

EXCEPTIONS TO PATENT RIGHTS IN DEVELOPING COUNTRIES

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ABBREVIATIONS AND ACRONYMS

ALRC	Australian Law Reform Commission
CBD	Convention on Biological Diversity
CPC	Community Patent Convention
EC (EU)	European Community (European Union)
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GURTS	Genetic Use Restriction Technologies
ICTSD	International Centre for Trade and Sustainable Development
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
LDC	Least Developed Country
MFN	Most Favoured Nation
NAFTA	North American Free Trade Agreement
OAPI	Organisation Africaine de la Propriété Intellectuelle
OAU	Organisation of African Unity
OECD	Organisation for Economic Cooperation and Development
SMEs	Small and Medium sized Enterprises
SPC (1)	Supplementary Protection Certificate
SPC (2)	Supreme People's Court (China)
SPLT	Substantive Patent Law Treaty
TRIPS	(Agreement on) Trade Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade & Development
UNICE	Union des Industries de la Communauté Européenne
UPOV -	Union Internationale pour la Protection des Obtentions Végétales
USTR	United States Trade Representative
VCLT	Vienna Convention on the Law of Treaties
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

FOREWORD

Intellectual property rights (IPRs) have never been more economically and politically important or controversial than they are today. Patents, copyrights, trademarks, utility models, industrial designs, integrated circuits and geographical indications are frequently mentioned in discussions and debates on such diverse topics as public health, food security, education, trade, industrial policy, traditional knowledge, biodiversity, biotechnology, the Internet, the entertainment and media industries. In a knowledge-based economy, there is no doubt that a better understanding of IPRs is indispensable to informed policy making in all areas of human development.

Empirical evidence on the role of intellectual property protection in promoting innovation and growth in general remains limited and inconclusive. Conflicting views also persist on the impacts of IPRs on development prospects. Some argue that in a modern economy, the minimum standards laid down in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) will bring benefits to developing countries by creating the incentive structure necessary for knowledge generation and diffusion, thus including innovation, technology transfer and private investment flows. Others counter that intellectual property, especially some of its elements, such as the patenting regime, will adversely affect the pursuit of sustainable development strategies by raising the prices of essential drugs to levels that are too high for the poor to afford; limiting the availability of educational materials for developing country school and university students; legitimising the piracy of traditional knowledge; and undermining the self-reliance of resource-poor farmers.

It is urgent, therefore, to ask the question: How can developing countries use intellectual property tools to advance their development strategy? What are the key concerns surrounding the issues of IPRs for developing countries? What are the specific difficulties developing countries face in intellectual property negotiations? Is intellectual property directly relevant to sustainable development and to the achievement of agreed international development goals? Do developing countries have the capacity, especially the least developed among them, to formulate their negotiating positions and become well-informed negotiating partners? These are essential questions that policy makers need to address in order to design intellectual property laws and policies that best meet the needs of their people, as well as to negotiate effectively in the future.

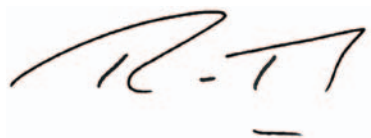
It is to address some of these questions that the UNCTAD/ICTSD Project on Intellectual Property Rights and Sustainable Development was launched in July 2000. One central objective has been to facilitate the emergence of a critical mass of well-informed stakeholders in developing countries - including decision makers, negotiators but also the private sector and civil society - who will be able to define their own sustainable human development objectives in the field of intellectual property and effectively advance them at the national and international levels.

Against this background, the present paper on Exceptions to Patent Rights in Developing Countries is a part of the efforts of the UNCTAD/ICTSD Project to contribute to a better understanding of the use of patent exceptions for the pursuit of various national policy objectives. Exclusive patent rights may constitute important tools for the promotion of a country's technological capacities, depending on that country's level of development in a particular sector. On the other hand, a Government may prefer to keep certain activities outside the scope of exclusive rights, considering it more beneficial for society to have unlimited access to the products or services related to such activities.

The present paper approaches the issue of patent exceptions on two interrelated levels: first, it reviews a number of long established practices and principles of patent exceptions and their implementation in both developed and developing country legislation. Second, in analyzing pertinent

WTO jurisprudence, the study highlights the possibilities of developing broader interpretations of the TRIPS provision on exceptions to exclusive patent rights.

We hope you will find this study a useful contribution to the debate on IPRs and sustainable development and particularly on the experience and use of patents in developing countries.

A handwritten signature in black ink, appearing to read 'R. Ortiz'.

Ricardo Meléndez-Ortiz
Executive Director, ICTSD

A handwritten signature in black ink, appearing to read 'S. Panitchpakdi'.

Supachai Panitchpakdi
Secretary-General, UNCTAD

EXECUTIVE SUMMARY

This Paper examines the principles and practice of “exceptions to patent rights”, especially as regards developing countries.

Many WTO Members (“Members”) are convinced of the utility of the patent system in encouraging research and development activity for new inventions. Many other Members are less confident of the benefits of the patent system and indeed are concerned about the dangers that the patent system poses, in terms of, for example, the impact that it and other intellectual property rights systems will have on their economic and social welfare. Where the line is drawn between those areas that are the preserve of the patent holder to control, and those areas which the patent holder may not control, is therefore a very important policy question for Members. The subject of this Paper relates to one aspect of this policy question, that is to say, “exceptions to patent rights”, which for present purposes, is taken to mean certain “safe harbour” areas of activity where the rights of a patent holder do not extend. Other limitations of the rights of patent holders and other matters such as the scope of patentability of inventions or the compulsory licensing of patents are outside the scope of this Paper, although they are touched on as and when appropriate.

This Paper is divided into four sections: Exceptions existing at the time of the TRIPS Agreement, Exceptions under the TRIPS Agreement, State practice on exceptions under the TRIPS Agreement and a Policy Process for considering new exceptions.

Exceptions existing at the time of the TRIPS Agreement

The world of international intellectual property protection was transformed markedly by the entry into force of the 1994 Agreement on Trade Related Aspects of Intellectual Property Rights (the “TRIPS Agreement”). The TRIPS Agreement is in fact Annex 1C of the Marrakesh Agreement establishing the World Trade Organisation (the “WTO Agreement”).

Prior to the TRIPS Agreement, countries had been largely free to adopt exceptions to patent rights as they saw fit. However, it was envisaged that the TRIPS Agreement would introduce some substantive provisions on exceptions, to regulate the validity of such exceptions. During the negotiation of the TRIPS Agreement the treatment of exceptions to patent rights underwent something of an evolution. In the July 23rd 1990 draft of the TRIPS Agreement, it was proposed to list a number of exceptions that were agreed to be acceptable. The approach eventually adopted for the treatment of exceptions in what became Art. 30 TRIPS was rather different however in that language was borrowed from an earlier Convention to provide a set of functional tests that any acceptable exception must pass. Notwithstanding this change in approach, the exceptions that had been well known before the negotiation of the TRIPS Agreement, continued to be regarded as valid exceptions after the entry into force of the TRIPS Agreement.

The following table outlines various exceptions to patent rights known at the time of the negotiation of the TRIPS Agreement (including for illustrative purposes a couple of Exhaustion based exceptions) in terms of the nature of the policy problem that they are intended to address.

Exception to patent rights	Nature of policy problem addressed
Private & Non-commercial Use	de minimus activity should be shielded from patent infringement.
Experimental Use	Scientific/technical progress must not be hindered by the patent system.
Prior Use	Prior users should be treated fairly vis-à-vis patent holders.
Pharmacy	Pharmacists should be free to make medicines for supply to patients on the basis of individual medical prescriptions submitted to them by doctors without fear of patent infringement.
Foreign Vessels	Freedom of international movement of foreign vessels must not be hindered by patents.
International Civil Aviation (Chicago)	Freedom of international movement (and maintenance) of foreign aircraft must not be hindered by patents.
Regulatory Review (Bolar)	Competition between patented medicines and generic medicines must be enabled as swiftly as possible after the expiry of the medicine patent.
(National Exhaustion)	(Once a patent holder has sold a patented product, they ought not to be able to control subsequent dealings with the product e.g. resale or repair)
(European Regional Exhaustion)	(Once a patented product has been sold on the European market, freedom of movement of goods throughout the rest of the market must not be hindered by patents)

Exceptions under the TRIPS Agreement

Under the TRIPS Agreement, the rights that patent holders are to be accorded are provided for in Art. 28.1 TRIPS. In terms of the exceptions that may be made to these rights, Art. 30 TRIPS provides that:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided 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 account of the legitimate interests of third parties.

Accordingly, following the adoption of the TRIPS Agreement, the validity or otherwise of exceptions falls to be determined under Art 30 TRIPS. If a policy maker wishes to craft a new exception, in order for it to be valid, it must meet these tests set out in Art. 30 TRIPS. How are they to be understood though? This is a critical question.

In fact, it was not long after the entry into force of the TRIPS Agreement that two exceptions, the known Regulatory Review exception, and a new Stockpiling exception were tested at the WTO in the *Canada-Generics* dispute in 2000. Both measures were aimed at bringing forward the day on which generic versions of a patented medicine could be marketed so that competition could bring the price of that medicine down as soon as possible. In making their decision, the Panel introduced an important legal test in their interpretation of a “limited” exception. Under this test the Panel found that the Stockpiling exception was not “limited” and so was not consistent with Art. 30 TRIPS. By contrast the Regulatory Review exception was “limited” and since it passed the other tests of Art. 30 TRIPS, at least so far as the Panel needed to interpret them, the Regulatory Review exception was found to be consistent with Art. 30 TRIPS. It is tremendously important from a public health point of view that this the Regulatory Review exception was found to be, crudely speaking, a “WTO approved” exception. Other Members can adopt a Regulatory Review exception with a high degree of confidence that they will not be challenged by any other Member for doing so.

However, for at least the following reasons, the approach of a new Panel to the issue of exceptions under Art. 30 TRIPS must likely be expected to be different from that which the Panel took back in 2000.

It is argued in this Paper that, among other things, the Panel erred in their interpretation of “limited” in not systematically taking account of *all* the pre-existing exceptions which were known to be valid at the time of the entry into force of the TRIPS Agreement. To take two examples of exceptions that provide broad exceptions to the rights of patent holders, the Foreign Vessels exception is *mandatory* for all WTO Members and the Chicago exception is *mandatory* for all parties to the International Civil Aviation Convention (nearly all countries in the world). When interpreting “limited” in accordance with the rules of the Vienna Convention on the Law of Treaties, it is argued that whatever “limited” means it *must* embrace both the Foreign Vessels and Chicago exceptions. However, the Panel’s interpretation of “limited” arguably excludes both of these exceptions. The same consideration applies to all the other terms in Art. 30 TRIPS.

It is also true to say, of course, that much has happened since 2000, including the Doha Declaration on TRIPS and Public Health. An “evolutionary” approach to the interpretation of the provisions of the TRIPS Agreement is certainly to be expected. Caution must therefore be counseled in taking too strict a view of *Canada - Generics* as a precedent as to how any new patent exception needs to be designed.

There are, and there must be, limits to the scope of exceptions from patent rights under Art. 30 TRIPS, whether in terms of legal or economic tests, but they have not yet been fully explored.

State practice on exceptions under the TRIPS Agreement

Following the legal examination of Art. 30 TRIPS, this Paper reports the results of a review of developments in patent rights accorded, and exception to those rights, in respect of more than 30 countries. This review reveals a rich variety of developments.

Exceptions that were well known at the time of the TRIPS Agreement continue to evolve.

- In some cases the scope of an exception has narrowed (or has been confirmed to be narrow) through judicial decisions, for example, that of the US Experimental Use exception.
- In some cases the scope of an exception has been forced to become more narrow (or to remain narrow) through, for example, a bilateral dispute such as that between the US and Argentina which narrowed Argentina’s International Exhaustion exception, or a bilateral agreement such as the Free Trade Agreement between the US and Morocco which required Morocco to maintain only narrow Regulatory Review and International Exhaustion exceptions.
- In some cases the scope of an exception has broadened (or has been confirmed to be broad) through judicial decisions, for example, that of the US Regulatory Review exception.
- In some cases the scope of an exception has been broadened through legislation to address economic policy issues, for example, the Indian and Kenyan International Exhaustion exceptions.
- In some cases, an exception has been broadened through legislation to embrace continuing technological change, for example, the US Foreign Vessels exception being widened to include spacecraft so that US patents will not interfere with the launching of foreign satellites.
- In some cases, due to legal and political developments, an exception has been adopted on the basis of a foreign model, for example, the adoption of a Regulatory Review exception by the EC following the *Canada-Generics* Panel and the expansion of the EC to include Eastern European states.
- In some cases, it is suggested that an exception thought no longer to have much practical utility may become useful again due to technological changes, for example, the Pharmacy exception and somatic genetic and somatic cell therapies.

Whether in respect of a pre-existing exception or a new exception, uncertainty as to the scope of an exception will likely have a negative impact. This may be particularly so where patent infringement

is criminalised, for example as in Brazil. In an optimal case, a country's patent legislation would be periodically reviewed to ensure that its present form is continuing to operate in the best interests of the country, as is, for example, the case in China. Discrete policy review processes may also be undertaken to address just one problematic area, as in the case of the Australian Law Reform Commission and the Experimental Use and Medical Practitioner exceptions. Monitoring the incidence of use of these patent exceptions may be expected to yield interesting insights into underlying economic and technological changes in developing countries and would assist such a review process. However, this is difficult at the present time however given the lack of systematic empirical data.

New exceptions, to solve new policy problems (typically resulting from the expansion of patentability into a new field) have also been adopted. These new exceptions are summarised as follows:

Exception to patent right	Nature of policy problem addressed
Business Method Prior Use	Prior users of business methods should be treated fairly vis-à-vis patent holders.
Medical Practitioner	Freedom for medical practitioners to carry out medical treatments
Farmers Privilege	Need for farmers to be able to harvest and re-sow their own seeds
New Variety Breeding	Need for breeders to be able to use present varieties as a basis from which to breed new varieties
Teaching	Freedom to teach students

It is particularly interesting that the European implementation of the Farmers Privilege exception includes an element of compensation.

Policy process for considering new exceptions?

The Paper concludes by examining the policy space which is still available for Members to adopt new exceptions in the light of the arguments presented on *Canada-Generics* and the review of the practice of Members. A factor that might be expected to increase that policy space is the possibility of providing compensation under an exception, as in the European Farmers Privilege exception. However, there are also factors that will conversely decrease that policy space, include bilateral or multilateral TRIPS-plus agreements, in particular the present round of US Free Trade Agreements. An attempt to solve the “paragraph 6” problem of the Doha Declaration on TRIPS and Public Health with an Art. 30 TRIPS exception was rebuffed although the possibility remains if the solution now adopted does not work effectively.

By way of conclusion, a number of options are suggested for policy makers considering solving a present or future policy problem with an exception under Art. 30 TRIPS. These include:

- Operationalising or modifying an exception already present in national law.
- Adopting a new exception, either on the basis of a foreign model or by analogy.
- Adopting a wholly new exception, either within the bounds of the *Canada-Generics* tests, or, for example, with justification based on a comparative and international law study and with the possible inclusion of compensation, beyond the *Canada-Generics* tests.

Notional examples are provided relating to satellite launching (consider the Foreign Vessels exception), saving seeds for re-use (consider the Farmers Privilege exception), stockpiling pandemic medicines (consider an analogy to the Chicago exception?), developing Free and Open Source software (consider an analogy to the Pharmacy or Medical Practitioner exceptions?) and Humanitarian Use (consider a Noncommercial exception approach?).

1 INTRODUCTION

This Paper examines the principles and practice of “exceptions to patent rights”, especially as regards developing countries.

Many WTO Members (“Members”) are convinced of the utility of the patent system in encouraging research and development activity for new inventions. Many other Members are less confident of the benefits of the patent system and indeed are concerned about the dangers that the patent system poses, in terms, for example, of the impact that it and other intellectual property right systems will have on their economic and social welfare. Where the line is drawn between those areas that are the preserve of the patent holder to control, and those areas which the patent holder may not control, is therefore a very important policy question for Members. The subject of this Paper relates to one aspect of this policy question, that is to say, “exceptions to patent rights” which for present purposes, is taken to mean certain “safe harbour” areas of activity where the rights of a patent holder do not extend. Other limitations of the rights of patent holders and other matters such as the scope of patentability of inventions or the compulsory licensing of patents are not the subject of this Paper, although they are touched on as and when appropriate.

Section 2 of this Paper outlines the nature and history of a number of long established exceptions to patent rights. In the light of the fact that exceptions to patent rights now have

to be tested for validity or invalidity against the TRIPS Agreement, Section 3 reviews the *Canada-Generics* Panel report, the first WTO dispute to interpret the relevant exception-related provisions of the TRIPS Agreement. This Paper argues that the Panel erred in interpreting the TRIPS Agreement in neglecting to systematically take into account all the relevant pre-existing exceptions to patent rights discussed in Section 2. Section 4 reviews the practice of Members as regards exceptions to patent rights, in particular since the entry into force of the TRIPS Agreement, both in terms of the pre-existing exceptions discussed in Section 2 and new exceptions. Section 5 examines the policy space likely now available for Members to adopt new exceptions, in the light of the arguments presented on *Canada-Generics* in Section 3 and the practice of Members reviewed in Section 4. Conclusions are presented in terms of a recommended process for Members considering the use of exceptions to patent rights to solve their continuing policy needs.

It should be noted that every Member is different and it is often difficult to make generalisations about the developmental status of groups of Members. However, this Paper does utilise terms such as developed country Members and developing country Members, by way of a rough differentiation. They should not be relied upon for too specific a meaning. Where a more specific term is needed, such as OECD or LDC, these terms are used instead.

2 LONG ESTABLISHED EXAMPLES OF EXCEPTIONS TO PATENT RIGHTS

The world of international intellectual property protection was transformed markedly by the entry into force of the 1994 Agreement on Trade Related Aspects of Intellectual Property Rights (the “TRIPS Agreement”). The TRIPS Agreement is in fact Annex 1C of the Marrakesh Agreement establishing the World Trade Organisation (the “WTO Agreement”).

Prior to the TRIPS Agreement, countries had been largely free to adopt exceptions to patent rights as they saw fit. However, it was envisaged that the TRIPS Agreement would introduce some substantive provisions on exceptions, to regulate the validity of such exceptions. During the negotiation of the TRIPS Agreement the treatment of exceptions to patent rights underwent something of an evolution. In the July 23rd 1990 draft of the TRIPS Agreement¹, it was proposed to list a number of exceptions that were agreed to be acceptable, specifically:

- 2.2 Exceptions to Rights Conferred
- 2.2 [Provided that legitimate interests of the proprietor of the patent and of third parties are taken into account], limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as:
 - 2.2.1 Rights based on prior use.
 - 2.2.2 Acts done privately and for non-commercial purposes.
 - 2.2.3 Acts done for experimental purposes.
 - 2.2.4 Preparation in a pharmacy in individual cases of a medicine in accordance with a prescription, or acts carried out with a medicine so prepared.
 - 2.2.5 A Acts done in reliance upon them not being prohibited by a valid claim present in a patent as initially granted, but subsequently becoming prohibited by a valid claim of that patent changed in accordance with procedures for effecting changes to patents after grant.
 - 2.2.6B Acts done by government for purposes merely of its own use.

This list is consistent with other such lists, for example, the list of exceptions mentioned in the WIPO Draft Treaty discussions or the WIPO Model Patent Law for Developing Countries, both as discussed further below.

There are a number of important things to note about it. Firstly this list is not a closed one, as is clear from the use of “...such as...”. This is beyond contention as, in 1990, there were certainly other widely accepted exceptions which had existed for many decades. Secondly, it is clear that these exceptions are optional given the use of “...may be made...”. Finally, this list includes both exceptions *per se* and matters which are in the nature of compulsory licensing (“government use” in this case, which is a very similar concept).

The approach eventually adopted for the treatment of exceptions in what became Art. 30 TRIPS was rather different in that language was borrowed from an earlier copyright Convention, the Berne Convention for the Protection of Literary and Artistic Works (1971), to provide a set of functional tests that any acceptable exception must pass. Matters such as compulsory licensing and government use were split off into their own article, Art. 31 TRIPS. Notwithstanding this change in approach, exceptions including those in the list above that had been well known before the negotiation of the TRIPS Agreement, continued to be regarded as valid exceptions after the entry into force of the TRIPS Agreement.

This section outlines the history and nature of a number of long established exceptions to patent rights. As will be evident they relate to a disparate set of areas of activity. The areas of policy problems that they address include science & technology, international travel, international trade and public health. Some of the exceptions are generally very well known and so little need be said about them. Others are less well known and so a more full explanation is provided. A table (Table 1) at the end of the section summarises the list of exceptions and the nature of the policy problem that they are aimed at solving.

2.1 Private and Non-commercial Use exception

Relevant Policy area: General

There is a good deal to be said for the view that patent rights have been habitually thought of in terms of providing a monopoly over commercial activity, but not extending so far as to catch non-commercial activity. It was observed more than a century and a quarter ago that:

“Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way. But if there be neither using nor vending of the invention for profit, the mere making for the purposes of experiment, and not for a fraudulent purpose, ought not to be considered within the meaning of the prohibition, and if it were, it is certainly not the subject of an injunction”².

Similarly, some thirty years ago it was said that:

*The patent laws generally recognize a limitation of the patentee's right with regard to acts constituting noncommercial or non-industrial uses of the patented invention. However, the precise definition of what acts are such may differ in the various countries. Generally use of the patented invention for strictly private or experimental purposes is not to be deemed to be use for industrial and commercial purposes*³.

Two different approaches may be considered in making the boundary between commercial and non-commercial acts concrete. On the one hand, the rights of the patent holder could be limited to only preventing unauthorised third parties from carrying out acts of a commercial or industrial nature, thereby providing an *implicit* exception to the patent holders rights for all non-commercial or non-industrial activity. In fact, this is the approach that a number of developing countries have taken, presumably as it gives them, at least in theory, somewhat more latitude in confining the rights of patent holders. On the other hand, patent holders could be accorded broad rights over all manner of activities and an *explicit* exception to the patent holders rights could be provided

to permit third parties to carry out acts of a non-commercial or non-industrial nature, either broadly defined, or in specific case-by-case terms. This is the approach most often taken by developed countries where an explicit exception for acts which are “private and non-commercial” is provided. In this formulation the “and” is particularly significant. It is usually regarded as a conjunctive “and”, which is to say that the exception only covers activities which are *both* private *and* non-commercial. Under such an exception it would not be expected that either private commercial activities or public non-commercial activities would be covered.

