and manufacturer trying to recoup its R&D expenses in addition to generating a profit, and the unscrupulous parallel trader who has a profit motive without any interest in adding value to services or products.
- Recognition should be given to the fact that most African countries are in need of more affordable and more available medicines. However, at the same time it should be confirmed that Africa cannot become the dumping ground of poor quality pharmaceutical products. In endeavouring to make more medicines available more cheaply, no compromise can be made as to quality and purity.
- An attempt has been made in South Africa in the recent Medicines legislation to create a mechanism for more affordable medicines to be made available, presumably by way of parallel importation. This legislation met with forceful opposition by pharmaceutical companies. This is not the appropriate opportunity to go into more detail, but my own belief is that the same result could have been achieved with less exposure to opposition, if a different legal mechanism had been used. Legalising parallel importation evoked strong opposition.
- Finally, the subject of the abuse of IP rights (eg. patent rights in the case of pharmaceuticals), needs to be revisited, and clear principles, applicable to present circumstances, and in the context of the needs of African countries, should be defined. A balance should be attained between the adequate protection of IP rights, on the one hand, and the adequate supply of and access to technology to the people of Africa, on the other.

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