Before the TRIPS Agreement, discussions on this exception took place, for example, within the ambit of an ambitious attempt in the 1980s to bring about a degree of international patent harmonisation in the form of a WIPO Draft Treaty⁴, before such efforts were overtaken by the transference of “trade-related” intellectual property rights to the GATT/WTO negotiations⁵. Art. 302 (2)(ii) of the WIPO Draft Treaty provided an option for an exception relating to “acts done privately and for non-commercial purposes”. The delegations of Switzerland and Australia and the representative of UNICE⁶ indicated that they had difficulties with this formulation: “It was pointed out that a process might be worked by public utilities in such a way that no commercial purpose was involved, although clearly an unauthorised use of the invention might be involved. The Delegation of Switzerland suggested that the term “non-professional” might be more appropriately used that “non-commercial”⁷. The Swiss government did not get their way. Nevertheless, it is the case that in terms of entities carrying out activities which may be professional but not for profit, this exception is likely to be viewed narrowly, at least in Europe:

“...activities carried out by non-profit Organizations such as public utilities and charities (e.g. schools, hospitals, churches) or state organs, do not fall within the purview of the exemption. This is in conformity with the former

laws of France and Germany; the German law regarded such activities as "commercial". The Supreme Court of Austria decided that "commercial use" is broader than "business activity" and includes use by non-profit Organizations for the sick, charities, or communal public utilities...The justification for not exempting activities by non-profit institutions is that although they do not compete with the patentee, their use of the invention may well be done on a scale which significantly impairs his exclusivity in working the invention..."⁸

Under these conditions the adverse consequences that a patent holder will suffer under this exception must be very limited.

This exception may be seen as providing a *de minimus* threshold for patent rights. In general, patent holders would very likely not bother to sue such individual users of an invention in any case. It would usually be far more sensible, from the perspective of a patent holder, to interdict the supply of any allegedly infringing products by suing the manufacturer or supplier.

A Private and Non-commercial Use exception in national patent law is very widespread. By way of one example, Section 60(5)(a) of the 1977 UK Patents Act, in force at the present time, provides that "[An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if] - (a) it is done privately and for purposes which are not commercial"⁹.

2.2 Experimental / Scientific Use exception

Relevant Policy area: Science & Technology

This is one of the most widely known exceptions to patent rights and, as with the exception for private and non-commercial use above, grew out of an early conviction that patent rights ought not to restrain non-commercial or non-industrial activity. The concern that patent rights should not hamper the scientific process is a long standing one and the tradition of permitting "*bona fide*" experiments therefore has similar vintage¹⁰. In much the same way as with the Private and Non-commercial use exception, such activity could be regarded as simply not falling within the rights of a patent holder, or as a specific exception to those rights.

The long standing question is the proper extent of an Experimental Use exception. Various types of activities that might be considered to fall within this exception include experimenting on an invention to see how it works, or to test it against the disclosure that the patent holder made in the patent application, experimentation on the invention to "design around" it (in order to develop a functional equivalent which does not infringe the patent) or improve upon the patented invention, and "blue sky" academic

interest. Much has been written on this subject and there is certainly no need to rehearse the detailed arguments again here¹¹. The essence of the matter however is whether or not the experimental activities permitted under such an exception should be limited to ones which are non-commercial or whether experimentation with a commercial element or of a commercial nature ought to be embraced as well and if so, to what extent¹². This judgement will condition the amount of adverse impact that patent holders will experience under such an exception. It might be, for example, that initial experimental activity carried by an unauthorised third party is sufficiently non-commercial to be covered by the exception, but as the activity grows in scale and commercial importance, the activity will "evolve" out of the exception and into patent infringement territory, where a patent licence may be required. A patent holder will want this to happen at a very early stage. Public policy concerns may dictate otherwise.

Some form of Experimental Use exception is provided in a great many countries to permit third parties to carry out experimental or scientific activities relating to the subject matter of the patent¹³. By way of one example, Section 60(5)(b) of the 1977 UK Patents Act, in

force at the present time, provides that “[An act which, apart from this subsection, would constitute an infringement of a patent for an

invention shall not do so if] - (b) it is done for experimental purposes relating to the subject-matter of the invention”.

2.3 Prior Use exception

Relevant Policy area: General

There is little or nothing to be gained in granting even a limited patent monopoly for an invention which the public is already aware of before a patent application is filed¹⁴. A problem arises however where an inventor makes an application for a patent for their invention and it turns out that before this inventor made their application, a third party had already, and independently, been carrying out activities relating to the invention, or making substantial preparations to do so, but *in secret*.

Since the public was not in possession of the details of the invention till the inventor filed the patent application, or rather till it was published, then it is widely regarded as fair that the inventor should be allowed to obtain the grant of a patent¹⁵. However, equally, it is widely considered that it would not be fair to permit such a patent holder to enforce their patent against the secret prior user, as this would take away the right to do what they had already been doing before the patent application was filed, and therefore the rights of the patent holder must be limited accordingly. Hence, a Prior Use exception may be provided to permit a limited exception to the patent holders rights to allow the prior user to carry on doing what they were doing before.

A long standing question is what the permissible scope of this exception ought to be. Imagine that the prior user has been using a manufacturing process to produce a stockpile of items which, subsequent to the grant of the patent, will be infringing items. Later discussion in Section 3.4.1 will show that one suggestion for the limitation of this exception is simply that the prior user ought to be able to dispose of any such stockpile. Another suggestion is that the prior user ought to be able to carry on doing whatever they were doing before. That is to say, if they were manufacturing the item, they ought

to be allowed to carry on manufacturing that item, although how much modification of the item would be permissible whilst still remaining within the exception is a difficult question¹⁶. Broadly speaking it is this latter approach that it usually adopted when a Prior Use exception is discussed. As with the form of words reflected in the 1990 draft of the TRIPS Agreement, protection is usually explicitly provided for those that subsequently deal with the products of the prior user. A matter not reflected in the 1990 draft formulation, but widely subscribed to nevertheless, is the limitation of the use of the exception to the prior user alone, a licensee of the prior user not being covered for example: “The third party’s right is called a right of personal possession, because while the patentee may grant licences for the working of his invention, the person in question can work it only personally and cannot transfer it, except together with the business in connection with which he uses the invention”¹⁷.

Lest it be thought, though, that this exception must be of little practical effect, imagine that the prior user in question is a large corporation and the patent holder a small or medium sized enterprise (SME). The scope for activity which adversely affects the patent holder could potentially be very large indeed. Depending on the precise nature of the activity which the prior user corporation had already carried out in secret, in theory it could for example be enabled to make and sell its product in direct competition with that of the SME, without any limitation on quantity and without any compensation due to the patent holder.

By way of one example of a Prior Use exception, Section 64 of the 1977 UK Patents Act, in force at the present time, provides:

64.- (1) Where a patent is granted for an invention, a person who in the United Kingdom before the priority date of the invention -

- (a) does in good faith an act which would constitute an infringement of the patent if it were in force, or
- (b) makes in good faith effective and serious preparations to do such an act, has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the grant of the patent; but this right does not extend to granting a licence to another person to do the act.
- (2) If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (1) may -
- (a) authorise the doing of that act by any partners of his for the time being in that business, and
- (b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.
- (3) Where a product is disposed of to another in exercise of the rights conferred by subsection (1) or (2), that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the registered proprietor of the patent.¹⁸

This Prior Use exception is understood in broad terms:

"It is submitted that the 1977 Act imposes no quantitative restrictions. If a person has manufactured one potentially infringing product he should be at liberty to repeat that act as and when he pleases even if this involves the purchase of new plant since any quantitative restriction would be inconsistent with one of the objects of patent law which is to contribute to the increase of knowledge without fettering the right of others to use their pre-existing knowledge. The right is restricted to continuing to do that act and not any infringing act. Thus, if the potentially infringing act was making (which no doubt would also be effective and serious preparations for disposal), this would not entitle the person in question to import instead of make"¹⁹.

Indeed, it is interesting to note that in one UK decision this exception was described as providing "what can be called a statutory licence"²⁰. The question of whether a given act should be treated as falling under an exception, or whether it needs to be treated as a matter for a compulsory licence, or whether the dividing line between the two is not so clear, as seems to the case here, is discussed further below in section 5.2. If this provision is regarded as any form of licence however, it is one with zero remuneration for the patent owner.

2.4 Extemporaneous Preparation of a Medicine in a Pharmacy ("Pharmacy") exception

Relevant Policy area: Public Health

For a long time it was thought self-evident that permitting patent monopolies in areas such as medicine (or food) was a bad idea, as potentially leading to the monopolisation of an essential commodity²¹, but during the last fifty to a hundred years there has been a significant shift in attitudes to the patenting of various inventions in the medical field. A number of different approaches could be taken, taking into account continuing concerns:

- Make all medical inventions unpatentable
- Make all medical inventions patentable but provide for patent exceptions, for example for doctors or pharmacists
- Make only some medical inventions patentable, for example products such as medicines, but not processes such as methods of medical treatment²².
- Make all medical inventions patentable

Each approach has its supporters and its critics. Some indicate that it is simply not acceptable

to subject public health to the economic rigours of the patent system and that access to medical inventions should be maximised by removing this field from patentability: all medical inventions should be “generic”. R&D would therefore have to be funded in some other fashion. Others indicate that the incentive effect is of paramount importance to the private sector in driving medical development forward and that there can be no conceptual problem with doctors having to pay royalty fees to carry out a patented surgical technique if they have to obtain the tools they use in their medical practice, such as patented medicines, on the terms of a patent holder anyway. Others take a middle course, that it is fine for medical products to be patented and for the private sector to develop new medical products on that basis but as a matter of medical ethics, methods of medical treatment must not be patentable.

As a matter of fact, countries are no longer able to choose between these approaches. Hesitant steps were made decades ago in the now developed countries, as and when industrial and societal developments permitted, to extend patentability into areas of health related inventions²³. This approach has now become general for all Members under the TRIPS Agreement, for example mandating the patentability of pharmaceutical products²⁴, and at least permitting the patentability of methods of medical treatment.

The policy balance that Europe has struck is of interest here in that not only has it excluded methods of medical treatment from patentability but it has also adopted a particular patent exception relating to pharmacists. This exception, the “extemporaneous preparation of a medicine in a pharmacy” exception (the “Pharmacy” exception), purports to permit a pharmacist to prepare a (generic version of a patented) medicine in accordance with an individual prescription provided by a doctor, or a dentist, and to supply that medicine to the patient, without permission from the patent holder. The term “extemporaneous” is derived from the Latin *ex tempore*, “on the spur of the moment”²⁵.

This exception was well known before the negotiation of the TRIPS Agreement and was, for example, included in the draft 1990 TRIPS Agreement list. It would appear that the exception is aimed at solving the fundamental problem of ensuring that patients are not prevented from receiving the medicine that they have been prescribed by a doctor due to the existence of a patent. It is often emphasised however that the use of the Pharmacy exception must be medically, rather than economically motivated:

“...the exception probably only matters in situations where there is medical justification for the pharmacy making up the medicament on the premises. In other situations pharmacy staff doubtless prefer to sell an existing, ready packaged medicament. Economic considerations are usually of minor importance in these situations. Should it ever happen that hospital pharmacies systematically, but still for individual patients, and for economic - that is not medical - reasons choose to manufacture patented medicinal products under their own auspices, a teleological interpretation of the provision suggests that such action must be regarded as patent infringement, because the provision implies only sporadic, improvised and medically prompted use of patented medicinal products...”²⁶

It might well be said that this only represents a European or OECD view though. In many developing countries there is no such nice distinction between medical and economic reasons for doing things. A patient that cannot be provided with the necessary essential medicines, for reasons of either personal or state poverty, will die just as finally as if they can’t be treated for medical reasons. However, even if a developing country were to include an economic rationale (aimed at lowering the price of the medicine rather than the pharmacy making a profit) within the scope of this Pharmacy exception, there is still an obvious practical reason why this Pharmacy exception is unlikely to provide much, if any, assistance at the present day.

The simple fact of the matter is that the average pharmacy, even in the OECD, is not in a position to access comparable production resources to a pharmaceutical company and is not in a position therefore to be able to make a generic version of any patented medicine that a doctor asks for. Not only does the Pharmacy exception not extend to cover suppliers of active ingredients (unlike the Regulatory Review (“Bolar”) exception discussed below), even the remaining activity to create the final product will likely be beyond the resources of a pharmacy, especially since enough is only being made for one patient at a time. Stockpiling ahead of time would not be permitted given the “extemporaneous” nature of the exception. In practice therefore, despite what might once have been good intentions on the part of the legislature, the utility of this Pharmacy exception seems likely to be aimed at relatively simple matters such as making up, for example, variations of strength of topical creams²⁷. A typical pharmaceutical company is unlikely to be commercially concerned about inroads into its exclusive rights made by pharmacists if armed with only, for example, a pestle and mortar and basic chemical ingredients.

Perhaps the exception would mainly have been of use in past years where the making up of patented medicines was not such a sophisticated affair²⁸. Perhaps, it may be speculated that the exception will be of use again in years to come when pharmacies do have access to more sophisticated technologies. It is an interesting thought experiment to consider what would happen if the technical resources available to pharmacists were to change. The Pharmacy exception makes no reference to the level of technical capability of a pharmacy. What if pharmacists one day acquire devices that are able to assemble any given medicine out of the basic constituent elements on the spot? Would the exception become objectionable if, as a strictly practical matter, it became able to be widely used? *A particularly interesting speculation as to the future utility of this exception perhaps relates to genetic therapies:*

“The fact that somatic genetic and somatic cell therapy require the use of genetic and cell material of the patient to be treated raises the question of the applicability of Sec 11, No. 3 Patent Act [Section 11(3) of the German Patent Act 1998 implements the Pharmacy exception]...Owing to the fact that initially neither a somatic genetic therapy nor a somatic cell therapy is possible independent of the patient to be treated, these pharmaceuticals are only made at the request of the doctor. If the hospital laboratory, where pharmaceuticals for therapy e.g. for a monogenic defect, are made using genetic engineering, can be considered equivalent to a pharmacy within the meaning of Sec. 11(3) Patent Act, the above-mentioned patent possibilities are of little value in the field of genetic therapy...On the basis of these considerations, Sec 11, No. 3 Patent Act can be said to apply, for the hospital laboratory, just like the traditional pharmacy, produces a pharmaceutical for a particular patient on the basis of a doctor’s prescription.”²⁹

Irrespective of whether or not this exception is likely to have much of a practical impact on pharmaceutical patent holders at the present time, objections to this exception have been expressed, no doubt because, in like fashion with the Prior Use exception, as a matter of law there is no quantitative limit on the amount of a medicine that a pharmacy could in theory produce under this exception. This, along with the fact that the provision is so clearly targeted at the pharmaceutical sector, meant objections were also raised in the context of discussions over the WIPO Draft Treaty.

Art. 302 (2)(iv) of the WIPO Draft Treaty provided for the option of an exception relating to “the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared”. The Delegation of Australia stated that “it considered that the wording of the exception was too broad, and

drew attention to the situation of a hospital where hundreds of prescriptions might be prepared for individual cases on a daily basis”³⁰. Furthermore, the representative of IFPMA “supported the deletion of the provision on the grounds that it unfairly discriminated against the pharmaceutical industry”³¹. Nevertheless, other delegations including those of the UK, France, Germany and Japan (and notably Ghana) supported the retention of the exception. The Japanese wanted the exception widened to include doctors making up the medicine, rather than just pharmacists. In conclusion, the Chairman stated that “... in spite of certain objections which had been voiced in respect of the provision, the majority of national delegations wished to retain the

provision, subject perhaps to some drafting alterations and to the inclusion of preparations by physicians”³².

At the present time, the Pharmacy exception is still widely provided for and not only in European patent legislation. One present day example is Section 60(5)(c) of the 1977 UK Patents Act, “[An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if] - (c) it consists of the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared’.

2.5 Foreign Vessels, Aircraft or Land Vehicles exception

Relevant Policy area: International Travel

This is the first of a pair of rather less well known exceptions, not mentioned in the 1990 TRIPS draft, but firmly established as valid exceptions³³. Concerns arose more than a century and a half ago about the impact that intellectual property rights might have on international transportation. For example:

In the United States it was held by the Supreme Court in 1856 that “the rights of property and exclusive use granted to a patentee do not extend to a vessel fully entering one of our ports; the use of such improvement, in the construction, fitting out or equipment of such vessel, whether she is coming into or going out of a port of the United States, is not an infringement of the rights of an American patentee, provided it was placed upon her in a foreign port, and authorized by the law of the country to which she belongs”³⁴.

A similar British decision had been reached in 1851. Such thinking progressed through various fora in the subsequent years until agreement was reached on its inclusion in the Paris Convention at the 1925 Hague Revision Conference. Article 5^{ter} of the Paris Convention provides that:

In any country of the Union the following shall not be considered as infringements of the rights of a patentee:

1. the use on board vessels of other countries of the Union of devices forming the subject of his patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter the waters of the said country, provided that such devices are used there exclusively for the needs of the vessel;
2. the use of devices forming the subject of the patent in the construction or operation of aircraft or land vehicles of other countries of the Union, or of accessories of such aircraft or land vehicles, when those aircraft or land vehicles temporarily or accidentally enter the said country.

This exception (the “Foreign Vessels” exception) must be beneficial in terms both of facilitating uninterrupted international travel and reducing tensions between countries over the treatment of vessels flying their flag. Unlike the exceptions discussed so far, it is interesting to note that this exception is not optional: “the following *shall* not be considered infringements”. Accordingly, for all those party to the Paris Convention (and more broadly now for all WTO Members, given that Art. 2.1 TRIPS provides that “In respect of

Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19 of the Paris Convention (1967)”) this exception *must* be provided for. Section 60(5)(d) and (e) of the UK 1977 Patents Act provides an example of the present day implementation of this Foreign Vessels exception:

[An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if -]

- (d) it consists of the use, exclusively for the needs of a relevant ship, of a product or process in the body of such a ship or in its machinery, tackle, apparatus or other accessories, in a case where the ship has temporarily or accidentally entered the internal or territorial waters of the United Kingdom;
- (e) it consists of the use of a product or process in the body or operation of a relevant aircraft, hovercraft or vehicle which has temporarily or accidentally entered or is crossing the United Kingdom (including the air space above it and its territorial waters) or the use of accessories for such a relevant aircraft, hovercraft or vehicle.³⁵

It might be thought that this exception will be of little practical impact. On the face it, it would seem rather difficult for a patent holder to expect to police their patent if it meant catching a trawler utilising some infringing piece of equipment if it passes briefly through the outer edge of that country's territorial waters. However, the use of the term “temporarily” in this provision is vital:

“Temporarily”, it was admitted at the Conference of the Hague, on the suggestion of the Czechoslovakian delegation, comprises also the periodical entries of vessels into the territorial waters of another country. The meaning of “temporarily” following the term “accidentally” is implied by the latter. Not only the accidental and unintentional entry but also the intentional and regular going into a port is within the scope of article 5ter, provided that the vessel or engine of locomotion does not remain permanently in the territorial waters

or the territory of the country. When the entry ceases to be temporary and becomes permanent is a question of fact.”³⁶

The practical impact of the use of the term “temporarily” understood in this way was made clear in the recent British *Stena* case³⁷ interpreting this exception in the context of the *Jonathan Swift*, a catamaran ferry vessel that made regular and frequent crossings between Ireland and the UK. It was the case that the superstructure of the catamaran infringed at least one valid claim of the patent holder's patent³⁸. The question at issue was therefore whether or not the activities of the vessel were covered by the Foreign Vessels exception to the patent holder's rights. The patent holder was of the belief that they were not, as they said “temporarily” ought to be understood as meaning “on isolated occasions or casually” (which was clearly not the interpretation placed on the term at the Hague Conference). In fact the Court of Appeal upheld the decision of the High Court, finding that the primary purpose of the term “temporarily” was to distinguish between vessels that essentially remained in the territorial waters, and those that left territorial waters to travel to a foreign country (firmly in accordance with the Hague Conference view). The fact that the catamaran entered UK territorial waters frequently did not alter the fact that the intention was always to leave again and accordingly the activities of the ferry fell within the exception to the patent holders rights. In reaching this decision, Aldous L.J. found the earlier American *Cali* decision³⁹ persuasive. This case addressed the US implementation of the Foreign Vessels exception⁴⁰ and in particular, the meaning of “temporarily” (quoting from the *Cali* decision⁴¹):

“6. The enactment of s. 272 and the adoption of Art. 5 would be incomprehensible if they were intended to cover only trivia. Their adoption implies that they were understood to create a useful immunity from infringement liability that was of enough importance to occupy the attention of the Congress and the negotiators of two

treaties. Their language was chosen to deal with an internationally significant matter arising in a world in which schedules freight and passenger services by established international carriers by air and sea were likely to require such an immunity to cover countless articles aboard aircraft or vessels that could turn out to be covered by patents in the US that were without counterpart abroad. It is difficult to see any other purpose in s. 272 and Art. 5 than to meet the needs and realities of international trade and navigation. 'Temporarily', then, could not sensibly mean any less than entering for the purpose of completing a voyage, turning about, and continuing or commencing a new voyage..."

A notably broad interpretation of the US Foreign Vessels exception was also provided by a Federal Circuit decision in 2004⁴² (and a rather narrower one in Germany in 1990⁴³).

As was implicitly noted in the *Cali* case, there may now be a practical limitation on the impact of the Foreign Vessels Exception insofar as a patent holder may very likely have the opportunity to obtain parallel patents in many, most or all other countries where the relevant products could be manufactured. If the supply of infringing products, whether they be an element of a vessel, or the superstructure of the vessel itself, can be cut off "at source" then the patent holder may not worry so much about the impact of this exception. Nevertheless, given the wide range of inventions that may be involved, it is certainly still a practical possibility that the Foreign Vessels Exception will have the intended effect, as in the *Stena*

case. Putting aside consideration of the likely practicality of the manufacture of infringing vessels or elements of vessels elsewhere, from a legal perspective, in terms of considering the activities that are permitted under the Foreign Vessels Exception, it is pertinent to note that the rights of the patent holder to prevent "use" and "importation" for that purpose would appear to be entirely abrogated for the entire term of the relevant patent as far as international travel is concerned. It was presumably extremely galling in the *Stena* case for the patent holder to see something as commercially significant as an international ferry service being operated under their very noses, without any remuneration needing to be paid, effectively limiting their domain to the national ferry service arena⁴⁴. No doubt it would have been equally galling, if not more so, for the passengers, ferry company and Irish and British governments, if the catamaran had been seized as an infringing item.

As to possible future developments, an interesting example of the utility of this exception in protecting satellites constructed in one country and then brought to another country for launching into space (Could this therefore be a foreign vessel for the purposes of this exception?) is discussed in section 4.6 below.

The fact that this sweeping Foreign Vessels exceptions is mandatory for all WTO Members reveals the outcome of a hierarchical norm contest between the rights of patent holders and the need to ensure the freedom of international travel. The latter undoubtedly trumps the former: "This wide exemption is justified by... a desire to exempt vessels from all necessary inconveniences and impediments"⁴⁵.

2.6 International Civil Aviation (Chicago) exception

Relevant Policy area: International Travel

There is a similar exception to the Foreign Vessels Exception but which, if anything, is even broader in scope of permitted activities.

For the same reasons as in the previous section, it is, and has been for a long while now, regarded as essential to the smooth operation of the global economy that international civil aviation activities are able to take place on a secure and relatively free footing. This is, to a

great extent, a reflection of the fact that a set of international rules for the operation of civil aviation was agreed in the closing stages of the Second World War, in the form of the Chicago Convention on International Civil Aviation of 1944. Although there were differences of opinion between States as to the extent of the freedoms that ought to be provided for, the Chicago Convention represented a great step forward in terms of agreement on basic principles and institutions⁴⁶. Necessarily the system established under the Chicago Convention must concern itself with provisions in numerous areas of law and regulation but for the purposes of this Paper, it suffices to note that, among the provisions relating to enhancing the efficiency and safety of international civil aviation, Article 27 of the Chicago Convention provides that:

Exemption from seizure on patent claims

(a) While engaged in international air navigation, any authorized entry of aircraft of a contracting State into the territory of another contracting State or authorized transit across the territory of such State with or without landings shall not entail any seizure or detention of the aircraft or any claim against the owner or operator thereof or any other interference therewith by or on behalf of such State or any person therein, on the ground that the construction, mechanism, parts, accessories or operation of the aircraft is an infringement of any patent, design, or model duly granted or registered in the State whose territory is entered by the aircraft, it being agreed that no deposit of security in connection with the foregoing exemption from seizure or detention of the aircraft shall in any case be required in the State entered by such aircraft.

(b) The provisions of paragraph (a) of this Article shall also be applicable to the storage of spare parts and spare equipment for the aircraft and the right to use and install the same in the repair of an aircraft of a contracting State in the territory of any other contracting State, provided that any patented part or equipment so stored shall not be sold or distributed internally in or exported commercially from the contracting State entered by the aircraft.

(c) The benefits of this Article shall apply only to such States, parties to this Convention, as either (1) are parties to the International Convention for the Protection of Industrial Property and to any amendments thereof; or (2) have enacted patent laws which recognize and give adequate protection to inventions made by the nationals of the other States parties to this Convention.

The Chicago Convention is now very widely adhered to, with some 189 Contracting States⁴⁷, such that “almost all countries around the world are now party to the Chicago Convention”⁴⁸.

The exception called for under Art. 27 of the Chicago Convention (the “Chicago Exception”), in similar fashion to the Foreign Vessels exception above, is a *mandatory* one for all parties to the Chicago Convention, subject to the Paris Convention / reciprocity provisions of Art. 27(c).

In like fashion to the case of the Foreign Vessels Exception above, there are a great many possibilities for something as sophisticated as an aircraft used in international civil aviation activity to infringe patents, whether in terms of a portion of the aircraft itself e.g. relating to a wing or engine, or to a module within the aircraft e.g. relating to the navigation system, or, perhaps, the entertainment system. The range of technologies that is brought together in such aircraft is very broad. Under the Chicago Exception, such aircraft may come and go on international flights at will, without any possibility that the aircraft could be interfered with in any way as the result of the existence of a relevant patent in that country. Perhaps even more surprisingly, the Chicago Exception also embraces spare parts and equipment for the aircraft, to the extent that they would be independently regarded as infringing a relevant patent, such that these generic spare parts may be imported and stockpiled for use at any time during the term of a relevant patent, so long as they are neither sold nor distributed in, nor exported commercially from, that country. Again, it is true to say that patent holders will now very likely have the possibility of obtaining the grant of parallel patents in other countries where the relevant products could

be manufactured. Nevertheless, again, the range of products that could be involved is very broad.

Putting aside consideration of the likely practical impact, from a *legal* perspective, in terms of considering the activities that are permitted under the Chicago Exception, it is pertinent to note that, as with the Foreign Vessels exception, the rights of the patent holder to prevent “use” and “importation” for that purpose would appear to be entirely abrogated for the entire term of the relevant patent as far as international air travel is concerned. In going beyond the activity permitted under the Foreign Vessels Exception, insofar as stockpiling of otherwise infringing products is expressly covered as well,

the Chicago Exception demonstrates even more clearly than the Foreign Vessels exception the impact of privileging the freedom to conduct international civil air travel over the rights of patent holders.

By way of one concrete example, section 60(5)(f) of the UK 1977 Patents Act⁴⁹, presently in force, provides that “[An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if] - (f) it consists of the use of an exempted aircraft which has lawfully entered or is lawfully crossing the United Kingdom as aforesaid or of the importation into the United Kingdom, or the use or storage there, of any part or accessory for such an aircraft”.

2.7 Regulatory Review (“Bolar”) exception

Relevant Policy area: Public Health

Another exception known at the time of the negotiation of the TRIPS Agreement, is the Regulatory Review, or “Bolar” exception. This exception is however of comparatively recent origin compared to the other exceptions which have so far been discussed.

An important requirement for new medicines is typically that they obtain marketing approval from a regulatory authority before they can be sold. To obtain this approval it is necessary to demonstrate that the medicine is, for example, safe and effective. In order to prove this to the satisfaction of the regulatory authority it will usually be necessary to carry out a number of tests and trials and to provide the data from these to the authority. It is often very expensive to carry out this activity (although there is still a great degree of disagreement as to the actual figures, with the typical sums that are claimed by pharmaceutical companies being seen as overly high). Where an “originator” version of a medicine has already been registered there is the possibility that a generic version of that medicine will be sought to be registered as well. A tremendously important distinction may be made between these two cases. Instead of requiring that the full set of data provided for the originator medicine be repeated for

the generic medicine, it may suffice that it is demonstrated that the generic medicine is equivalent to the originator medicine. This is a far less stringent requirement which does not, for example, require repeating all the clinical trials. It is often the case now that generic medicines may be registered on this basis. However, with such an “abbreviated” procedure for generic medicines, the pharmaceutical companies registering the originator medicines have obviously complained that these generics are “free-riding” on their investments, such as clinical trials.

Protection is now afforded to these originator pharmaceutical companies in a number of ways. In the first place they may very likely have patent protection for their medicine. In the second place, a degree of protection is also afforded to the data itself, although whether in the form of patent-like exclusive rights or not is still the subject of debate, as discussed below. Protection of the data, rather than patent protection for an invention, is attractive to pharmaceutical companies as it is the result of investment alone and need not demonstrate any Inventive activity.

As far as the patent protection is concerned, the underlying problem related to this patent exception originally arose in the US. Bolar

Pharmaceuticals Co. wished to obtain regulatory approval from the Food and Drug Administration (FDA) for their generic version of a medicine patented by Roche Products Inc, and they wished to obtain this approval *whilst the patent was still in force* so as to speed their entry to the market after the patent has expired. To do this, Bolar Pharmaceuticals Co. began carrying out the necessary equivalence tests to prepare their regulatory dossier. Roche Products Inc. understandably wished to prevent them from doing this, so as to put off as far as possible the day when they would begin to experience competition from this generic product, and therefore filed suit for patent infringement.

Bolar Pharmaceuticals Co. pleaded that they were covered by the American common law Experimental Use exception. The Court of Appeals for the Federal Circuit decided that they were not as, so the court determined, under US law the Experimental Use exception was insufficiently broad to cover the commercial activity involved⁵⁰. However, it was felt by the legislature that permitting such activity was a necessary policy goal, and since the Experimental Use exception could not cover it, a new exception would have to be created instead. This Regulatory Review exception, or “Bolar” exception as it is commonly known is now explicitly provided for in US patent law⁵¹:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (...) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

A third party taking advantage of the “safe harbour” provided by this Regulatory Review exception is enabled to carry out a wide range of activities. This includes “selling” and “offering for sale”, fundamentally commercial activities, in order to permit a generic medicine manufacturer to purchase, for example, active ingredients from a fine chemical supplier. It is interesting to note the contrast here with, for example, the Pharmacy exception, which does not extend so far as to cover suppliers.

It is interesting to speculate why this Regulatory Review exception was enacted instead of enabling the requisite activity under a compulsory licence? This point is returned to below.

In the meantime it is pertinent to note that in the US, as a *quid pro quo* for this exception, pharmaceutical patent holders were “compensated” with an extension of the lifetime of their patents. It may seem curious to the outside observer to try to speed competition between the patented and generic medicines on the one hand (introducing such an exception to permit the early registration of the generic medicine), and slow it down again with the other (by delaying the point at which the competing medicines can actually be sold). The key to resolving this apparent paradox was that both measures had to be negotiated as part of a larger package (The 1984 Drug Price Competition and Patent Term Restoration Act, also known as “Hatch-Waxman”). A degree of agreement therefore had to be reached between those representing the interests of the patent holding pharmaceutical industry and the generic pharmaceutical industry.

Subsequently, having gone through such a difficult legislative negotiation, the US was anxious to make sure that any international harmonisation moves on the issue of exceptions did not foreclose their Regulatory Review exception, as for example in the case of the negotiations over the WIPO Draft Treaty⁵². This concern was still strong at the time of the TRIPS negotiation:

“...in the Statement of Administrative Action, which accompanied the Uruguay Round implementing legislation, the United States asserted in 1994, “The Agreement permits limited exceptions to the exclusive rights conferred by a patent if certain conditions are met. United States law contains some such exceptions, such as those set out in section 271(e) of the Patent Act (35 USC 271 (e))...As the chief U.S. TRIPS negotiator, it is understandable

that Michael Kirk defends the TRIPS compatibility of the U.S. "Bolar exemption". Kirk argues that Hatch-Waxman was, in a sense, grandfathered by the negotiators. The statute was in effect at the time of the negotiations and the other negotiators knew that the United States would not have agreed to an intellectual property agreement that would call into question Hatch-Waxman."⁵³

Since the American adoption of a Regulatory Review exception, many other Members, including developing country Members have followed their lead. It is true to say that such a measure will likely assist generic companies. In terms of the more general benefits of competition between the originator or "branded" medicines and generic version of that medicine, however, the impact on public health in developing countries will likely be very positive in terms of making those medicines more affordable more quickly.

2.8 Exhaustion of patent rights

The exceptions discussed so far remove certain activities from the ambit of patent infringement, irrespective of the behaviour of the patent holder. However there are other exceptions to the rights of patent holders which depend on the actions of the patent holder.

There are, for example, important limitations on the rights of a patent holder that relate to dealings with a patented product once the patent holder, or their licensee, has made a commercial sale of that product to a third party.

2.8.1 National Exhaustion exception?

Relevant Policy area: General

The question arises as to whether all the activity subsequent to that sale, including for example, repair or subsequent sale to another party, falls within the scope of the patent monopoly. The concept of the patent holder *exhausting* their rights once they have sold the patented product (and thereby made use of their exclusive rights to obtain what in an ideal situation for a patent holder would be a monopoly price) is therefore an important one. It may condition whether or not a patent holder is able to make the sale of their product subject to certain conditions relating to subsequent use and thereby control subsequent post-sale activity relating to the patented product⁵⁴. It may condition whether the patent holder is able to control such matters as whether purchasers should be allowed to

repair the patented product, or to let someone else do it on their behalf⁵⁵.

The implementation of this doctrine can perhaps be conceptualised as an exception to patent rights, in the same way as the previously discussed exceptions. Alternatively, it can perhaps be viewed in terms of the fact that since the relevant rights are exhausted they simply do not exist any more, for example: "Exhaustion, for example, is not an exception because the right, as a consequence of the first sale, has been consumed and thus does not exist"⁵⁶. However, this latter point of view, turning patent rights into an assurance of simple first sale, is not entirely persuasive. Whichever view is taken, this is clearly a matter of enormous significance to a patent holder in terms of how extensive their rights under a patent are to be. Indeed, one of the U.S. TRIPS negotiators is quoted as indicating that he regarded the national exhaustion of patent rights as having a greater adverse impact on patent holders than the Regulatory Review ("Bolar") exception:

*"... In fact, Kirk argues that, without Article 30, the following three articles would be TRIPS violations: national exhaustion, experimental use and Bolar type activities...In fact, Kirk opined that Bolar-type pre-expiration activities have less of an adverse impact on the patent holder than national exhaustion, where the unauthorised exploitation of the product after the first sale occurs during the life of the patent."*⁵⁷

This, of course, clearly indicates that the notion of the national exhaustion of rights may be considered as a discrete exception to the rights of a patent holder: the National Exhaustion exception.

2.8.2 Regional or International Exhaustion exceptions?

Relevant Policy area: International Trade

The doctrine of the exhaustion of rights may also, however, condition the extent to which the patent holder is able to control regional or international distribution of a patented product once it has been sold.

If the same thinking as in the preceding section is followed to its logical end on global scale, i.e. if all countries were to apply an *international* exhaustion regime, then once a commercial sale had been made in *any* country, the patent holder would be rendered powerless to be able to prevent third parties from dealing subsequently with that patented product in whichever way they saw fit⁵⁸. It should perhaps be emphasised that the rights which are exhausted in this way are those relating to “that patented product” which has physically been sold, rather than the patent rights covering the patented product in general. Such a third party could, for example, purchase the patented product from the patent holder on the market in one country and then “parallel import” it into another country for re-sale there, but they could not start to manufacture and sell the product themselves.

In a best case scenario this might allow a developing country to purchase patented products at the lowest prices charged for that product on foreign markets. In being able to purchase from a variety of different international sources, a greater degree of international competition ought to be fostered. What portion of price difference such “parallel traders” pass on to the consumer is an important practical question though. Furthermore, a rational patent holder might be driven in these circumstances to adopt a single price for the whole market. It may therefore be difficult to reconcile differential

pricing in such a market with the possibility of parallel importation, although there of course are many other factors involved in the end price charged to a consumer.

If a regional exhaustion of patent rights approach is adopted then it might be expected that the above consequences would apply in respect of this region. A leading practical example of the application of the doctrine of the regional exhaustion of rights occurs in Europe, where a clear distinction between the *existence* of intellectual property rights and their *exercise* has been drawn. On the one hand, the developed countries of Europe tend to be strongly in favour of strong intellectual property protection. On the other hand, at a patent level, Europe is still a patchwork of individual nation states⁵⁹. A patentee with parallel patents in each European state could, in theory, utilise their rights to divide the European market into smaller markets, if they felt that was in their interests from an optimal exploitation of their patent rights point of view. However, one of the highest aims of the European Community is the assurance of the fundamental principle of the freedom of movement of goods within the single European market. The exercise of patent rights at a national level, including the control of importation of patented goods, and the assurance of the free movement of those goods throughout the whole European market place are not immediately reconcilable. Which norm, protection of patent rights or free movement of goods, is the most important? This is a very similar policy problem to that encountered with the Foreign Vessels and Chicago exceptions, how to assure freedom of international movement in the face of territorially determined exclusive rights? In a groundbreaking decision in 1974, the European Court of Justice established that the free movement of goods within the single European market must prevail over the rights of the patent holder⁶⁰. When a party with parallel patents in a number of European states places the patented product on the market in one of those states, or it is done with their consent, their patent rights in the other states are exhausted and they cannot prevent third parties from importing the marketed product to those other countries⁶¹.

Another approach to an international exhaustion regime may be considered. In much the same way as may be considered at a national level, Japan, for example, adopted a policy of international exhaustion of rights subject to any import/export conditions that the patent holder places on the sale of the product⁶². Accordingly, if the patent holder simply sells a product abroad without any notice, it may be imported into Japan without the permission of the patent holder. By contrast, if the patent holder has sold the product subject to the condition that it may not be exported to Japan, then the patent in Japan will continue to act as a barrier to unauthorised importation.

These different approaches to the exhaustion of patent rights have the effect of partitioning the global market in patented products into smaller regional and national markets. A developing country may adopt an international exhaustion regime, in which case it could parallel import products put on the market in any other country. However, a developed country is likely to adopt either a regional exhaustion regime or, in effect, a national exhaustion regime, such that products may only be parallel imported from other countries in the region, or may not be parallel imported at all. The net effect of this is that prices for national or regional markets in developed countries may be kept high, without the possibility of low-priced products being parallel imported back from developing

countries. Developing countries would still be free to parallel import and export among themselves though.

In theory then, as with the notion of the National Exhaustion exception, this notion of regional or international exhaustion of rights can be conceptualised as a limited exception to the rights of a patent holder. Given that the national exhaustion of rights has seemingly already been regarded by no less than one of the US TRIPS negotiators as being a matter for an Art. 30 exception, it seems difficult to perceive a substantial objection to treating regional or international exhaustion of rights in the same way, i.e. to the National Exhaustion exception could be added the Regional Exhaustion exception and/or the International Exhaustion exception.

Whatever the pros and cons of adopting a regional or international exhaustion of rights regime, it is clear that the rights of the patent holder are significantly diminished under such regimes: contingent on an act *outside* the jurisdiction, *all* the patent holders' rights are removed in respect of subsequent dealings with that patented product.

A number of important issues arise as regards the doctrine of the exhaustion of rights under the TRIPS Agreement, as discussed below in section 4.8.1.

2.9 Other exceptions to, or otherwise limitations on, the rights of patent holders

There are a number of rather different mechanisms which also enable significant exceptions or limitations to be made to the rights of a patent holder although, as they are not exceptions in the sense utilised for the purposes of this Paper, they are mentioned here only in passing. The TRIPS Agreement itself contains such further mechanisms.

- The provisions of Art. 73 TRIPS ("Security Exceptions") are one obvious example.
- Another is the transitional provisions applying to Least Developed Country (LDC) Members under Art. 66.1 TRIPS and paragraph 7 of the WTO Doha Declaration on TRIPS and Public

Health, such that, as far as pharmaceutical products are concerned, LDC Members need neither implement nor apply Section 5 and 7 of Part II TRIPS, *nor enforce rights provided for under those sections* till 1st January 2016. In some cases, no patents will have been granted and therefore no rights will arise. In other cases though, although patents may have been granted, the rights arising under these patents need not be enforced. Given that these special provisions apply on the international plane (i.e. Members could not bring a dispute as the result of non-compliance with the TRIPS

Agreement), it is an interesting question as to how the provisions are implemented on a national level, for example in terms of constitutional protections of acquired rights, although it may be that patent rights in the LDCs in question are unlikely to be litigated (over) anyway.

There are also however a number of mechanisms which are applied at the national level which are not explicitly based on TRIPS provisions.

- For example, in common law jurisdictions, the concept of “laches” limits the period of time after which a patent holder is able to bring a suit against an alleged infringer for an act of patent infringement. A period of six years is typically set in common law countries. The common law concept of “estoppel” is a similar example. In both cases it would be regarded as unconscionable to permit the patent holder to proceed after such a lapse of time or, for example, after a representation that they would not sue.

These limitations may be better judged in terms of enforcement of rights rather than exceptions to rights *per se*, i.e. a matter for Part III TRIPS, and so a different set of tests as to compliance with the TRIPS Agreement must be applied⁶³.

- Another interesting example relates to immunity from suit. Following a 1999 Supreme Court decision in the US on the Eleventh Amendment to the US Constitution⁶⁴, neither an American State nor an organ of that State, including a State University, may be sued for patent infringement without their consent. This is not to say that these actors may behave with impunity, as it appears that courses of action other than filing a straightforward suit for patent infringement should still be open to obtain an effective remedy, but nevertheless, it is a noteworthy, if not controversial, situation⁶⁵. A similar concept is discussed below with regard to medical practitioners.

Table 1 Pre-trips Exceptions to Patent Rights

The following table summarises various exceptions to patent rights known at the time of the negotiation of the TRIPS Agreement (including for illustrative purposes a couple of Exhaustion based exceptions) in terms of the nature of the policy problem that they are intended to address.

Exception to patent rights	Nature of policy problem addressed
Private & Non-commercial Use	<i>de minimus</i> activity should be shielded from patent infringement.
Experimental Use	Scientific/technical progress must not be hindered by the patent system
Prior Use	Prior users should be treated fairly vis-à-vis patent holders.
Pharmacy	Pharmacists should be free to make medicines for supply to patients on the basis of individual medical prescriptions submitted to them by doctors without fear of patent infringement
Foreign Vessels	Freedom of international movement of foreign vessels must not be hindered by patents.
International Civil Aviation (Chicago)	Freedom of international movement (and maintenance) of foreign aircraft must not be hindered by patents.
Regulatory Review (Bolar)	Competition between patented medicines and generic medicines must be enabled as swiftly as possible after the expiry of the medicine patent.
(National Exhaustion)	(Once a patent holder has sold a patented product, they ought not to be able to control subsequent dealings with the product in that country e.g. resale or repair)
(European Regional Exhaustion)	(Once a patented product has been sold on the European market, freedom of movement of goods throughout the rest of the market must not be hindered by patents)

3 PATENT EXCEPTIONS UNDER ART. 30 TRIPS: CANADA - GENERICS

Under the TRIPS Agreement, the rights that patent holders are to be accorded are provided for in Art. 28.1 TRIPS:

A patent shall confer on its owner the following exclusive rights:

- (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling or importing (footnote: "[TRIPS Agreement note] This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6") for these purposes that product;
- (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling or importing for these purposes at least the product obtained directly by that process.

In terms of the exceptions that may be made to these rights, Art. 30 TRIPS provides that:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided

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 account of the legitimate interests of third parties.

Accordingly, following the adoption of the TRIPS Agreement, the validity or otherwise of exceptions falls to be determined under Art 30 TRIPS. If a policy maker wishes to craft a new exception, in order for it to be valid, it must meet these tests set out in Art. 30 TRIPS. How are they to be understood though? This is a critical question. In fact, it was not long after the entry into force of the TRIPS Agreement that two exceptions, including the Regulatory Review exception, were examined in this way at the WTO. Given the public policy importance of the Regulatory Review exception in the area of public health, this was an important test of the ability of the WTO dispute settlement mechanism to reconcile different sets of interests.

This section of the Paper first reviews the subject matter of this dispute and then examines the views of the parties as to patent exceptions in general, before moving on to analyse one important aspect of the decision in detail.

3.1 Introduction

Canada, like many other countries, has long been concerned by the need to balance the incentives for innovation in the pharmaceutical field provided by the patent system with the need to ensure affordable access to medicines for its population. In particular, Canada was concerned about the issue of cost containment in terms of its spending on new medicines and, as a result, was desirous of encouraging early and effective competition between branded and generic medicines. Up to the 1990s, indeed dating from 1923, Canada had struck what it saw as the appropriate balance by implementing a liberal compulsory licensing system for pharmaceutical patents⁶⁶. Numerous

compulsory licences were granted under this regime, particularly after 1969 when the law was amended to remove a previous requirement that the active ingredient in a pharmaceutical product had to be manufactured in Canada. Significant change occurred in 1993 with the entry into force of the Patent Act Amendment Act 1992 (Bill C-91). This amendment, caused not so much by the TRIPS Agreement *per se* which was still the process of being negotiated but by the 1992 North American Free Trade Agreement (NAFTA), whose provisions were naturally very similar, eliminated the compulsory licensing regime but introduced two new exceptions to the rights of patent holders.

In the first place Canada introduced a Regulatory Review exception, modelled on the US example. The Canadian provision differed from the US one however in that it permitted the activity to be carried out in respect of regulatory submissions anywhere in the world, rather than just in respect of domestic submissions, as in the US case, as provided by Section 55.2(1) of the Canadian Patent Act:

“It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under the law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.”

This Canadian Regulatory Review exception embraced both import and export activities. It is important to be able to import under such a provision as it may well be the case that the domestic industry does not make the active ingredient of the pharmaceutical product in question⁶⁷. Canada explained the importance of being able to export under such a provision in terms of the fact that the Canadian domestic market, unlike the US market, was too small by itself to be able to support generic manufacturers⁶⁸.

The other, the Stockpiling exception, was an extension of the thinking behind the Regulatory Review provision, but was not something which the US, or any other Member had previously adopted⁶⁹. Section 55.2(2) of the Canadian Patent Act provided that:

*“It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires.”*⁷⁰

The applicable period was determined, under Section 55.2(3) of the Canadian Patent Act and the “Manufacturing and Storage of Patented Medicines Regulations” to be “the six month period immediately preceding the date on which the term of the patent expires”.

A Regulatory Review exception is designed to significantly bring forward the date on which competition between branded and generic medicines may commence, as the whole process of obtaining regulatory approval for the generic medicine may be undertaken during the lifetime of the patent instead of waiting till afterwards. However, there will still likely be a delay in the onset of competition after patent expiry since the generic medicine still has to be produced and distributed, which takes time. This is where the Stockpiling exception would come into play. In permitting a party that had obtained such regulatory approval to carry out the additional activities of manufacture and stockpiling of that product as well during the last six months of the life of the patent, such delay would be minimised as shipments could be made on day one after the patent expiry. Although, between the two exceptions, it must be the Regulatory Review exception that would have the greater adverse impact on patent holders (since it reduces the patent holders monopoly by a period of time measured in years⁷¹), the Stockpiling exception must nevertheless also have an impact in terms of shaving off much of the remaining *de facto* monopoly period (measured in months) that the patent holder would otherwise enjoy after patent expiry.

In providing for both these exceptions, and arguing that they were justified under Art. 30 TRIPS, Canada demonstrated that it did not believe that a patent holder was entitled to either of these extra periods of *de facto* monopoly⁷². The fact that Canada had developed a strong generic pharmaceutical sector under the previous legislation also no doubt strengthened its resolve.

The EC believed otherwise. The EC viewed these two exceptions as, in effect, an attempt by Canada to perpetuate something similar to the compulsory licensing regime that had been

in force before Bill C-91. Presumably the EC was strengthened in its resolve by its domestic research based pharmaceutical industry (and no doubt given the communality of interest, by the equivalent foreign firms as well). Relatively soon after the entry into force of the TRIPS Agreement therefore, the EC challenged both the Regulatory Review exception and the Stockpiling exception, as provided for under Canadian patent law, as inconsistent with Canada's obligations under the TRIPS Agreement. Broadly speaking, the EC believed that the exceptions offended variously against Arts. 27.1, 28.1 and 33 TRIPS and could not be saved by Art. 30 TRIPS.

The first formal set of consultations between the EC and Canada took place in the first half of 1998. The parties could not resolve their differences amicably however and thus, in

November 1998, the EC requested the WTO Dispute Settlement Body (DSU) to establish a Panel to examine this matter. The Panel, whose composition had to be determined by the WTO Director-General due to disagreement between the parties, was chaired by the distinguished international trade lawyer Mr Robert Hudec⁷³. The task of the Panel, as with all such trade disputes, was a difficult one. The political weight of the parties and the economic interests at stake (and of those whose interests they represented) was great. From a broader perspective though, approving or disapproving exceptions enabling the early introduction of competition in pharmaceutical products would clearly have an important impact on public health, especially in developing countries.

The Panel began hearing the representations of the parties in mid-1999.

3.2 Different views - general approach to Art. 30 TRIPS?

Although this dispute was about two particular patent exceptions, it belied a deeper disagreement between Canada and the EC over the role that Art. 30 TRIPS could be called on to play. How should exceptions to patent rights under Art. 30 TRIPS be approached as a *general* matter?

A view may be taken that the interests of patent holders and the interests of society at large are wholly in alignment. Given that the patent system has proved to be a beneficial institution in terms of encouraging innovation, this argument goes, patent holders ought to be accorded more extensive and more secure rights, the better to provide an incentive for innovation, and the greater the benefit for society in the long run. Exceptions to those rights must therefore be minimised as far as possible. This may be crudely characterised as the "patent rights are good therefore more patent rights are better" approach.

A different view holds that the interests of patent holders and the interests of society at large are to a greater or lesser extent in conflict. It is true that some degree of exclusive patent rights may be necessary to tackle the

"free rider" problem, this argument goes, but in general, given that patent rights are a limited exception themselves to a more general rule against monopolies⁷⁴, the extent of the rights provided to patent holders ought to be confined to the minimum that will encourage the desired degree of innovation, either through a limitation of the rights initially accorded, or through commensurate exceptions. This may be crudely characterised as the "patent rights are a necessary evil" approach, such that they should therefore be confined to just the right degree, neither too extensive nor too meagre. An analogy with taxation is obvious. Most people would agree that it is necessary for governments to levy taxes to pay for government expenditure. Opinions differ however as to the level of taxation that is appropriate, depending on the view taken of the proper scope of government activity. Hardly anyone would argue though that because some taxation is a good thing, that more taxation is better.

In terms of the views of the parties to this dispute, broadly speaking, Canada was of the latter view and accordingly took an expansive view of the exceptions to patent rights that ought to be permitted under Art. 30 TRIPS,

whereas the EC was of a view rather closer to the former one and accordingly took a very much more narrow view of acceptable patent exceptions under Art. 30 TRIPS.

Canada argued that if the provisions of Art. 30 TRIPS were to be interpreted in the context of, for example, the preamble to the TRIPS Agreement and Art. 7 TRIPS⁷⁵, in accordance with the rules of treaty interpretation laid down in Art. 31 of the Vienna Convention on the Law of Treaties⁷⁶, "...it became apparent that Article 30 provided a *general and flexible authority* for Members to adopt measures that balanced the interests of patent owners with the interests of others..."⁷⁷ (italics added).

Canada pointed out that the exceptions to rights provided for under Art. 30 TRIPS were markedly different from those provided for, for example, under Art. XX GATT insofar as there was no need to demonstrate that the measure was not a disguised restriction on international trade or that it was necessary to protect human life or health. Unlike, for example, Art. 2.2 of the Agreement on Technical Barriers to Trade, there was no need to demonstrate that the measure was the least restrictive possible or that consideration had been given to the need to fulfill a particular objective or take account of the risks that non-fulfillment would create. Likewise Art. 30 TRIPS is also markedly different from Art. 13 TRIPS (modelled on Art. 9(2) of the Berne Convention for the Protection of Literary and Artistic Works) insofar as it contains no limitations to only adopting exceptions "in *certain special cases which do not conflict* with a normal exploitation of the work...", Art. 30 TRIPS is not limited to special cases and conflict with a normal exploitation of the patent is permitted, so long as it is not unreasonable. Canada submitted that the TRIPS Agreement did not contemplate that the interests of patent owners should override other important societal interests. A full application of all Art. 28 TRIPS patent owners rights at all times and in all circumstances would not be consistent with the balanced objectives of the TRIPS Agreement and therefore "...Article 30 granted Members the discretion to limit

the full application of patent rights in light of the particular circumstances that prevailed in their respective jurisdictions, when balance was required and when societal and economic welfare had to be considered."⁷⁸

In terms of the role that Art. 30 TRIPS could be called on to play, the EC argued by contrast that "It was one of the major features of the TRIPS Agreement that its implementation was in principle neutral vis-à-vis societal values", evidenced by the fact that Art. 8 TRIPS only permitted the adoption of, for example, measures to protect public health "provided that such measures are consistent with the provisions of this Agreement", continuing that "This demonstrated that the public health, nutrition and other public interests were to be considered *subordinate* to the protection of intellectual property rights insofar as the minimum rights guaranteed by the TRIPS Agreement were concerned"⁷⁹ (italics added). The EC maintained that societal interests had already been taken into account by the TRIPS negotiators and therefore "individual WTO Members could not now rebalance these interests unilaterally by modifying the level of protection provided for in the Agreement"⁸⁰. The EC believed that a hierarchy existed as between Art. 30 TRIPS and Art. 31 TRIPS: "While Article 30 constituted the fine-tuning mechanism, Article 31 allowed more important interferences with patent rights. A military person might refer to Article 30 of the TRIPS Agreement as the air rifle and to Article 31 as artillery"⁸¹. The EC therefore entirely rejected the Canadian view that, for example, in the light of Art. 7 TRIPS, Art. 30 TRIPS could be used as a discretionary mechanism to balance the rights of patent owners against the broader interests of society:

"As to the term "limited" in Article 30, Canada seemed to suggest that all exceptions to the rule which were not unlimited would meet the requirements of "limited". If this interpretation were the right one, Article 30 could be invoked to reduce the patent term to one day or to reduce the patent rights to an exclusive

marketing right, thus reversing the rule-exception principle⁸². The EC therefore disagreed with Canada's statement that limited exceptions could have very important consequences, but still qualify as limited because they were restricted in duration"⁸³

The disagreement between the parties was not simply a narrow technical matter therefore but went to the heart of the philosophy of the patent rules established under the TRIPS Agreement. Was Art. 30 TRIPS a "cornerstone" provision, allowing Members to adjust the rights of patent holders as they saw fit to meet the policy needs at hand, or was Art. 30 TRIPS merely a device

for trimming patent holders rights at the margin in certain *de minimus* cases?

Of course, arguing that, if another parties view of the interpretation of Art. 30 TRIPS differs from one's own that they are necessarily re-balancing the TRIPS Agreement, begs the question. What is the proper interpretation of Art. 30 TRIPS? If Art. 30 TRIPS is properly interpreted then the exceptions that pass the requisite tests will be part of the bargain established under the TRIPS Agreement. If they do not, if Art. 30 TRIPS is interpreted too broadly, or too narrowly, then the balance struck by the negotiators will have been altered, improperly weakening or strengthening the rights of patent holders as the case may be.

3.3 The Panel report

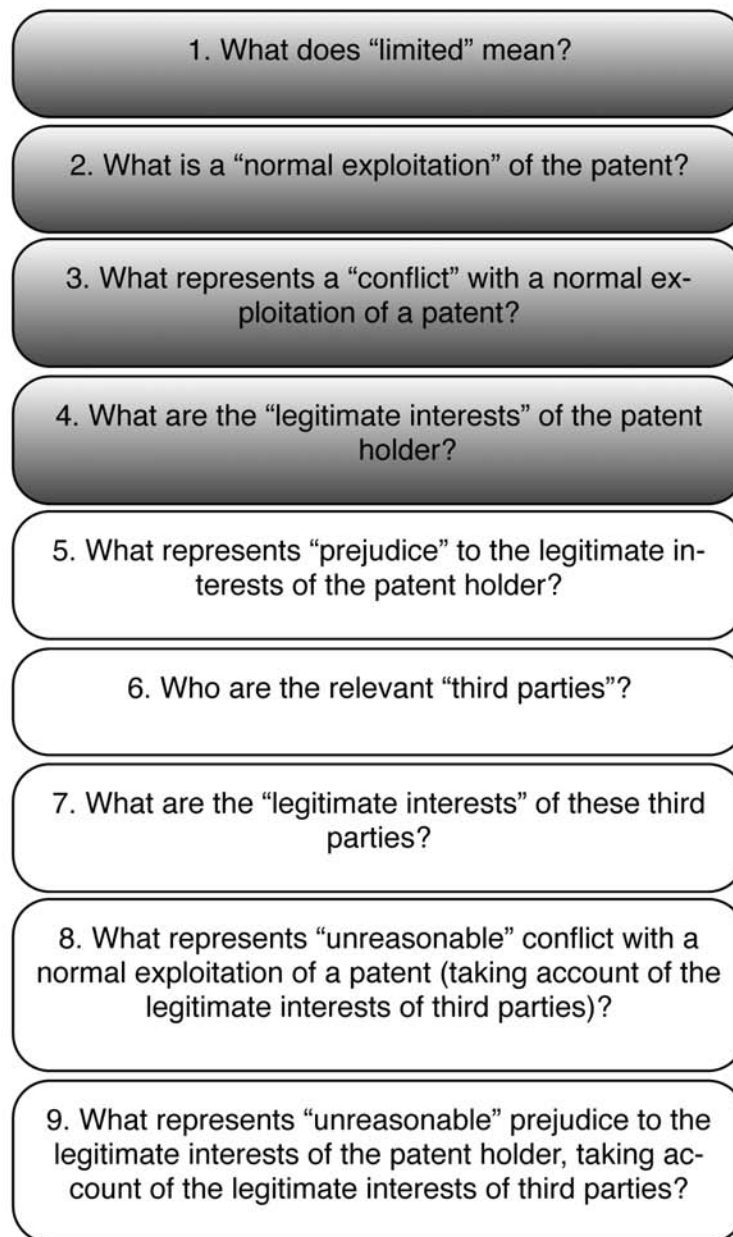
The report of the Panel was delivered on 17th March 2000: "Canada - Patent Protection of Pharmaceutical Products"⁸⁴ ("Canada - Generics"). Neither Canada nor the EC appealed to the Appellate Body.

In order to resolve the dispute resulting from the difference of views of Canada and the EC as to Art. 30 TRIPS, the Panel considered only those portions of Art. 30 TRIPS (and its interrelation with other provisions of the TRIPS Agreement) that were necessary to reach a decision as to the consistency of the Regulatory Review and Stockpiling Exceptions with the provisions of the TRIPS Agreement.

In its report, the Panel therefore expressed an opinion in respect of the issues of: (i) the meaning of the word "limited" when used to qualify "exception" (sections 7.34 - 7.36); (ii) the meaning of a "conflict with the normal exploitation" of a patent (sections 7.54-7.59); (iii) what might be identified as the legitimate interests of the patent holder" (sections 7.68-7.69, 7.75-7.76, 7.82, 7.83); and, in passing,

(iv) what might be identified as the "legitimate interests of third parties" (section 7.69), and as a result who these third parties might be considered to be (section 7.69). The Panel did not however have to express an opinion on the issues of (v) what constitutes "unreasonable" conflict with the normal exploitation of a patent (section 7.59); (vi) what constitutes "prejudice" or "unreasonable" prejudice to the legitimate interests of the patent owner (section 7.83); and (vii) whether the legitimate interests of third parties have to be taken into account in determining whether there is unreasonable conflict with the normal exploitation of a patent as well as whether there is unreasonable prejudice to the legitimate interests of the patent owner (footnote 382, section 7.59).

As far as the interpretation of the text of Art. 30 TRIPS is concerned therefore, the Panel only had to interpret a fraction of the provision in order to settle this dispute. As Figure 1 shows (shaded boxes being those elements the Panel arguably formally interpreted) the larger part of the Art. 30 TRIPS remains uninterpreted.

Figure 1

However, it is not the intention of this Paper to conduct a minute examination into every aspect of this decision, either in terms of the elements of Art. 30 TRIPS that were interpreted, or those that were not.

Rather, the focus is placed on the one element of interpretation of Art. 30 TRIPS which became the battleground on which the philosophical

question raised above was played out. This is, of course, the meaning of the term “limited” in the phrase “Members may provide for limited exceptions to the exclusive rights conferred by a patent...”. The Panel found that the meaning of “limited” was such that they could draw a line between acceptability and unacceptability for at least one of the exceptions in question.

3.4 The key test introduced by the Panel: what is a “limited exception”?

3.4.1 The arguments of the parties on the meaning of “limited”.

As was only to be expected, Canada and the EC expressed very different views as to how the term “limited” should be interpreted in Art. 30 TRIPS.

In general, the interpretation of the TRIPS Agreement is to be carried out in accordance with the provisions on the Vienna Convention on the Law of Treaties (VCLT) and, in particular, Arts. 31 and 32 VCLT:

Article 31

General rule of interpretation

1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.
2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:
 - (a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty;
 - (b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.
3. There shall be taken into account, together with the context:
 - (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;
 - (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;
 - (c) any relevant rules of international law applicable in the relations between the parties.

4. A special meaning shall be given to a term if it is established that the parties so intended.

Article 32

Supplementary means of interpretation

Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:

- (a) leaves the meaning ambiguous or obscure; or
- (b) leads to a result which is manifestly absurd or unreasonable.

Canada was of the view that the term “limited” should be understood in the ordinary sense of the word. Reference was made to the New Shorter Oxford English Dictionary definition: “confined within definite limits; restricted in scope, extent, amount”⁸⁵ and the Black’s Law Dictionary definition: “[r]estricted; bounded; prescribed. Confined within positive bounds; restricted in duration, extent or scope”⁸⁶, and should not be associated with any particular substantive test as to the scale of the exception. Accordingly, so long as it was properly circumscribed, a “limited” exception could perfectly validly have significant consequences for the exercise of a patent holders rights. Canada pointed to important elements of context for Art. 30 TRIPS, arguing for example that attributing meanings to “limited” which would cause it to only permit *de minimus* exceptions would fundamentally alter the balance contemplated by Art. 7 TRIPS, “In such circumstances, Articles 7 and 30, at least, would be reduced to “inutility””⁸⁷. Canada also referred to the preamble of the TRIPS Agreement in terms of this context.

Accordingly, on its interpretation of the term “limited”, given that Canada had outlined

the precise definition of the extent of both exceptions and, as a consequence, who may take advantage of them and what they are permitted to do, Canada took the view that both the Regulatory Review and the Stockpiling exceptions were “limited” for the purposes of Art. 30 TRIPS.

Canada also referred to the travaux préparatoires of the TRIPS Agreement and subsequent practice relating to the TRIPS Agreement. Specifically, Canada indicated that:

“...the United States, the major demandeur with respect to patent protection, was intent on securing an exception that allowed its pre-existing “Bolar exemption” to be preserved. This was confirmed by the United States Trade Representative (and subsequently reiterated by his successor): “Our negotiators ensured that the TRIPS Agreement permits the “Bolar exemption” to be maintained. The “Bolar exemption” had been in existence for several years before the TRIPS Agreement was negotiated and negotiators must have known of its existence. They apparently did not take issue with the proposition that it was a limited exception. Accordingly, the “Bolar exemption” must be an example of the type of exception that was intended to come within Article 30.”⁸⁸

and made reference to the fact that a number of Members, such as Germany, Italy, Japan, Portugal, Hungary, Argentina, Australia and Israel, had provided for such Regulatory Review exceptions *after* the entry into force of the TRIPS Agreement, which was relevant in terms of subsequent practice for the purposes of interpretation under the VCLT.

The EC took a far more stringent view of the term “limited” in Art. 30 TRIPS. Although reference was made to the standard definition in Black’s Law Dictionary⁸⁹, in oral testimony the EC indicated that, for the purposes of Art. 30 TRIPS, “limited” must therefore be understood as connoting a narrow exception characterised by

such terms as “narrow, small, minor, insignificant or restricted”⁹⁰. The EC presented a legal theory by which they counted up the number of individual rights of the patent holder that were interfered with by an exception to patent rights and indicated that an interference with three or more of these rights must represent an exception that could not be considered “limited”, although failing that the EC looked to, for example, the quantity of activities purportedly permitted under an exception⁹¹.

The EC also rejected Canada’s appeal to “subsequent practice” in terms of what other Members had provided for in their legislation, indicating that, for example, there had been insufficient time after the entry into force of the TRIPS Agreement to demonstrate any subsequent practice and in any case, “the European Communities and their member States had contested Canada’s practice which was the subject of the present dispute ever since the legislation on which it was based had been notified to the Council for TRIPS in 1996. It was therefore impossible to claim that there had been anything approaching agreement on the matter.”

The EC argued that neither the Regulatory Review nor the Stockpiling exception could be regarded as “limited” for the purposes of Art. 30 TRIPS. The EC indicated that the Regulatory Review exception curtailed all the rights of the patent owner, that is to say “even the rights to prevent selling and offering for sale” at any time during the term of the patent, through what may be very broad ranging activities producing significant amounts of product undertaken by a wide range of operators⁹². The EC indicated that the Stockpiling exception curtailed the patent owners rights to make, use and import, with no limitation on the quantity of material produced during the significant six month period of eligibility⁹³.

Further to the representations of the parties as to the two exceptions in question however, a key issue for the purposes of this Paper is the manner in which the other, pre-existing patent exceptions were taken into account in terms of interpreting Art. 30 TRIPS.

The EC and Canada did not make systematic representations on all their respective exceptions, perhaps for the reason suggested in the following:

"In response to a question from the Panel, Canada explained why the "prior use" exception and the "scientific/experimental use" exception would satisfy each of the criteria of Article 30 and would therefore qualify as permissible exceptions under Article 30. While both the "prior use" and the "experimental use" exceptions were common to the patent laws of many nations, there was also considerable variation in the specifics of how either of the exceptions was expressed in or applied pursuant to those national laws. Since no particular laws creating such exceptions were in issue in these proceedings, Canada's response must therefore be general in nature".

That being said however, this is not true of all the pre-existing exceptions. The Foreign Vessels and Chicago exceptions, for example, do not admit of a great deal of variation in form or extent. The issue of the extent to which the Panel ought to have taken these other exceptions into account is returned to below. For the moment it suffices to examine the representations of the parties as to these exceptions.

Although the proper scope of the Scientific / Experimental Use exception could be debated, its conceptual legitimacy as an exception to the rights of a patent holder cannot. Both parties accepted this exception as an acceptable exception and argued accordingly that it was "limited". Canada indicated that such an exception was "limited" in that "it only applied to non-commercial experimentation, i.e. testing for academic or scientific purposes, or to commercial experimentation where a licence was anticipated". The EC indicated that the exception was "limited" in that it typically only touched one out of the five rights of the patentee, "use", whereas offering for sale, selling and importing were not allowed⁹⁴,

although it was also noted that whilst it used to be limited to academic research, it had become largely accepted that it could also cover industrial research.

Again, the acceptability of the Prior Use exception was not challenged by either party. Canada indicated that a typical prior use exception was limited since:

"...(a) it applied only to persons who had purchased, constructed or acquired the invention or subject matter which subsequently became patented subject matter prior to the date of issue, application or priority as the case may be; and (b) it only protected the specific article, machine, manufacture or composition of matter acquired prior to the relevant date, and since in most cases the specific articles, etc, would be finite in number, they would be unlikely to be put into the channels of commerce for any lengthy period of time. In the latter respect, it was important to note that, while the exception did not accord any right to continue to manufacture the invention after the grant of the patent, the specific article, machine, manufacture or composition of matter previously acquired might continue to be used or disposed of after the patent issued..."⁹⁵

The EC noted a definition of a Prior Use exception prepared under the aegis of the WIPO discussions in the 1980s⁹⁶. The EC indicated that the scope of activities protected by such an exception would be very small insofar as they would have taken place in secret, even only in terms of preparations, and the more "effective and serious" they were, the more likely they were to come to the attention of the public. Due to this stark practical restriction, the EC argued likewise that such an exception would be "limited"⁹⁷. The EC later indicated that:

"...a classical "prior use" exception would be covered by Article 30, in order to sell off the stock manufactured prior to patent protection as long as the

*quantities concerned could be considered as reasonable and would not constitute unreasonable conflict. However, if a "prior use" exception should allow continued manufacture after patent protection had started, then one clearly left the scope of Article 30. This became patently clear when one looked at Article 70.4 of the TRIPS Agreement, which required, as a minimum, that continued manufacturing was only permissible against payment of equitable remuneration to the right holder. This, indeed, was nothing other than a compulsory licence solution."*⁹⁸

It is curious that both parties seemed to adopt a rather more limited view of what a Prior Use exceptions permits than is generally regarded to be the case, notably that the Prior Use right *will* allow such a prior user to carry on manufacturing if that was what they were doing before the patent was granted⁹⁹.

The Pharmacy exception was the subject of more contention between the parties, on the issue of discrimination by field of technology rather than "limited", although not such as to challenge its legitimacy. Canada explicitly indicated, albeit only in passing, that it believed such an exception was "limited"¹⁰⁰. The EC defended this exception, widely adopted in Europe (provided for in "ten of the 15 EU Member States (Belgium, Denmark, France, Germany, Greece, Ireland, Luxembourg, Netherlands, Sweden and the United Kingdom) as well as the Czech Republic, Hungary, Iceland, Norway, the Slovak Republic and Slovenia"¹⁰¹) without explicitly passing comment on any justification to demonstrate that it is adequately "limited". No justification was therefore provided by either side as to why this exception should be regarded as being "limited", although both clearly did so.

It would appear that no mention was made by either party as to the Foreign Vessels or Chicago exceptions, or to exceptions based on the doctrine of the exhaustion of rights.

3.4.2 Third party observations

A number of Members (Australia, Brazil,

Colombia, Cuba, India, Israel, Japan, Poland, Switzerland, Thailand and the United States) submitted third party observations. It is fair to say that these observations largely supported the Canadian position, especially as regards at least the Regulatory Review exception but often also highlighting the crucial concept of the need for a *balance* of rights and obligations. However Switzerland joined the EC position in considering both exceptions to be wholly invalid whereas the US considered the Stockpiling exception to be invalid and the Canadian Regulatory Review exception to be invalid to the extent that activity relating to foreign regulatory submissions was permitted (i.e. the US considered that its own "properly crafted" Bolar exception was valid).

Of these third party observations, the US submitted the most detailed argumentation as to the meaning of "limited" and its impact for the Regulatory Review and Stockpiling exceptions:

- Under Article 30, WTO Members could provide only "limited" exceptions to the rights conferred by a patent. Article 30, thus, did not excuse a Member from providing all five exclusive rights, but merely permitted limited exceptions to be made to any one (or all) of those rights. The requirement that exceptions be limited precluded a Member from deciding, for example, that one of the exclusive rights was relatively unimportant, and therefore from providing only the other four exclusive rights. Moreover, the mere imposition of any kind of condition on the availability or scope of an exception did not convert it, automatically, into a "limited" one within the meaning of Article 30.
- Properly crafted, a "pre-expiration testing" provision represented a limited exception to the exclusive rights of patent holders, if it was restricted to certain specific and well-defined activities linked directly to the stated purpose of the exception - to permit the development and submission of information required by domestic regulatory authorities.

- Canada's "pre-expiration testing" exception limited, to a certain extent, three exclusive rights - the right to make, use and sell. It permitted third parties to engage in such activities without the authorization of the patent owner if, and only if, the purpose of the activity was to provide information required by regulatory authorities. It should be noted, however, that Canada's "pre-expiration testing" exception was not limited to acts by third parties to meet requirements imposed by Canadian regulatory authorities, but also shielded infringing acts that were done to satisfy the requirements of regulatory authorities of any country.

[...]

- First, a "stockpiling" exception was less limited than "pre-expiration testing". For the period during which it applied, it resulted in the abrogation of two of the five exclusive rights conferred by a patent (the exclusive rights to make and use). The only limitation imposed by Canada during the "stockpiling" period was the requirement that the "stockpiling" be done by the same person that took advantage of the "pre-expiration testing" exception - in other words, the patent holder's competitors. In reality, this limitation had little meaning, as it applied to the entire universe of parties that would be in a position to use the patented invention after the term expired.¹⁰²

In general therefore the US position on the meaning of "limited" was somewhat less strident than that of the EC. Interestingly, the US did not say that the Stockpiling exception was *not* "limited" for the purposes of Art. 30 TRIPS but only indicated that it was "less limited" than the Regulatory Review exception. The difficulty of drawing a clear borderline between "limited" and not "limited" is clear.

For the purposes of this Paper however, it was the Australian submission which was perhaps the most interesting, in terms of highlighting the presence of other pre-existing exceptions. Australia *did* mention the Foreign Vessels

exception, and explicitly mentioned that it was mandatory under the Paris Convention and hence the TRIPS Agreement, and indicated that both it and the Prior Use exception were "*uncontroversial*" and "*conformed with the scope of the exceptions permitted by Article 30 of the TRIPS Agreement*" (italics added)¹⁰³. Australia further drew attention to the National Exhaustion exception, indicating that "Commentators on the TRIPS Agreement had illustrated the scope of exceptions permitted by Article 30 by citing provisions allowing scientific research and experiment, simultaneous invention and prior use. Other possible exceptions included *implied licences for dealing with or repairing patented goods which had been legitimately purchased*" (italics added)¹⁰⁴.

The Chicago exception was seemingly not mentioned by any third party.

3.4.3 The view of the Panel on the meaning of "limited"

The Panel reviewed the parties various submissions on interpretation, including reference to Arts. 31 and 32 of the VCLT. The Panel indicated that it regarded Art. 9(2) of the Berne Convention for the Protection of Literary and Artistic Works (1971), and its negotiating history, as an important contextual element for the interpretation of Art. 30 TRIPS. The Panel acknowledged that Canada had, in effect, conceded a violation of Art. 28 TRIPS and the burden of proof therefore lay with Canada to demonstrate that the Regulatory Review and Stockpiling exceptions could be saved by Art. 30 TRIPS. The Panel reviewed the submissions on Arts. 7 and 8 TRIPS and indicated that "Article 30's very existence amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments. On the other hand, the three limiting conditions attached to Article 30 testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement"¹⁰⁵.

The Panel believed that reference to the

negotiating history of Art. 30 TRIPS and in particular why the negotiators had decided to adopt the language of Art. 9(2) Berne, did not illuminate the meaning of “limited”. It is worth following the Panel in some detail in their reasoning as to the interpretation of “limited” exception, in the context of its findings as to the Stockpiling Exception:

7.30 The Panel agreed with the EC that, as used in this context, the word “limited” has a narrower connotation than the rather broad definitions cited by Canada. Although the word itself can have both broad and narrow definitions, the narrower being indicated by examples such as “a mail train taking only a limited number of passengers”, the narrower definition is the more appropriate when the word “limited” is used as part of the phrase “limited exception”. The word “exception” by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term “limited exception”, the word “limited” must be given a meaning separate from the limitation implicit in the word “exception” itself. The term “limited exception” must therefore be read to connote a narrow exception - one which makes only a small diminution of the rights in question.

7.31 The Panel agreed with the EC interpretation that “limited” is to be measured by the extent to which the exclusive rights of the patent owner have been curtailed. The full text of Article 30 refers to “limited exceptions to the exclusive rights conferred by a patent”. In the absence of other indications, the Panel concluded that it would be justified in reading the text literally, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact. In support of this conclusion, the Panel noted that the following two conditions of Article 30 ask more particularly about the economic impact of the exception, and provide two sets of standards by which such impact may be judged. The term “limited exceptions” is the only one of the three conditions in Article 30 under which the extent of the curtailment of rights as such is dealt with.

7.32 The Panel does not agree, however, with the EC’s position that the curtailment of legal rights can be measured by simply counting the number of legal rights impaired by an exception. A very small act could well violate all five rights provided by Article 28.1 and yet leave each of the patent owner’s rights intact for all useful purposes. To determine whether a particular exception constitutes a limited exception, the extent to which the patent owner’s rights have been curtailed must be measured.

7.33 The Panel could not accept Canada’s argument that the curtailment of the patent owner’s legal rights is “limited” just so long as the exception preserves the exclusive right to sell to the ultimate consumer during the patent term. Implicit in the Canadian argument is a notion that the right to exclude sales to consumers during the patent term is the essential right conveyed by a patent, and that the rights to exclude “making” and “using” the patented product during the term of the patent are in some way secondary. The Panel does not find any support for creating such a hierarchy of patent rights within the TRIPS Agreement. If the right to exclude sales were all that really mattered, there would be no reason to add other rights to exclude “making” and “using”. The fact that such rights were included in the TRIPS Agreement, as they are in most national patent laws, is strong evidence that they are considered a meaningful and independent part of the patent owner’s rights.

7.34 In the Panel’s view, the question of whether the stockpiling exception is a “limited” exception turns on the extent to which the patent owner’s rights to exclude “making” and “using” the patented product have been curtailed. The right to exclude “making” and “using” provides protection, additional to that provided by the right to exclude sale, during the entire term of the patent by cutting off the supply of competing goods at the source and by preventing use of such products however obtained. With no limitations at all upon the quantity of production, the stockpiling exception removes that protection entirely during the last six months of the patent term,

without regard to what other, subsequent, consequences it might have. By this effect alone, the stockpiling exception can be said to abrogate such rights entirely during the time it is in effect.

7.35 In view of Canada's emphasis on preserving commercial benefits before the expiration of the patent, the Panel also considered whether the market advantage gained by the patent owner in the months after expiration of the patent could also be considered a purpose of the patent owner's rights to exclude "making" and "using" during the term of the patent. In both theory and practice, the Panel concluded that such additional market benefits were within the purpose of these rights. In theory, the rights of the patent owner are generally viewed as a right to prevent competitive commercial activity by others, and manufacturing for commercial sale is a quintessential competitive commercial activity, whose character is not altered by a mere delay in the commercial reward. In practical terms, it must be recognized that enforcement of the right to exclude "making" and "using" during the patent term will necessarily give all patent owners, for all products, a short period of extended market exclusivity after the patent expires. The repeated enactment of such exclusionary rights with knowledge of their universal market effects can only be understood as an affirmation of the purpose to produce those market effects.

7.36 For both these reasons, the Panel concluded that the stockpiling exception of Section 55.2(2) constitutes a substantial curtailment of the exclusionary rights required to be granted to patent owners under Article 28.1 of the TRIPS Agreement. Without seeking to define exactly what level of curtailment would be disqualifying, it was clear to the Panel that an exception which results in a substantial curtailment of this dimension cannot be considered a "limited exception" within the meaning of Article 30 of the Agreement.

7.37 Neither of the two "limitations" upon the scope of the measure are sufficient to alter this conclusion. First, the fact that the exception can only be used by those persons who have

utilized the regulatory review exception of Section 55.2(1) does limit the scope of the exception both to those persons and to products requiring regulatory approval. In regard to the limitation to such persons, the Panel considered this was not a real limitation since only persons who satisfy regulatory requirements would be entitled to market the product. In regard to the limitation to such products, the Panel considered that the fact that an exception does not apply at all to other products in no way changes its effect with regard to the criteria of Article 30. Each exception must be evaluated with regard to its impact on each affected patent, independently. Second, the fact that the exception applied only to the last six months of the patent term obviously does reduce its impact on all affected patented products, but the Panel agreed with the EC that six months was a commercially significant period of time, especially since there were no limits at all on the volume of production allowed, or the market destination of such production.

Thus according to interpretation of the Panel, a "limited" exception for the purposes of Art. 30 TRIPS is one "which makes only a small diminution of the rights in question", from a purely legal perspective. For both the reasons noted, including that there were no bounds on the amount of production that was allowed to take place during the relevant, significant six month period, such that the rights of "making" and "using" were deemed to have been effectively abrogated for that duration, the Panel found that the Stockpiling exception is *not* a "limited" one for the purposes of Art. 30 TRIPS.

As regards the Regulatory Review exception, the Panel dismissed the travaux préparatoires and "subsequent practice" arguments raised by Canada:

"the Panel also considered Canada's additional arguments that both the negotiating history of Article 30 of the TRIPS Agreement and the subsequent practices of certain WTO Member governments supported the view that Article 30 was understood to permit

regulatory review exceptions similar to Section 55.2(1). The Panel did not accord any weight to either of those arguments, however, because there was no documented evidence of the claimed negotiating understanding, and because the subsequent acts by individual countries did not constitute “practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation within the meaning of Article 31.3(b) of the Vienna Convention.”¹⁰⁶

The Panel applied their interpretation to the Regulatory Review Exception:

7.44 In the previous part of this Report dealing with the stockpiling exception of Section 55.2(2), the Panel concluded that the words “limited exception” express a requirement that the exception make only a narrow curtailment of the legal rights which Article 28.1 requires to be granted to patent owners, and that the measure of that curtailment was the extent to which the affected legal rights themselves had been impaired. As was made clear by our conclusions regarding the stockpiling exception, the Panel could not accept Canada’s contention that an exception can be regarded as “limited” just so long as it preserves the patent owner’s exclusive right to sell to the ultimate consumer during the patent term.

7.45 In the Panel’s view, however, Canada’s regulatory review exception is a “limited exception” within the meaning of TRIPS Article 30. It is “limited” because of the narrow scope of its curtailment of Article 28.1 rights. As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded. Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner’s rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and

no commercial use is made of resulting final products.

In this case of the Regulatory Review Exception therefore, the Panel found that given that the “diminution” of the patent owners rights is the consequence of acts the extent of which are “small and narrowly bounded”, the exception is “limited” for the purposes of Art. 30 TRIPS.

3.4.4 Analysis of the Panel’s interpretation of “limited”

Crucially, the Panel found that the term “limited” introduces a *legal*, rather than, for example, an *economic* test which measures the extent of the impairment of a patent holders rights by a patent exception. The test is an absolute one in the sense can it cannot be relativised by reference to some external factors, such as the legitimate interests of third parties, but rather sets an absolute threshold of impairment over which an exception can never be regarded as consistent with Art. 30 TRIPS. It might be expected that, in the nature of things, it would be difficult to determine this threshold with clarity, and the Panel perhaps recognised this in indicating that it did not wish to “to define exactly what level of curtailment would be disqualifying”. Nevertheless the Panel was content to apply the test arising from their interpretation of “limited” to the two exceptions in question with the result that the Regulatory Review exception was found to be limited whereas the Stockpiling exception was not. The threshold must therefore lie somewhere between these exceptions.

The Panel focussed on two matters of importance:

- *The extent to which the rights of “making” and “using” were abrogated.*

The Panel explains that in the case of the Stockpiling exception, given that there was no limitation on the quantity of production during the relevant six month period, the patent holders rights of “making” and “using” were effectively entirely abrogated during this time. However, Canada had indicated that the Regulatory Review exception can be used as frequently as

was necessary in terms of entities wishing to make regulatory submissions¹⁰⁷, and, as the EC had complained, whenever this was done there are in fact no legal limits on the quantity of production that could be undertaken, at any time during the lifetime of the patent¹⁰⁸. How could the Panel find that the rights of the patent holder were abrogated to a greater extent in the case of the Stockpiling exception than in the case of the Regulatory Review exception? The Panel pointed to a difference in the quality of the acts. In the case of the Stockpiling exception, the view was apparently taken that the “making” of each new batch would harm the patent holder further, presumably since they would all be later sold. By contrast, in the case of the Regulatory Review exception, at some point a new batch wouldn’t harm the interests of the patent holder any more than had already been done, presumably on the theory that the damage is all done in the gaining of the regulatory approval, and that any batches produced for these purposes would not be eventually sold. It is not clear though that this is a completely watertight distinction (For example, certain acts of sale are permitted under the Regulatory Review exception? Regulatory approval in more than one country is different from regulatory approval in just one country?).

• *The extra period of monopoly enjoyed after the expiry of the patent as a consequence of the enjoyment of the rights of “making” and “using” during the patent term.*

The Panel seemingly recognised the legitimacy of the “extended period of market exclusivity” enjoyed after patent expiry as a consequence of enforcing the rights to “make” and “use” during the patent term. In the case of the Stockpiling exception, where a matter of months is shaved off this *de facto* period of monopoly, the Panel found that a reason to support the finding that the exception was not limited. By contrast, in the similar case of the Regulatory Review exception, where a matter of years is shaved off instead, the Panel seemingly addressed the issue instead in the context of the “legitimate interests” of the patent holder?

The reasoning of the Panel therefore seems far from clear. In any case though, the purpose of this Paper is not to subject the reasoning of the Panel as to the meaning of “limited” to detailed investigation on these points. It is rather to point to an issue which the Panel didn’t take into account but arguably ought to have done, as a pre-cursor to coming to any opinion as to the meaning of “limited”.

3.4.5 Interpretation of “limited” in Art. 30 TRIPS in the light of pre-existing exceptions

This matter is, of course, the question of the extent to which the parties and the Panel took into account the pre-existing exceptions.

The parties had referred to a number of other exceptions than the Regulatory Review and Stockpiling exceptions. As noted above, their representations as to these other exceptions were not systematic and were often implicit rather than explicit. For example the EC defended the Pharmacy exception in terms which clearly indicated that the EC believed that the Pharmacy exception was a valid one, hence the EC must regard it as a limited one. Only Australia, as a third party, mentioned the Foreign Vessels exception and nobody mentioned the Chicago exception at all. The Panel followed the lead of the parties and confined its attention largely to the Regulatory Review and Stockpiling exceptions, mentioning only one of the other exceptions, the Scientific Use exception, and that only in passing.

It is perhaps difficult to say whether it ought to have been expected that the parties should have mentioned all the relevant exceptions in making their submissions, or indeed that the Panel ought to have picked up for consideration all those exceptions which the parties did not mention. Perhaps there were very good reasons for deliberately not acknowledging the full set of exceptions, including that the parties may, correctly or otherwise, have regarded a number of them as irrelevant. Alternatively, it may just be that because the full set of exceptions is not often discussed, even in the

context of the TRIPS Council legislative review process, some were missed.

As a general point, as noted above, it was said during the course of the proceedings that one difficulty in making judgements about exceptions is that there is a potentially wide variation in the particular scope of any given exception between Members. Having said this, as was also noted above, it seems to the case that this will be more of a difficulty in respect of some exceptions than others. The central point is that it is perhaps hard to understand how a sensible definition of the term “limited” in Art. 30 TRIPS can be reached without a reasonable consideration, in some way or another, of *all* the exceptions which are certainly regarded as valid by Members. Unless and until a systematic analysis of *all* these exceptions is carried out, including either all the exceptions whose scope is agreed upon and/or a common core in terms of the more contentious ones, it would seem that a definition of “limited” cannot be reached which embraces them all.

The various exceptions have differing legal relationships with the TRIPS Agreement. In terms of how a Panel might approach these exceptions in the light of the rules of the VCLT, they can perhaps be usefully classified as follows:

A. *Exceptions mandated under the TRIPS Agreement*

Although textually located in the Paris Convention, the Foreign Vessels exception is arguably to be treated as part of the text of the TRIPS Agreement by virtue of its *mandatory* provision under the provisions of Art. 2.1 TRIPS requiring adherence with the relevant portions of the Paris Convention. Australia, in its third party submission indicated that this exception was mandatory under the TRIPS Agreement and was “uncontroversial” as an Art. 30 exception. In accordance with Art. 31(1) and the preamble to Art 31(2) VCLT, the existence and nature of the Foreign Vessels exception should surely therefore be taken into account as proper context by any Panel interpreting Art. 30 TRIPS.

Surely the result of this is that, whatever the term “limited” in Art. 30 TRIPS means, it must embrace the Foreign Vessels exception?

B. *Exceptions mandated under a (widely adhered to) treaty other than TRIPS*

The Chicago exception is not mandatory under the TRIPS Agreement. However, it is mandatory for any party to the Chicago Convention. Art. 31(3)(b) VCLT provides that “[There *shall* be taken into account, together with the context:] (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation”. Art. 30 TRIPS must again be the proper mechanism under which to consider this exception. It would appear that adherence to the Chicago Convention is so widespread that it is a reasonable assumption that all WTO Members now provide for this exception¹⁰⁹ and that none have objected to this exception as being in conflict with that article since the entry into force of the TRIPS Agreement. Canada had indicated in response to a question from the Panel that:

“...In the case of an important global agreement like the WTO Agreement, which was the subject of constant scrutiny and debate by WTO Members, within an institutional framework, there was a strong presumption that legislation passed by important Members in the immediate aftermath of an agreement and not challenged or protested by other parties was, in fact, accepted or acquiesced in by the other contracting parties. As such, a pattern of unprotested legislative practice enacted at a critical time by key parties did establish the “agreement of the parties regarding its interpretation...”¹¹⁰

Now, this did not assist Canada in terms of the Regulatory Review exception because not only was there a lack of widespread enactment of that exception but more importantly because the EC had protested and opposed the validity of the exception from the start¹¹¹. The situation

of the Chicago exception is very different however. Accordingly, given the consistently positive view of the Chicago exception by, it would appear all Members, it is arguable that, under Art. 31(3)(b) VCLT, Members' acceptance of this article can be regarded as meaning that the existence and nature of this exception *must* be taken into account as "subsequent practice" in any interpretation of Art. 30 TRIPS. Again, whatever the term "limited" in Art. 30 TRIPS means, it surely must embrace the Chicago exception.

C. Exceptions which Members agree are permissible under the TRIPS Agreement.

It is into this category that the majority of the exceptions so far discussed fall. Unlike the exceptions in categories A and B above, exceptions in this category are not mandatory. However, many of them are widely, albeit not universally, provided for and, in that form, have not been objected to by other Members. A comparative law investigation reveals relatively rapidly how widespread is the provision for a given exception, although the scope with which it is applied may be harder to discern. Nevertheless, it is interesting to take, for example, the case of the Pharmacy exception. Both Canada and the EC referred to this exception in their representations and both, albeit implicitly, agreed that this was a valid exception under Art. 30 TRIPS. Widespread agreement in support of this exception was expressed at a WIPO Draft Treaty meeting. No dispute settlement procedure has been launched in respect of the presence of this exception in, for example, European law. It seems reasonable to assert therefore that all Members have at least implicitly acknowledged the validity of this exception. Noting the arguments of the parties above, at precisely what stage such implicit acceptance would rise to become "subsequent practice" is perhaps not a trivial judgement¹¹². Nevertheless, given the difference in the factual situation between the Pharmacy exception and the Regulatory Review exception (as it was at the time of this dispute), it must be arguable that the existence and nature of this exception must be taken into account in any interpretation

of Art. 30 TRIPS. Another example is the Prior Use exception. Although there is evidently still some degree of variation as to the scope of this exception, comparative investigation may reveal a sufficient common core to be able to demonstrate the necessary degree of "subsequent practice". Again, no dispute settlement procedure has been launched by any Member objecting to the consistency of a Prior Use exception with Art. 30 TRIPS. A weaker example is perhaps those exceptions based on the doctrine of the exhaustion of rights: In its third party submission, Australia pointed to possible exceptions to enable dealing with or repairing patented goods, i.e. a National Exhaustion exception.

Accordingly, in respect of the exceptions in this third category, it will be a matter of evidence as to the degree of "subsequent practice" demonstrated by Members for each given exception. Where there is established for a given exception the requisite degree of common thinking and behaviour, then it must be highly likely that, again, whatever the term "limited" in Art. 30 TRIPS means, it ought to embrace that exception (Anticipating section 4 below, this will be true equally of patent exceptions of long standing and *new* ones which are accepted as valid).

These different classes of exception and the need to take them into account when interpreting ART. 30 TRIPS are summarised in Table 2.

The central problem raised in this part of the paper is, bluntly stated, that the interpretation of "limited" adopted by the Panel seems to exclude a number of these exceptions to patent rights which must surely be regarded as valid and properly "limited" for the purposes of Art. 30 TRIPS.

Under the Foreign Vessels exception, with regard to vessels that are engaged in international travel and only visit the territory in question, a patent holders right to prevent unauthorised third parties from "using" (and arguably "importing" for that purpose) the patented invention is entirely removed. Even

Table 2

Exception	Source	Provision	Take into account when interpreting Art. 30 TRIPS?
Foreign Vessels	Paris Convention	Mandatory (for all Members)	Yes
Chicago	Chicago Convention on International Civil Aviation	Mandatory (for ~/all Members?)	Yes
Others such as Private Non Commercial Use, Experimental Use, Prior Use, Pharmacy etc	Historical (case-by-case)	Permissible (for all Members)	Yes, depending on the evidence

if a sea-going international ferry vessel which infringes a relevant patent docks in port on the hour, every hour, for a decade, so long as each time it leaves the port to exit the territorial waters and travel to a nearby foreign port before returning to that port, the patent holder has no possibility of acting against it. At no time during the lifetime of the patent can the patent holder seek an injunction or damages in respect of what would otherwise be a straightforward infringement. It is difficult to see how this exception can meet the Panel's *legal* test as to "limited".

The situation is similar, if not more compelling, for the Chicago exception. Not only is the right of a patent holder to prevent unauthorised third parties from "using" (and, again, arguably "importing" for that purpose) their invention entirely removed in respect of the international movement of aircraft flying into and out of the territory in question, but spare parts for those aircraft, which could otherwise also be infringing items, are permitted to be imported and *stockpiled* for use at any time during the lifetime of a relevant patent. A party owning a patent relating to a spare part for an aircraft could presumably only sit back and watch if an aircraft maintenance company decided to import and use generic versions of that part to keep the relevant aircraft maintained, at any time during the lifetime of that patent. It is again difficult to see how this exception can meet the Panel's *legal* test as to "limited".

Although probably a counsel of perfection strengthened with the benefit of at least five years of hindsight, it is curious that the Chicago exception was not mentioned in this dispute, either by Canada or by those third parties supporting Canada's position. Those using the disputed Stockpiling exception could have "made" and "used" the invention to create a stockpile of generic products only during the last six months of a patent's lifetime and could only have sold this stockpile after the patent has expired. Those using the Chicago exception may "import" generic products to create a stockpile for "use" at any time during the lifetime of the patent. In terms of a straightforward comparison between the Stockpiling and Chicago exceptions, which is admittedly not a trivial thing to do, it seems arguable to this author at least that the indisputably valid Chicago exception could be thought to have an adverse impact on a patent holder's *legal* rights which is comparable to that of the Stockpiling exception? Even when practical considerations are introduced, for example the nature of patent holders and their competitors in the fields of pharmaceuticals and aircraft, it seems arguable that the level of adverse impact could still be comparable? Perhaps readers will point to a difference in the structure of R&D funding for the pharmaceutical and aircraft industries, or otherwise differences in the market structure, to show that patent rights are regarded as being less important in the aircraft industry than in the pharmaceutical industry (which

seems very likely the case). Nevertheless, to return to the point at issue, the *legal* impact on a relevant patent holder still seems arguably comparable.

To put this another way, imagine that there was no Chicago exception at the present time and that Members were considering the problem of assuring the freedom of international travel from patent concerns. Is it likely that a proposal to simply render all international air travel and associated maintenance immune from patent infringement would be peaceably received?

The situation is similar for the more commonly known exceptions. For example, under the Pharmacy exception, again as widely accepted at the present day, there is no bound on the amount of production that can be made by a pharmacy at any time during the lifetime of the relevant patent. Again, the rights under this exception are not limited to “make” but can also include “use”, “offer for sale” and “sell”, all, again, at any time during the lifetime of the relevant patent. Under a Prior Use exception, as widely accepted at the present day, there is no bound on the amount of production that can be made by the prior user at any time during the lifetime of the relevant patent. The rights under the Prior Use exception are not limited to “make” either, but can also include “use”, “offer for sale” and “sell”. This wide range of acts can be carried out at any time during the lifetime of the relevant patent. It is difficult to see how either of these exceptions can meet the Panel’s *legal* test as to “limited”. The same is true of the National Exhaustion exception, to the extent that this exception is regarded as needing to comply with that test. An amelioration of the impact of some of these exceptions can be seen when practical considerations are introduced, for example, the actual frequency with which prior users appear, or the limitations on the technical capabilities of pharmacies, but there are not the considerations that the Panel adverted to for their purely legal “limited” test.

This is not the first time that this apparent conflict has been discussed in print. For example, Nuno Pires de Carvalho has noted that there are problems reconciling the interpretation of “limited” adopted by the Panel and the Prior User and Pharmacy Exceptions:

“Many WTO Members have established an exception concerning the manual preparation of medicines by pharmacists and medical doctors, in accordance with a medical prescription. Following the reasoning of the Panel in Canada - Patent Protection of Pharmaceutical Products, it is difficult to accept that such exclusion could be a “limited” one, because it gives third parties the unqualified and unlimited right to “make” and “sell” the patented medicine...The same can be said of the “prior user” exception, according to which “...”. The prior user exception, like the pharmacist exception is not “limited” because the prior user will be allowed to make, use and sell the product...”¹¹³

de Carvalho does not discuss the Foreign Vessels or Chicago exceptions though. Interestingly, de Carvalho seemingly takes the view that the inconsistency between the Prior Use and Extemporaneous Preparation exceptions and the “limited” test adopted by the Panel is best resolved in terms of the exceptions, that is to say that, in his view, it is the exceptions which are overly broad. This cannot be the best view of this conflict however. The conflict must surely be better resolved by considering an interpretation of “limited” which does embrace all the exceptions that Members considered and still consider to be valid. With the greatest respect to the Panel Members in this instance, and with the greatest respect to de Carvalho therefore, it seems that the better view must be that the Panel may have erred to the extent that they seem to have reached an interpretation of “limited” which arguably does not cover pre-existing broad exceptions which are indisputably regarded by Members as being so “limited”.

3.5 Other issues: the remainder of Art. 30 TRIPS and Art. 27.1 TRIPS

There are a number of commentaries on the Panel's findings on the other relevant terms in Art. 30 TRIPS¹¹⁴. This Paper will not dwell in detail on these other matters but points out that, in principle, the same process of *systematic* comparison of the language of Art. 30 TRIPS with *all* the pre-existing exceptions agreed to be valid, could be carried out in respect of all these other terms. In this way, some outline of what these other terms must embrace would be achieved, as a minimum, before further interpretation beyond that minimum could take place, including not only the meaning of a "normal exploitation of the patent" and "the legitimate interests of the patent holder" but the other key issues of "third parties" and their "legitimate interests" and how to strike a reasonable balance between these elements. The same exercise can also take place of course in respect of another important aspect of this dispute, the extent to which exceptions under Art. 30 TRIPS are subject to the non-discrimination provisions of Art. 27.1 TRIPS.

Three examples of important further points are taken for illustrative purposes.

3.5.1 The need for an extension of patent term to compensate for the Regulatory Review exception?

Importantly, the Panel found that there was insufficient evidence to suggest that Members held it necessary to balance the provision of a Regulatory Review exception with a patent term extension:

"...On balance, the Panel concluded that the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognised that it could be regarded as a "legitimate interest" within the meaning of Art. 30 of the TRIPS Agreement. Notwithstanding the number of governments that had responded positively to that claimed

*interest by granting compensatory patent term extensions, the issue itself was of relatively recent standing, and the community of governments was obviously still divided over the merits of such claims..."*¹¹⁵

3.5.2 "Third parties", their "legitimate interests" and striking a reasonable balance

Canada submitted that the relevant third parties included "society at large, individual and institutional consumers of such regulated products and would-be competitor producers of those products. In the particular case of pharmaceutical products, the "third parties" included the individual users of Canada's health care system and the public and private sector entities that paid for it"¹¹⁶. The interests of such third parties could be viewed as very pressing, "society at large and individual and institutional consumers of the health care system had an undeniably legitimate, *indeed essential*, interest in assuring the availability of competitively priced generic medicines as soon as patent expiry as possible"¹¹⁷ (*italics added*). The relevant third parties were by no means limited to Canadian residents in the light of the exception's ability to shield activity which was aimed at foreign regulatory submissions. Strongly disagreeing with Canada, the EC took the view that the only relevant third parties to be considered were generic pharmaceutical firms¹¹⁸. The EC stated that "The purchase of consumption of a medicine by a patient was no act which was of any relevance in patent terms. This meant in turn that there could be no adverse interests between the consumer and the patent holder" (a telling illustration of the EC's philosophy) and therefore consumers of medicines cannot be regarded as having legitimate third party interests. Given that the EC did not believe that the interests of Canadian consumers in accessing medicines were legitimately to be taken into account, this analysis applied *a fortiori*, to consumers in other Members. The EC rejected any notion that exceptions could include aims of resolving,

for example, public health problems of third parties in other Members, “Article 30 of the TRIPS Agreement was not a clause aimed at solving the public health problems of the entire world”¹¹⁹.

The Panel did not have to decide this point as a formal matter but evidently believed that the Canadian position was the better one, seemingly approving the general thinking illustrated by a pre-existing patent exception, the Experimental Use exception (“...both society and the scientist have a “legitimate interest” in using the patent disclosure to support the advance of science and technology...” although the Panel declined to comment on the validity of an Experimental Use exception as an Art. 30 TRIPS exception *per se*.

Interestingly at least one decided court case in Thailand¹²⁰, relying on paragraph 4 of the Doha Declaration on TRIPS and Public Health (as discussed below in section 3.6), has determined that the population at large is sufficiently affected by the grant of a pharmaceutical patent to be able to have the legal standing to challenge the validity of a patent, clearly a similar recognition of legitimate third party interests.

Comparison with all the pre-existing exceptions (and valid new ones) will therefore shed further light on the nature of third parties, their legitimate interests and whether or not these legitimate interests should be used to judge both unreasonable conflict with a normal exploitation *and* unreasonable prejudice to the legitimate interests of the patent holders (which seems highly likely to be the case given the construction of the Article and the evident need to have some yardstick to judge the reasonableness or otherwise of both cases: if it determines one “unreasonably” then it must surely likewise determine the other).

3.5.3 Exceptions under Art. 30 TRIPS and discrimination by field of technology

Another important issue of interpretation of the TRIPS Agreement raised in the Canadian Pharmaceuticals dispute was whether or not

the non-discrimination provision of Art. 27.1 TRIPS applied to Art. 30 TRIPS, i.e. is it possible to provide for limited exceptions under Art. 30 TRIPS to the rights of patent owners provided for under Art. 28 TRIPS in certain fields of technology to solve specific policy problems, without offending against the requirement of Art 27.1 TRIPS. Canada argued that Art. 27.1 TRIPS did not so apply to Art. 30 TRIPS (although in any case Canada indicated that the exceptions in question applied to all regulated products and did not therefore discriminate by field of technology anyway). The EC was strongly of the opposite opinion, that the discrimination provision of Art 27.1 TRIPS did apply to Art. 30 TRIPS. The EC pointed to the previous practice of Canada in adopting a compulsory licensing system which applied more liberal conditions to pharmaceutical patents than others as precisely the sort of behaviour which Art 27.1 TRIPS was designed to prevent, and concluded by extension that that same prohibition should apply to exceptions to patent rights under Art. 30 TRIPS as well.

Both parties referred to a pre-existing exception, the Pharmacy exception, in connection with their arguments. Canada stated that “the EC’s ‘across-the-board’ interpretation of the non-discrimination requirement left no room for the survival of the exception, since in the EC approach any differentiation at all amounted to prohibited discrimination”. Neither did Canada believe that the exception could survive under a lower test of differentiation justified by some “exogenous distorting circumstances”, since none had been referred to. The response of the EC was interesting:

“In response to a question from the Panel, the EC said that the “practicing pharmacist” exception, which existed in a number of countries, concerned a unique, in the meantime mostly historic situation, in which a pharmacist could produce on the prescription of a doctor a small quantity of a pharmaceutical product for an individual patient without the consent of the patent holder. There existed no comparable situation in other fields of

technology; no car mechanic would give a "prescription" to the car owner to have a single piece of patent protected car component or accessory manufactured by a mechanical or electronic manufacturer. Therefore it lacked comparability and thus discriminatory character" ¹²¹

It is tempting to suggest that many others will find utility in characterising their situations as "unique" and therefore above considerations of discrimination. In fact, as regards the exception in question, since the Panel found that there was in fact no evidence of discrimination demonstrated there was no need

for them to make a further pronouncement on the subject. Nevertheless they did, drawing a clear distinction between well founded *differentiation* between different technical fields (which was permissible) and *perjorative discrimination* (which was not). The Panel declined to indicate whether they believed that limiting an exception to one field of technology was necessarily discriminatory¹²².

Again, comparison with all the pre-existing exceptions (and valid new ones) will shed further light on the ability to differentiate by field of technology.

3.6 Appraisal - Life after Canada - Generics

3.6.1 The Regulatory Review, Stockpiling and future exceptions

It must be recalled that, although now cloaked in rather more legal clothing than under the GATT regime, disputes at the WTO are still trade disputes. It cannot be an easy task to pretend that all parties to disputes, or that all interests, have the same standing at law given the enormous disparities in real-world power that lie behind them. Although the EC took aim at both the Canadian Stockpiling and Regulatory Review exceptions, in doing so it also implicitly took aim at the US Regulatory Review exception. The US is not notably reticent in protecting the interests of the originator pharmaceutical industry but presumably in this case there was a tension in that they wished to keep their Regulatory Review exception. Presumably, in an ideal situation for them, others would have been persuaded that a patent term extension was a necessary *quid pro quo* for such an exception, but this did not come to pass. In these circumstances, it may have been that the EC did not really expect to be able to knock out the Regulatory Review exception, but was really taking aim at the Stockpiling exception. Given the political weakness of the Canadian position, in terms of being such an outlier in adopting such an exception, it was not entirely surprising that it was found more difficult

to defend. Canada may have not been too distressed at losing the Stockpiling exception as they had kept most of what they needed from a public policy viewpoint by retaining the Regulatory Review exception.

However, the broader issue was not merely the Stockpiling exception. It seems perfectly possible to regard this dispute as an attempt to draw a distinction between acceptable exceptions, in effect confined to the list of pre-existing and well known exceptions, and unacceptable exceptions, in this case new ones that had been designed and implemented after the entry into force of the TRIPS Agreement. In distinguishing between the Regulatory Review exception and the Stockpiling exception as it did, the Panel's interpretation of Art. 30 TRIPS presumably chilled Members enthusiasm for crafting such new exceptions. In this way the "floodgates" holding back new and expansive exceptions could remain firmly shut (notwithstanding this, the following section details examples of new exceptions that have been crafted since the entry into force of the TRIPS Agreement).

The most obvious consequence of the Panel's findings though is that the Regulatory Review exception, without the need for any compensatory patent term extension, has been found to be, crudely speaking, a "WTO approved"

exception. This has had tremendously important consequences for public health and the Panel, and in particular the Chairman, have rightly been congratulated from that perspective¹²³. Other Members can adopt a Regulatory Review exception along the same lines as the Canadian exception, therefore including export activity, with a high degree of confidence that they would not be challenged by any other Member for doing so. As noted, in terms of the public policy aim of the two disputed exceptions, it was much more important that the Regulatory Review exception would survive than the Stockpiling exception.

And yet, here is a dilemma. Which interpretations of Art. 30 TRIPS could reasonably be expected to preserve the more important of these exceptions, but invalidate the less important? The reasoning of the Panel is clever, if not apparently entirely free from inconsistency. The use of the “limited” test by the Panel as a sort of “fortified front gate” to keep out purportedly overbroad exceptions is an inventive one in the circumstances of the dispute but it is not perhaps a particularly compelling one. Aside from the reasoning of the Panel *per se*, this section has presented an argument that the Panel erred in not taking into account a number of pre-existing and indisputably valid exceptions, in determining the meaning of “limited”. For example, whatever the term “limited” means, the Foreign Vessels and Chicago exceptions must surely be so “limited”. The same consideration applies to all the other terms in Art. 30 TRIPS.

It is pertinent to note that the findings of the Panel were not appealed by either party to the Appellate Body. The Appellate Body has not demonstrated too much reluctance in disagreeing with first instance Panels¹²⁴, and has already done so in at least one TRIPS related dispute between the US and India largely concerned with the Indian implementation of the “mailbox” required under Art. 70.8 TRIPS¹²⁵.

In any case, and perhaps more conclusively, the circumstances in which this dispute were brought can now be seen to be very much of their time. There have been significant

developments since this Panel report which cast doubt on the continuing value of the findings. It is interesting to reflect on the submissions of the EC in this dispute, and wonder to what extent the EC would be inclined to make those same submissions again today. Notwithstanding the heartfelt arguments submitted by the EC as to the utter inability of the Regulatory Review exception to meet the requirements of Art. 30 TRIPS, it is interesting to note that the EC has now adopted a Regulatory Review exception of its own.

The issue of TRIPS and Public Health burst onto the consciousness of the world in unprecedented fashion after the South African court case debacle of 1998-2001. Subsequently the Members of the WTO agreed the 2001 Doha Declaration on TRIPS and Public Health¹²⁶, paragraph 4 of which indicates that:

“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.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

The issues surrounding Art. 30 TRIPS, and the EC’s changed view of them, were raised again in respect of Paragraph 6 of this Declaration, as discussed in the following section.

3.6.2 Conclusion: the weak precedent effect of *Canada-Generics*

For at least two reasons, the approach of a new Panel to the issue of exceptions under Art. 30 TRIPS must likely be expected to be different from that which the Panel took back in 2000.

- In the first place, apart from any difficulties with their own reasoning, it is arguable that the *Canada-Generics* Panel erred in their interpretation of “limited” in not systematically taking account of all the pre-existing exceptions which were known to be valid, including, for example, the broad Foreign Vehicles and Chicago exceptions. The same consideration applies to all the other terms in Art. 30 TRIPS.
- Secondly, much has happened since 2000, including the Doha Declaration on TRIPS and Public Health. An “evolutionary” approach

to the interpretation of the provisions of the TRIPS Agreement is certainly to be expected¹²⁷.

Caution must therefore be counseled in taking too strict a view of *Canada - Generics* as a precedent as to how any new patent exception needs to be designed.

There are, and there must be, limits to the scope of exceptions from patent rights under Art. 30 TRIPS, whether in terms of legal or economic tests, but they have not yet been fully explored.

4 REVIEW OF STATE PRACTICE ON PATENT EXCEPTIONS

Following the legal examination of Art. 30 TRIPS in the preceding section, it is interesting to review how Members have in fact behaved in respect of their implementation of patent exceptions, especially (but not exclusively) since the entry into force of the TRIPS Agreement in 1995 and the *Canada-Generics* case in 2000. This section includes exceptions not previously discussed in this Paper. In some cases this is because the exceptions in question are new, that is to say they have been created in response to a new policy problem since 1995. In other cases, the policy problem is familiar

but has perhaps been conceptualised largely in terms of other intellectual property rights, such as plant breeders rights, and has only relatively recently become a concern for the patent system as well.

In terms of understanding how the TRIPS Agreement is working out in terms of practical effects, it is also interesting to try to study the incidence of the use of these exceptions, and to consider what conclusions may be drawn from such empirical data, as discussed in the final section of this portion of the Paper.

4.1 Introduction

A review of developments in patent rights accorded, and exception to those rights has been carried out in respect of Argentina (Law 24.481 of 1995 as amended), Australia (Patents Act 1990, Act. No. 83 of 1990), Bangladesh (Patents Act 1911 as amended), States party to the Bangui Agreement (1977, as amended February 24, 1999) (Member States: Benin, Burkina Faso, Cameroon, Central Africa, Congo, Cote d'Ivoire, Gabon, Guinea Bissau, Guinea, Mali, Mauritania, Niger, Senegal, Chad and Togo.), Botswana (Industrial Property Act No. 14, 1996, as amended), Brazil (1996 Industrial Property Law as amended), China (Patent Act 1984 as amended 1992, 2000), Egypt (IPR Law No. 82, 2002), Ghana (Patent Law 1992 as amended), India (Patent Act 1970 as amended 1999, 2002, 2005), Jamaica (Patents and Designs Act 2001), Kenya (Industrial Property Act 2001), Malawi (Patents Act No. 13, Chapter 49.02 of 1958 (1968) based on the UK Patents Act of 1949), Malaysia (Patents Act 1983 as amended), New Zealand (Patent Act 1953 No 64 as amended 1972 - 2002), Nigeria (Patents and Designs Act, Chapter 344, Laws of the Federation of Nigeria, 1990 as amended), Papua New Guinea (Patent and Industrial Property Act 2000), Singapore (Patents Act 1994 as amended), Sri Lanka (Code of Intellectual Property Act No. 52 of 1979, amended 2000, Article 82(1)) and Uganda (Patent Statute No. 10, 1991)¹²⁸.

Subsequent references to legislative provisions should be understood as referring to these acts. However, these references are made for illustrative purposes only and are not to be relied on as reflecting the specific legal situation presently prevailing in any of these countries. It may be, for example, that only an informal translations of the legislation is available.

In discussing examples of each exception, attention is paid to the different modes of adopting, modifying or operating exceptions. In particular, there are a number of factors that may shape the patent legislation of any given country, including:

- A country may have adopted a provision specific to its own needs after carrying out a policy review. Ideally, each country would monitor its policy needs such that these provisions are kept up to date.
- A country may have been persuaded of the advantage to be gained from adopting a foreign provision, either from another country, or for example, from an international model code.
- A country may have been persuaded of the advantage to be gained from adopting a provision from a parallel intellectual property system.
- A country may be bound by an international obligation to adopt a certain form of provision provided for in, for example,

a treaty, which may be bilateral or multilateral in nature.

- Alternatively, the shape of a country's patent legislation may be the result of a degree of historical inertia. Many developing countries were, within living memory, still colonies of European countries. Much of the legislation that was enacted in these colonies was, or was derived from, the legislation of the former colonial power¹²⁹. It is the case therefore that in many developing countries, traces of this original legislation still exist, either in terms of the overall design, or in terms of the substantive provisions of the domestic patent legislation. Another element in this latter factor is the degree of weight that may still be accorded to judicial

(or administrative) decisions reached in the context of the former colonial power. This may lead to some difficulty for developing countries in terms of balancing their need to act in accordance with the coherent legal philosophy and community that exists, for example, in the common-law Commonwealth, and their need to reach legal and policy decisions that best suit their own needs. Where Australia, Britain or Canada decide to draw the line on patent law decisions will take into account a very different policy balance than the circumstances of, for example, Uganda, Vanuatu or Zambia.

Examples of each of these possibilities are outlined in the following.

4.2 Private and Non-commercial Use exception

4.2.1 Narrow vs broad approaches

Section 2.1 above noted two different approaches to this exception. Either a narrow exception could be provided to broadly defined patent rights, or the rights of the patent holder could be specified to only extend to commercial uses of the invention. It might be expected that developed countries would tend to adopt the former form, perhaps privileging patent rights, and developing countries would tend to adopt the latter form, restricting patent rights to the commercial domain. A third possibility is, of course, that no specific provision is made, which still leaves open the possibility of addressing such an exception under case law.

For a first group of countries, one example of a developed economy implementation of the former, more narrow, approach is that provided under the Singaporean Patents Act 1994 in section 66(2):

Section 66.-[...]

- (2) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if-
 - (a) it is done privately and for purposes which are not commercial;

The Singaporean exception provisions are

largely identical to those of the present UK 1977 Patent Act, which is not too surprising as Singapore is a developed country member of the Commonwealth. Furthermore, Singapore has recently entered into a Free-Trade Agreement with the US, which will keep the patent system at a US par, as discussed further below. However, Jamaica is an example of a developing country with this same provision (s. 78(1)(a)).

By contrast, in a second group, many other developing countries have adopted the latter, more broad, approach. It is interesting to note the origin of a number of provisions in the patent law of developing countries that are members of the Commonwealth. Often, for example on matters relating to compulsory licensing or government ("Crown") use, the provisions in those countries' laws are identical to either the present UK provisions, or previous UK provisions, depending on when the country's patent legislation was last amended. A different situation pertains as regards exceptions though. In the UK 1949 Patents Act, there was no listing of acceptable exceptions in the patent legislation, rather they were applied as a matter of case law. This situation only changed with the UK 1977 Patents Act. For many developing countries in the 1960s and 1970s there was evidently a desire to make more specific the exceptions

that were allowable and it appears that, since the UK model did not help, many turned to the WIPO Model Patent Law for Developing Countries. Art. 23 of this Model Patent Law indicated that “use of the patented invention for strictly private or experimental purposes is not to be deemed to be use for industrial or commercial purposes”¹³⁰. Accordingly, many developing countries who are members of the Commonwealth share the same provisions on exceptions, which are not derived directly from a UK model, although they are still very similar. Nevertheless, UK precedents, and those from other parts of the Commonwealth are still regarded as persuasive in the interpretation of those provisions.

One example of a wealthy but still developing country that has adopted this approach is Malaysia. Under section 37 of the Malaysian Patents Act 1986:

37. Limitation of rights.

- (1) The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done only for scientific research.

A leading commentary on the Malaysian legislation refers to UK precedents in terms of interpreting and applying the legislation¹³¹.

Nigeria has a similar provision:

6. (3) The rights under a patent—

- (a) shall extend only to acts done for industrial or commercial purposes¹³².

Virtually identical approaches are seen in Ghana (s. 30(a)), Kenya (s. 58(1)) and Sri Lanka (s.82(1)).

By contrast to the above, in a third group of countries, notably including LDCs, it is not clear that any specific provision is made, although other individual exceptions are listed (if only in some cases the Foreign Vessels exception). This group includes Bangladesh, Botswana, Malawi, Papua New Guinea and Uganda where there is seemingly no explicit provision, either to limit the patent holders rights to commercial or industrial activity or for a Private and Non-commercial Use exception. Perhaps such *de*

minimus activity would be provided for as a matter of case law, should any patent holder even bring a relevant suit.

Given the influence of the WIPO Model Patent Law, it is no surprise that other, non-Commonwealth countries have also adopted a similar approach. For example, under the prevailing Chinese patent legislation, the rights of a patent holder are provided as follows:

Article 11

After the grant of the patent right for an invention or utility model, except where otherwise provided for in this Law, no entity or individual may, without the authorization of the patentee, exploit the patent, that is, make, use, offer to sell, sell or import the patented product, or use the patented process, and use, offer to sell, sell or import the product directly obtained by the patented process, *for production or business purposes*. After the grant of the patent right for a design, no entity or individual may, without the authorization of the patentee, exploit the patent, that is, make, sell or import the product incorporating its or his patented design, *for production or business purposes*. (italics added)

An interesting restriction is seen in the case of Brazil though. A number of explicit exceptions were introduced into the Brazilian patent legislation with the advent of the 1996 Industrial Property Law, of which a Private and Non-commercial Use exception was one¹³³. However it includes an element which is clearly aimed at narrowing even further than normal the scope of the acts which may be carried out:

Article 43: The provisions of the previous article do not apply:

Acts practiced by unauthorized third parties privately and without commercial purposes, *provided they do not result in damage to the economic interests of the patentee*; (italics added)¹³⁴

The Bangui Agreement (Art 8) seems not to include any specific provision on non-commercial or non-industrial activity.

4.2.2 Comment

The narrow form of this exception, i.e. a discrete Private and Non-Commercial Use exception is not likely of great practical use. It will likely shield those from infringement that patent holders wouldn't bother suing anyway. However, the broad form i.e. restricting a patent holders rights to the commercial or

industrial sphere could have a more significant utility. For example, in theory, it could provide a shield to those carrying on non-commercial activities on a more broad scale, including the activities of not-for-profit entities. Developing countries may like to explore further the policy space available under this option.

4.3 Experimental / Scientific Use exception

Professor Carlos Correa has just completed a comparative study of the Research exception ("Experimental/Scientific Use exception"), comparing and contrasting the scope of the exception across many countries, concluding that:

*"The analysis of the legislation in developing countries and economies in transition indicates that the research/ experimentation exception has been widely recognised in patent law both before and after the TRIPS Agreement. Many countries - including the most technologically advanced - have not used, however, the full room for manoeuvre left by the Agreement to legislate on the matter"*¹³⁵.

It should be noted that this Paper refers to this exception in general terms whereas Professor Correa's study distinguishes between, for example, experimentation, scientific research and technological research.

4.3.1 OECD countries

A clear example of the importance of the Experimental Use exception, and a good example of the sort of policy review process that is helpful in matching the appropriate scope of an exception to the policy needs in hand, is given by the recent Australian Law Reform Commission (ALRC) enquiry into the Australian Experimental Use exception¹³⁶. Although the present Australian patent legislation¹³⁷ does explicitly provide for, for example, a Foreign Vessels and Chicago Exception¹³⁸, and a Prior Use Exception¹³⁹, it does not explicitly provide for an Experimental Use Exception. There is believed

to be a common-law implied Experimental Use exception¹⁴⁰, although this is disputed:

*"[14.9] While no Australian court has ruled on the matter, the existence of an experimental use defence is widely assumed. For example, Australia's third party arguments in the Canada - Patent Protection case stated that, in Australia, 'an experimental use exception did apply, but only to the extent that a court would find that specific experimental activities did not constitute infringing use'. [14.10] Others have argued that, as a matter of statutory interpretation, it is difficult to argue that the Patents Act implies an experimental use defence, especially given the breadth of the exclusive rights given to patent holders."*¹⁴¹

Many will think it strange that in such a sophisticated economy as Australia's, it is seemingly not possible to be sure whether or not there is an Experimental Use exception, and if there is, how broad or narrow it is. It was the impact of the uncertainty over the situation that gave the ALRC review such impetus: "The existing uncertainty is unhelpful to the research community and commercial Organizations. It has the potential to lead to under-investment in basic research and hinder innovation because researchers are concerned that their activities may lead to legal action by patent holders"¹⁴². The situation in New Zealand is somewhat similar, as the ALRC notes. The New Zealand patent legislation¹⁴³ only explicitly provides for a Regulatory Review Exception¹⁴⁴ (In fact the New Zealand patent legislation so closely mirrors the old UK 1949 Act that the Patent Act

does not even define what the rights of a patent holder are, this being left to the form of the grant of the patent¹⁴⁵, just as under the UK 1949 Act¹⁴⁶). Unlike Australia though, the existence of a common-law Experimental Use exception has been acknowledged by the courts in New Zealand in at least two cases. Continuing uncertainty as to the scope of this exception has caused New Zealand to undertake a similar exercise to Australia, with the Ministry of Economic Development, in consultation with the Ministry of Health, due to report to the Cabinet on the matter. The ALRC review included a comparative law element (other countries' Experimental Use exceptions), an international law element (the TRIPS Agreement background) and, of course, a policy element (what were the problems that Australia was facing?). In their final report the ALRC recommends that statutory provision be made for an Experimental Use exception on a model closer to that of the UK and Europe than the US¹⁴⁷:

Recommendation 13-1 The Commonwealth should amend the Patents Act 1990 (Cth) (Patents Act) to establish an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention; for example, to investigate its properties or improve upon it. The amendment should also make it clear that:

- (a) the exemption is available only if study or experimentation is the sole or dominant purpose of the act;
- (b) the existence of a commercial purpose or objective does not preclude the application of the exemption; and
- (c) the exemption does not derogate from any study or experimentation that may otherwise be permitted under the Patents Act.

Another fine example of developments and a degree of uncertainty relating to the scope of the Experimental Use exception is that of the United States. In a relatively recent case, *Madey v. Duke University*¹⁴⁸, the Court of Appeals for the Federal Circuit (CAFC) has effectively killed off the last vestiges of the US Experimental Use exception. The CAFC stated that the "very

narrow and strictly limited experimental use defense" applied only if use of the patented invention is "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry". The CAFC rejected Duke University's claims that it was primarily a not-for-profit entity indicating that even non-commercial academic research could be said to further the "legitimate business objectives" of the university "including educating and enlightening students and faculty participating in these projects", "increas[ing] the status of the institution and lucr[ing] lucrative research grants". Such a narrow view can clearly be expected to have a significant adverse impact on the ability of researchers to operate in the US. However a degree of uncertainty persists, given that the Supreme Court declined to review the case. It will be interesting to see whether this decision will spur fresh efforts to establish a statutory Experimental Use exception in the US to permit a more well defined and greater degree of research and experimentation than now seems to be permitted. An interesting related development is that, shortly after the CAFC has reduced the Experimental Use exception to virtual inutility in *Madey v. Duke University*, the Supreme Court in *Merck v. Integra* has recently widened the Regulatory Review ("Bolar") exception, as discussed below.

4.3.2 Non-OECD countries

As noted above, in Malaysia, the rights of the patent holder only extend to "acts done for industrial or commercial purposes and in particular not to acts done only for scientific research". In terms of how this provision might be interpreted it seems that as of 2003 there were not yet any domestic Malaysian cases on this exception¹⁴⁹. Other Commonwealth countries providing for a similar Experimental Use exception include Botswana (s. 24(3)(a)(iii)), Ghana (s.30(a)), Jamaica (s. 79(1)(b)), Kenya (s.58(1)), Papua New Guinea (s. 29(4)(c)), Sri Lanka (s.82(1)), Uganda (s.29(a)). Ghana explained at the TRIPS Council review of its legislation, in response to EC Question 24, that this "limitation concerns acts done only for experimental purposes, that is, for non-commercial purposes". The Bangui Agreement

also makes provision for an Experimental Use exception (Art. 8(1)(c)).

China has an Experimental Use exception and it is interesting to note that there certainly has been a degree of debate and discussion over the proper extent of its scope:

Article 63. None of the following shall be deemed an infringement of the patent right:

- (4) Where any person uses the patent concerned solely for the purposes of scientific research and experimentation.

In fact the Chinese patent legislation is regularly reviewed, presumably to ensure that the provisions presently adopted are best serving the policy needs of the country¹⁵⁰. For, example, following the entry into force of the 1984 Chinese Patent Law, one commentator observes that by 1990 it was necessary to revise the legislation in the light of domestic experiences gained since the legislation came into effect (as well as new policy requirements in terms of economic development, the influence of international patent harmonisation efforts at WIPO and within the framework of the GATT negotiations, and the impact of a bilateral Memorandum of Understanding signed with the US¹⁵¹). This review process continues at the present time - and a (third) comprehensive review of the Chinese Patent Act is now being undertaken. In the meantime, guidelines have been issued, and more are about to be issued, to provide some direction for the interpretation of, for example, the exceptions to the rights of a patent holder under Chinese patent law. At a local level, and yet of particular importance for intellectual property law and practice in China, a guidance note was issued by the Beijing High People's Court, providing a degree of further detail as to how the above exceptions should be interpreted¹⁵². In particular, as regards the Chinese Experimental Use exception, the note draws particular attention to the need to differentiate between experimentation on, and experimentation with, a patented product, to clarify that it is permissible to make the patented product if it is to be used solely for

the purpose of research and experimentation, and to indicate that one of the the main aims of this use is to permit the development of improvements in the patented invention. It is understood that a more comprehensive guidance note is currently under preparation by the Supreme People's Court (SPC) to the same end. Chinese commentators have analysed the scope of the Experimental Use exception, particularly in terms of indicating a need for a more formal Regulatory Review exception to be provided, alongside this exception¹⁵³.

Likewise Brazil has an Experimental Use exception:

Article 43: The provisions of the previous article do not apply:

- (ii) Acts practiced by unauthorized third parties for experimental purposes, regarding studies or to scientific or technological research;

On the face of it the provision would appear to be more broader than a number of the above provisions, as it includes use for the purposes of study. Nevertheless views have been expressed that the scope of this exception is narrow¹⁵⁴. India also has a similar provision:

"s. 47 [The grant of a patent under this Act shall be subject to the condition that:]

*(3) any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils..."*¹⁵⁵

Likewise, Argentina has a similar provision:

Article 36.

The right conferred by a patent shall have no effect against:

- (a) a third party who privately or in an academic environment and without gainful intent, conducts scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or applies a process identical to the one patented;

4.3.3 Comment

The Experimental Use exception, along with its adjunct the Regulatory Review exception, is one of the exceptions which is of the greatest practical importance. It is true to say that this practical importance will vary, from where it is of maximal importance in scientifically and technologically sophisticated developed countries, through developing countries where it is beginning to be important (as their scientific

and technical capabilities develop toward those of the developed countries) to where it is not so important, in poor developing countries with rather less in the way of science and technology base. Nevertheless, for observers, an active monitoring of debate and developments over the Experimental Use exception, whether in OECD countries or developing countries, is of interest in following underlying economic and technological developments. For policy makers in those countries, keeping track of developments (either in terms of domestic case law or changes in economic or social factors or in terms of, for example, foreign case law or legislative changes) and ensuring that the present form of the Experimental Use exception best serves the countries policy needs at that stage in development is an important challenge.

4.4 Prior Use exception

4.4.1 OECD countries

An interesting development as regards the Prior Use exception in OECD countries relates to the United States and its practice of permitting the grant of patents for pure business methods. In parallel with this extension of patentability (often deemed to begin with the CAFC *State Street* decision¹⁵⁶) has come the commensurate adoption in 1999 of a new exception: the Business Methods Prior Use exception¹⁵⁷. This exception permits a qualifying prior user (one who, acting in good faith, had “reduced to practice” the later patented business method at least one year before the patent application was filed for, and had commercially used the method before that filing date) to carry on practising that business method, within certain limits, in much the same way as the more general Prior Use exceptions discussed above.

4.4.2 Non-OECD countries

The Malaysian Prior Use exception (s. 37 (2)(ii)) has been raised in at least one dispute before the Malaysian courts¹⁵⁸. Nigeria has a similar provision:

- 6. (4) Where, at the date of the filing of a patent application in respect of a product

or process or at the date of a foreign priority validly claimed in respect of the application, a person other than the applicant—

- (a) was conducting an undertaking in Nigeria; and
- (b) in good faith and for the purposes of the undertaking, was manufacturing the product or applying the process or had made serious preparations with a view to doing so, then, notwithstanding the grant of a patent, there shall exist a right (exercisable by the person for the time being conducting the undertaking, and not otherwise) to continue the manufacture or application, or to continue and complete the preparations and thereafter undertake the manufacture or application, as the case may be, and in respect of any resulting products to do any other act mentioned in subsection (1) of this section¹⁵⁹.

Widespread provision is made in other Commonwealth countries including, for example, Botswana (s. 24(3)(a)(iv)), Jamaica (s.83), Papua New Guinea (s. 29(4)(d)), Sri

Lanka (s.83), Uganda (s.29(d)). Similar provision is made under the Bangui Agreement (Art. 8(1)(d)).

China has a Prior Use exception of the following form:

Article 63. None of the following shall be deemed an infringement of the patent right:

- (2) Where, before the date of filing of the application for patent, any person who has already made the identical product, used the identical process, or made necessary preparations for its making or using, continues to make or use it within the original scope only;

This Chinese Prior Use exception has been the subject of some detailed discussion. The necessary elements and bounds of the Chinese Prior Use exception were outlined in the Beijing High People's Court practice note, along the lines of a usual understanding of this exception, although, for example, it is specified that "The necessary preparation means having accomplished the design of the product drawings and the document of work process, prepared the specialised equipment and moulds or finalised the trial manufacture of the prototype and other preparatory work". However, given that it is difficult to draw such boundaries with clarity, it is pertinent to note that commentators have discussed at least one case which has been brought after the release of this note, being particularly concerned with the notion of the "original scope"¹⁶⁰.

Brazil also has a Prior Use exception, under Article 45 of its patent law, although on the face of it, it would appear not to extend to embrace those who were only making preparations for use, rather than actually using¹⁶¹. Interestingly,

in much the same way as with the Chinese Prior Use exception, the first decisions on the Brazilian Prior use exception are apparently beginning to appear:

*"Prior User rights are granted to a person who, in good faith, prior to the date of filing or of priority of a patent application, exploits its object in Brazil... According to available information, prior user rights were claimed for the first time in an infringement action, 8th Civil Court of Porto Alegre, Action No. 109177908. At the time of writing, the expert appointed by the judge had confirmed the prior use, but no decision had been issued."*¹⁶²

4.4.3 Comment

The issue of prior use continues to be a relevant one in many countries. In the same way as with, for example, the Experimental Use and Regulatory Review exceptions, it is perhaps an interesting reflection of the level and sophistication of economic activity being undertaken. If, for example, there are instances of prior user rights being asserted between domestic entities in a developing country, then it could be concluded that these entities are carrying out operations at much the same level of sophistication, in a market which has become worth litigating over. If instead there were instances of prior user rights being asserted, for example, between a domestic prior user entity in a developing country and a foreign patent holder from a developed country, then it could perhaps be concluded that the domestic and foreign entities are carrying out operations at much the same level of sophistication, which would be interesting from a developmental point of view.

4.5 Pharmacy exception

The EC, and apparently more particularly France, was the source of this exception but it has been adopted by other countries, notably with those with some historical connection with Europe. Brazil, for example, has provided for

this exception:

Article 43: The provisions of the previous article do not apply:

- (iii) The preparation of medicine according to a medical prescription for individual cases,

executed by a qualified professional, as well as to a medicine thus prepared.

Interestingly, the EC questioned Brazil as to how this Brazilian implementation was to be interpreted and received a firm response:

"Having examined Articles 43 to 45 of Law No. 9.279 of 1996, the European Communities are concerned as to how Article 43(iii) would be interpreted in Brazil. A medicine prepared in accordance with a medical prescription could be so prepared for many thousands of "individual cases". Please confirm that Article 43(iii) will be interpreted in Brazil in accordance with both the letter and spirit of Article 30 of the TRIPS Agreement.

*Yes. Article 43, III, of Law No 9.279 of 1996 is applicable only to individual cases. Therefore, there is no sense in the questioning, since it refers to a exception that does not unreasonably conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties"*¹⁶³.

Argentina has also provided for this exception (Art. 36), as has Jamaica (s. 79(1)(c)).

The possibility that the exception could rise to a greater practical prominence when considering somatic genetic or somatic cell therapies (due to the use of an individual patients genetic material) was noted above in section 2.4.

4.6 Foreign Vessels exception

4.6.1 Variations in the Foreign Vessels exception

As noted above in section 2.5 this exception is very widespread, being mandatory for all WTO Members. There is only slight variation in its implementation, in terms of the specific vehicles that are mentioned. A straightforward example of implementation is that of Ghana:

30. The rights under the patent shall—

- (c) not extend to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Ghana;

A similar implementation is found in Bangladesh (s.42), Botswana (s. 24(3)(a)(ii)), Ghana (s.30(c)), India (s.49), Jamaica (s. 79(1)(d),(e)), Kenya (s.58(3)), Malawi (s.9), Papua New Guinea (s.29(4)(b) , Sri Lanka (s.82(3)) and Uganda (s. 29(c)). Likewise under the Bangui Agreement (Art. 8(b)).

The British and, for example, Singaporean provisions include *hovercraft*:

66. (2) An act which, apart from this subsection,

would constitute an infringement of a patent for an invention shall not do so if-

- (d) it consists of the use of a product or process in the body or operation of a relevant aircraft, hovercraft or vehicle which has temporarily or accidentally entered or is crossing Singapore (including the air space above it and its territorial waters) or the use of accessories for such a relevant aircraft, hovercraft or vehicle;

The Malaysian provisions, seemingly on an American model, include *spacecraft*¹⁶⁴:

37. Limitation of rights.

- (3) The rights under the patent shall not extend to the use of the patented invention on any foreign vessel, aircraft, spacecraft or land vehicle temporarily in Malaysia.

4.6.2 Comment

As to the inclusion of spacecraft, this might not necessarily relate to spacecraft passing through the airspace of a Member *per se*, but might be aimed at the possibility that a foreign constructed satellite is brought to that

Member for launching, as in the US *Hughes Aircraft Company* case¹⁶⁵, and hence may be considered as a foreign vessel covered by this exception for patent infringement purposes. It might well be important for Members that have launch capabilities, in particular those who offer commercial launch facilities (such as, for

example, French Guiana (in fact a *départements d'outre-mer* part of France: would the French Foreign Vessels exception cover such a satellite?) or Kazakhstan (presently negotiating to become a WTO Member but already a party to the Paris Convention)), to consider this issue if they have not already.

4.7 Chicago exception

4.7.1 Patent and/or Civil Aviation legislation?

The Chicago Exception is interesting as an example of an exception which, although it may be explicitly provided for in national legislation, is not always provided for in the *patent* law. It is therefore dangerous to assume that only the exceptions listed in the patent law are provided for in any given country (doubly so considering common law countries where an exception may only be provided for as a matter of case law).

A review of a relevant practitioner work, "Aircraft Liens & Detention Rights"¹⁶⁶, indicates that the way in which the Chicago Exception has been provided for in Australia, Canada, New Zealand (and the United Kingdom) is primarily through the Patent Act, in Argentina¹⁶⁷, France¹⁶⁸ and Kenya¹⁶⁹ provision is primarily through the Civil Aviation Act, whereas in Brazil, Chile, China, Costa Rica, Egypt, Germany, India, Jamaica, Nigeria, Pakistan, the Philippines¹⁷⁰, Peru, the Russian Federation and the United States¹⁷¹, although it is indicated that the Chicago Exception is provided for, no detail is provided as to how. In fact Jamaica provides for this exception in its patent law (s. 79(f)).

4.7.2 Reciprocity and MFN?

An interesting legal issue arises where the provision is implemented with the "reciprocity" arrangement, as discussed in section 2.6. For example, China provides for the exception in the following form (although this seemingly treats both elements of the Foreign Vessels and Chicago exceptions):

Article 63. None of the following shall be deemed an infringement of the patent right:

- (3) Where any foreign means of transport which temporarily passes through the territory, territorial waters or territorial airspace of China uses the patent concerned, in accordance with any agreement concluded between the country to which the foreign means of transport belongs and China, or in accordance with any international treaty to which both countries are party, or on the basis of the principle of reciprocity, for its own needs, in its devices and installations;

In the TRIPS Council review of the Norwegian patent legislation¹⁷², which similarly provided for this provision on the basis of reciprocity, US Question 3 enquired as to how this could comply with the TRIPS MFN requirement. Norway replied that:

"This provision in the Patent Regulations is necessary in order for Norway to comply with Article 27 subparagraph (b) of the Chicago Convention. As it is the nationality of the aircraft and not the nationality of the patent holder, the owner of the aircraft or any other person that is decisive, this regulation does not seem to contravene the most-favoured-nation treatment obligation under the TRIPS Agreement. However, if there is a fairly clear and general view that such a privilege should be extended to aircraft from all Members of WTO, Norway will abide by that view, cf. Article 30 which allows for limited exceptions to the exclusive rights conferred by a patent."

4.8 Exhaustion exception(s)

4.8.1 The treatment of the doctrine of the exhaustion of rights under the TRIPS Agreement

Exceptions based on the doctrine of the exhaustion of rights may be treated rather differently under the TRIPS Agreement than the other exceptions discussed above. The TRIPS Agreement does not contain any explicit provision indicating that the adoption of any particular exhaustion of rights regime is, or is not, permissible. Disagreement between the TRIPS negotiators on the issue of exhaustion was so sharp that Art. 6 TRIPS, the only provision of the TRIPS Agreement explicitly addressing it, reflects a “we agree to differ” result:

“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”¹⁷³

Paragraph 5(d) of the Doha Declaration on TRIPS and Public Health affirmed that this meant that each Member could make their own choice of exhaustion regime:

“The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.”

This is not to say that disputes cannot be raised at all. Of course there is a question of the violation of Arts. 3 or 4 TRIPS, the National Treatment and Most Favoured Nation principles. Alternatively a dispute may be taken as a bilateral matter. Examples of both sorts of disputes are discussed in the following.

4.8.2 National exhaustion

There are a number of examples of countries

that have maintained a strictly National Exhaustion exception. Ghana, for example, has a straightforward National Exhaustion exception:

30. The rights under the patent shall—

- (b) not extend to acts in respect of articles which have been put on the market in Ghana by the owner of the patent or with his express consent¹⁷⁴;

Brazil has a very similar provision, *as a civil law matter*:

Article 43: The provisions of the previous article do not apply:

- (iv) A product manufactured in accordance with a process patent or a product that has been placed on the internal market directly by the patentee or with his consent;

One Brazilian commentator emphasises the role of consent in this provision and makes clear that the requirement that the product be “placed on the market” by the patentee or with his consent, means that it is not sufficient for the product simply to have been manufactured by the patentee or with his consent (and for example placed on the market by a licensee in breach of the terms of their licence)¹⁷⁵. This commentator also notes, however, the fact that where infringement of a patent is provided to constitute a *crime*¹⁷⁶, rather than a civil wrong, it would seem that there is no equivalent bar to effecting parallel importation if the product has been placed on a foreign market by the patent holder or with their consent. Accordingly: “... the patentee is entitled on the basis of Arts. 42 and 43 (iv) to obtain civil measures to prevent parallel importation and to recover losses and damages resulting from such acts, but may not sue the parallel importer in a criminal court”¹⁷⁷.

It must be even more important to have a clear understanding of the nature and scope of the relevant patent exceptions where patent

infringement is provided to be a crime as well as a civil wrong¹⁷⁸.

Likewise China presently has a National Exhaustion exception (although it is the case that a move to an International Exhaustion exception is at least under consideration in the present patent law review process):

Article 63. None of the following shall be deemed an infringement of the patent right:

- (I) Where, after the sale of a patented product that was made or imported by the patentee or with the authorization of the patentee, or of a product that was directly obtained by using the patented process, any other person uses, offers to sell or sells that product;

A variation on a National Exhaustion exception is provided in the case of Nigeria:

6. (3) The rights under a patent—

- (b) shall not extend to acts done in respect of a product covered by the patent after the product has been lawfully sold in Nigeria, except in so far as the patent makes provision for a special application of the product, in which case the special application shall continue to be reserved to the patentee notwithstanding this paragraph¹⁷⁹.

Notwithstanding this provision, it has been argued that an International Exhaustion exception is implicitly present in Nigeria such as to permit the parallel importation of products sold elsewhere by the patent holder or with their consent¹⁸⁰.

An interesting example where a country was previously free to choose *either* a National Exhaustion exception or an (unrestricted) International Exhaustion exception (and it has been argued that the latter was provided for¹⁸¹), but whose policy choice is now confined is that of Morocco, following its entry into a Free Trade Agreement with the United States¹⁸² (section 15-19 of the US-Morocco FTA¹⁸³):

- 4. Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory.

Although footnote 10 to this article provides:

A Party may limit application of this paragraph to cases where the patent owner has placed restrictions on importation by contract or other means.

Having said this the US maintains that “The FTA simply reflects current law in the U.S. and Morocco...In fact, in previous FTA negotiations with developing countries that do not have parallel import restrictions in their domestic law (e.g., Central America, Chile, and Bahrain), the final negotiated texts do not contain provisions on parallel importation”¹⁸⁴.

Some point to the provisions of Art 4^{bis} of the Paris Convention (“Independence of Patents Obtained For the Same Invention in Different Countries”; applicable for all Members under Art. 2.1 TRIPS) to demonstrate that only national exhaustion is permissible. A contrary view is that although this provision of the Paris Convention means that patents in different countries must be treated as independent legal instruments from one another (such that, for example, a patent cannot be revoked or caused to lapse simply because a parallel patent in a foreign country has done so) this does not mean that patent rights cannot be affected by events in a foreign country. Accordingly it would still be permissible to exhaust the rights of the patent holder in one country contingent on the *fact* that the patent holder placed the relevant patented product on the market in another country. Another contrary view holds that it is not permissible to maintain purely national exhaustion in the face of supervening GATT/WTO principles¹⁸⁵.

4.8.3 Regional Exhaustion: the MFN principle?

One step beyond the National Exhaustion exception is the Regional Exhaustion exception, famously provided for in the European Community but also within the French speaking countries of Africa party to the Bangui Agreement (Art. 8(1)).

An interesting question is the compatibility of such regional exhaustion with the Most Favoured Nation principle of Art. 4 TRIPS: "With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members".

On the one hand the EC has made a formal declaration confirming that it regards itself as covered by the "grandfather" provision of Art. 4 (d) TRIPS, that is to say that "[Exempted from this [MFN] obligation are any advantage, favour, privilege or immunity accorded by a Member] (d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement [WIPO Note: January 1, 1995] provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members":

"The EU and its member states formally notified the Council for TRIPS on December 19, 1995 that both the EC Treaty and the Treaty Concerning the Establishment of the European Economic Area including the whole of the present and future secondary law of the EU are international agreements within the meaning of this provision [Art. 4(d) TRIPS]" ¹⁸⁶

However, it is curious to note that when the same issue came up in the TRIPS Council review of EC legislation, in response to Japanese Question 19 the EC seemingly responded as follows:

*"The principle of national treatment in Article 3 of the TRIPS Agreement, and most-favoured-nation treatment in Article 4 of the TRIPS Agreement shall not apply to the principle of Communities exhaustion of patent rights, since the latter principle cannot be considered as an "advantage, favour, privilege or immunity" but is rather a limitation or restriction to the rights conferred by the patent. The principle of Communities exhaustion is applicable to all persons and companies (EC or otherwise) holding a patent within the European Communities"*¹⁸⁷.

An interesting question from a policy point of view is whether the exhaustion of rights doctrine could be applied between groups of countries that are economic peers, such as OECD countries, or middle-income developing countries, rather than on a wholly global level, a geographically determined regional level, or simply a national level? Perhaps the latter point of view expressed by the EC would lend support to such a development?

4.8.4 International exhaustion

There are a number of different "flavours" of International Exhaustion exceptions. A more limited form of International Exhaustion exception occurs where it only permits products to be imported if they have been placed on the market by the patent holder or with their consent in another country with no conditions on the sale, for example that they may not be exported. Japan, mentioned above in section 2.8.2 is one example. The US and, for example, Morocco (under the US-FTA), mentioned above in this section, provide other examples. A more broad form of International Exhaustion exception occurs where products may be imported if they have been simply placed on the market anywhere in the world by the patent holder or with their consent. An even broader form of International Exhaustion exception occurs where products may be imported if they have been placed on the market anywhere in the world either with the patent holders consent or where the patent holder has at least been

adequately remunerated for that first sale, for example under a compulsory licence.

The Malaysian International Exhaustion exception (under s.37 of the Malaysian Patent Act) includes elements of a number of these approaches:

- (2) Without prejudice to section 58A, the rights under the patent shall not extend to acts in respect of products which have been put on the market
 - (i) by the owner of the patent;
 - (ii) by a person having the right referred to in section 38; (iii) by a person having the right referred to in section 43; (iv) by the beneficiary of a compulsory licence within the meaning of section 48.

Only one limb of this International Exhaustion exception (under s.37(2)(i)) has however been examined in a Malaysian case so far. VC George J of the Malaysian High Court applied common law principles to find that the acts of parallel importation complained of by the plaintiffs did not infringe their patent, as the plaintiffs had not included clear notice on the packaging of the medicine products when sold in the UK that they could not be exported in this way¹⁸⁸.

The Indian provision of the International Exhaustion exception (Section 107A of the Indian Patent Act) was recently amended to broaden it from the “consent” form to the wider form.

107A. Certain acts not to be considered as infringement. - For the purposes of this Act -

- (b) importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights”

The relevant amendment changed “from a person who is duly authorised *by the patentee* to sell or distribute the product” (italics added) to the present form: “ from a person who is duly authorised *under the law to produce* and sell or distribute the product” (italics added)¹⁸⁹.

This clearly includes production under a compulsory licence. It might be argued that “duly authorised” requires specific positive permission, either from the patent holder or the government?

An example of a provision which seemingly goes beyond even the “compulsory licence” position is provided by Kenya under the Industrial Property Act 2001:

58.—(2) The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.

This International Exhaustion exception is apparently not limited to products put on the market with the consent of the proprietor, or even products put on the market under a compulsory licence. It would appear that, on the face of it, this provision would allow *any* product, whether “branded” or generic, to be imported and used or sold in Kenya without the patent holder having any recourse. Whether the provision would be interpreted quite this widely by a Kenyan court remains to be seen.

A dispute arose between the US and Argentina over a number of aspects of Argentinian intellectual property law, of which the Argentinian International Exhaustion exception was one element. At the time the relevant provision seemingly embraced both the “consent” and compulsory licence forms of the provision. Paragraph 3 of a 2002 Mutually Agreed Solution¹⁹⁰ provides that:

“The Governments of the United States and Argentina have analyzed article 36(c) of Law No. 24.481 and article 36 of Decree 260/96 in light of the provisions of Articles 6 and 28.1 of the TRIPS Agreement. Pursuant to this analysis, Argentina has confirmed that, according to its law and regulations, the owner of a patent granted in the Argentinean Republic shall have the right to prevent third parties not having the owner’s consent from the acts of making, using, offering for sale, selling or importing

the patented product in the territory of Argentina. However, a voluntary licensee in Argentina authorized by the Argentinean patent owner to import the patented product may import the product if he proves the product has been put on the market in a foreign country by the owner of the Argentinean patent or by a third party authorized for its commercialization. On this basis, Argentina and the United States agree that article 36(c) of Law No. 24.481, read in conjunction with article 36 of Decree 260/96, is consistent with Argentina's obligations under the TRIPS Agreement."

It is noteworthy, given that this Mutually Agreed Solution was entered into after the Doha Declaration on TRIPS and Public Health (explicitly affirming that Members are free to choose whichever exhaustion regime they wish), that the US would appear to have forced Argentina into recognising a very limited form of Exhaustion exception, seemingly a National Exhaustion exception (given that paragraph 3 refers to a "voluntary licensee")? Having said that, Article 36 of the Argentinian patent law now seemingly provides that

The right conferred by a patent shall have no effect against:

- (c) any person who acquires, uses, imports or in any way deals in the product patented or obtained by the patented process once the said product has been lawfully placed on the market in any country; placing on the market shall be considered lawful when it conforms to Section 4 of Part III of

the Agreement on Trade-Related Aspects of Intellectual Property Rights;

Section 4 of Part III of TRIPS relates to Border Measures and footnote 13 to Art. 51 TRIPS in that section, explicitly indicates that these Border, or Customs Authority, Measures need not be applied to "...imports of goods put on the market in another country by or with the consent of the right holder...". This would seemingly provide for an International Exhaustion exception based on the standard theory of "consent"?

4.8.5 Comment

Although National Exhaustion exceptions seem to be widely accepted, and the Regional Exhaustion exception adopted by the EC has remained unchallenged by other Members, there remains a great deal of contention over International Exhaustion exceptions. It is not possible to imagine a more clear statement affirming that Members are free to choose whichever form of exhaustion of rights regime best suits them than paragraph 5(d) of the Doha Declaration and yet the US, in particular, is using every available opportunity to force other Members not to adopt unrestricted International Exhaustion exceptions, whether through bilateral disputes, as with Argentina, or through Free Trade Agreements, as with Morocco.

Another legislative review (concentrating on classes of exceptions rather than their specific type) found that of 48 countries, 13 plus the Bangui Agreement countries provided for only national or regional exhaustion, and the remaining 14 plus the Andean Pact countries provided for international exhaustion¹⁹¹.

4.9 Regulatory Review exception

4.9.1 OECD countries

For obvious reasons in the light of the *Canada-Generics* dispute above, one of the important examples of the adoption of a Regulatory Review exception is that of Europe. To a great extent the impetus for this came as the result of a number of Eastern and Central European countries joining the European Union. Countries

such as Hungary and Poland had already adopted a Regulatory Review exception, indeed Poland was one of the countries making a third party submission in support of the Canadian position in the *Canada-Generics* case. There was already a significant degree of variation in what the existing Member States thought was acceptable under the Experimental Use exception, notably

Germany already having gone a long way down the road to permitting the sorts of activity that is enabled under a separate Regulatory Review exception¹⁹². Nevertheless, there was evidently a degree of pressure from the EU negotiators for the accession states to abandon their position and join an apparently common European position rejecting the Regulatory Review exception. The accession states prevailed, on this point at least, and Europe has now adopted its very own Regulatory Review exception. Following a recent amendment of EC pharmaceutical legislation¹⁹³ provision was made under Art. 10(6) (permitting an applicant for marketing approval of a generic version of a earlier “reference” medicine that has already been registered, to refer to the data submitted in respect of that reference medicine) as follows:

“Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products”

The last sentence points up an interesting issue. Europe had in fact adopted a measure to permit the extending of the lifetime of a patent, the Supplementary Protection Certificate (SPC), before it adopted a Regulatory Review exception. The justification given for the SPC system was, as usual, that it merely restored to the owners of patents relating to pharmaceutical patents the time taken in the regulatory process in order for them to be approved to market their products.

The issue of the protection of the data resulting from these tests and trials was noted above. One maximalist interpretation of Art. 39.9 TRIPS calls for patent-like exclusive rights over the data relating to a new medicine for a period of time typically varying between five and ten years (although three years in respect of new medical indications of known medicines, rather than new medicines *per se* is also known). This is called “data exclusivity”. In this European

legislation, data exclusivity is provided for under Art. 10(1) such that a generic medicine whose application for regulatory approval relies on such “reference” data may not be placed on the market less than 10 years after the approval of that original product.

An interesting recent development in the US, especially given the very narrow interpretation of the Experimental Use exception found by the Court of Appeals for the Federal Circuit (CAFC) in *Madey v. Duke University* as discussed above, is the broadening (or the confirmation of the broadness) of the Regulatory Review (“Bolar”) exception by the Supreme Court in *Merck v Integra*¹⁹⁴. Pharmaceutical companies investigate a great many compounds that do not turn out to have eventual application as medicines. Merck KGaA (not the same entity as Merck Inc) investigated some compounds patented by Integra Lifesciences but did not proceed with them further as they showed no promise for the indication that they were interested in. Integra filed suit against Merck for patent infringement. The question in this case was whether the Bolar exception only covers activity relating to a compound for which regulatory approval is actually sought, or whether it covers activity relating to any compound for which it could reasonably be believed that regulatory approval could be sought. In a unanimous opinion, the Supreme Court came down firmly on the side of the latter view, thus confirming that the scope of the Bolar exception is such as to embrace both pre-clinical and clinical research. However the Supreme Court expressly declined to rule on the issue of whether the use of “research-tool” patents could also be embraced within the Bolar exception.

4.9.2 Non-OECD countries

Recent examples of the adoption of Regulatory Review exceptions in the larger and more sophisticated developing countries are also easy to come by. It seems to be the case that these implementations of the Regulatory Review exception adopt the (WTO approved) Canadian form of the exception, permitting activity for regulatory review in foreign countries as well,

rather than the domestically limited US form. For example, in India:

107A. Certain acts not to be considered as infringement. - For the purposes of this Act -

- (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force in India, or in a country other than India, that regulates the manufacture, construction, use, sale, or import of any product;

Likewise in Brazil:

"The research exemption was further clarified by Law 10.196/01 of 14 February 2001 that exempts: acts aimed exclusively at producing information, data and results of tests, intending to obtain marketing approval, in Brazil or in another country, for the exploitation and commercialisation of the patented product after expiry of the patent term." (italics added)¹⁹⁵

And in Egypt:

Article 10

The following shall not be considered as infringements of that right when carried out by third parties:

- (5) Where a third party proceeds, during the protection period of a product, with its manufacturing, assembly, use or sale, with a view to obtain a marketing license, provided that the marketing starts after the expiry of such a protection period.

The situation is less clear in China. Certain measures relating to regulatory review have also been provided for in the Chinese Drug Regulation legislation, indicating that applications for the registration of generic versions of patented medicines may take place during a period of two years before the expiry of the relevant patent but no explicit provision is made for

shielding the necessary activity from patent infringement. In fact it is reported that this activity has been held to be an infringement under Chinese patent law¹⁹⁶, although the 2003 draft version of the forthcoming SPC note seemingly contemplates permitting it. It is no surprise therefore that comments have been expressed indicating the need for a more formal Regulatory Review exception to be provided in China¹⁹⁷.

Under section 54(1) of the Industrial Property Act 2001 Kenya has now introduced a Regulatory Review exception in its patent legislation.

By contrast, for example, it would appear that Ghana has not yet introduced a Regulatory Review exception in its patent legislation¹⁹⁸. Likewise, it is not clear that any provision has been made in the Bangui Agreement countries for this particular exception (at least up to the last revision of the Bangui Agreement in 1999). Whether the relevant activities could instead be considered to fall under, for example, an Experimental Use exception is perhaps an open question. Another legislative review found that of 49 countries, only 8 explicitly provided for a Regulatory Review exception¹⁹⁹, although for the others it could not be clearly said whether the activity might not be covered by another exceptions, for example, an Experimental Use exception.

4.9.3 Free Trade Agreements

The United States is including terms in recently agreed Free Trade Agreements under which, if a Party provides a Regulatory Review exception, it has to be restricted such that a product for testing cannot be made and exported to another country. This corresponds to the US view of its own "properly crafted" exception. The United States is also including patent term extension requirements to compensate pharmaceutical patent holders for time which is perceived to have been "lost" in the regulatory review process. In this way the US requires its FTA partners to provide the limited exception and "compensation package" that the US arrived at in its domestic arrangements but which the Panel in *Canada-Generics* declined to find

was necessary. Such provisions are found in, for example, the US - Central American Free Trade Agreement (Articles 15.9.5 and 15.10.2) and the US - Morocco Free Trade Agreement (Articles 15.9.6 and 15.10.3).

There are however further provisions in these FTAs providing for data exclusivity rights and patent “linkage” provisions. As discussed above, data exclusivity rights have the effect of providing parallel protection to that provided under the patent system, independently delaying the marketing of a generic version of an originator medicine until, for example 5 or 10 years after the original registration. Such provisions represent an additional threat to a developing country's ability to encourage the early onset of generic competition. Under a patent “linkage” provision, the regulatory authority is, in effect, turned into a patent enforcement agency, as such a provision prevents that authority from granting regulatory authorisation to a generic medicine where there is believed to be a relevant patent in existence. Of course, these processes are conceptually separate. The regulatory authority is supposed to deal with medicine safety and efficacy issues and intellectual property judicial or administrative entities to deal with intellectual property rights validity and infringement issues.

4.9.4 Comment

It can be no surprise that a number of developing countries, and certainly those with sufficient domestic pharmaceutical resources, have adopted a Regulatory Review exception. The approval of this exception by the Panel in *Canada-Generics* was an important event for public health in many developing countries. Policy makers in those developing countries will be wise to ensure that the manner in which they implement and operate their Regulatory Review exception best meets the needs of the country. They may well find it convenient, for example, to follow the recent example of the US in *Merck v. Integra* and ensure that their exception covers both pre-clinical and clinical research (to the extent perhaps that their Experimental Use exception does not already cover this).

However, these countries ought to be aware that certain developed countries are actively trying to restrict their ability to initiate competition between branded and generic medicines at the earliest date, and not only through limitations on this exception. Should they, for example, enter into a Free Trade Agreement with the US it is highly likely that they will be required to limit themselves to the US version of this exception, to extend the term of pharmaceutical patents to make up for the time medicines spend in the regulatory system and to introduce data exclusivity rights over, for example, clinical trial data (none of which is required by the TRIPS Agreement). In stipulating these requirements the US will point to the increased incentive for R&D investment that the strengthened exclusive rights will supposedly bring²⁰⁰. This may be acceptable to some developing countries and indeed some countries have introduced such protection even without being a formal US FTA partner. However, for others it will be a serious concern as they try to focus more on trying to gain access to existing IP protected pharmaceuticals.

The percentage increase in the global pharmaceutical IP protected market that results from introducing US FTA style protection in a poor developing country will be *negligible* (i.e. when such a country is added to the market of the OECD and likely that of more wealthy developing countries). The impact on the vast majority of the population of that country however will likely be *immense* in terms of delaying by some years their ability to benefit from generic competition. Policy makers therefore need to weigh very carefully the decisions they make as regards entering into such negotiations.

As with the Experimental Use exception above, empirical data on the use of this exception in developing countries will likely shed interesting light on the underlying developmental activity and increasing technical capabilities of these countries.

4.10 Medical practitioner exception

Relevant Policy area: Public Health

The question of whether or not medical practitioners ought to be subject to the rigours of the patent system is a long standing one, as discussed above in section 2.4. Granting patents for methods of medical treatment is currently an optional matter under Art. 27(3)(a) TRIPS but a number of Members, notably the US does do so.

American doctors were apparently scandalised even back in the 1930s by the grant of, for example, the Morton patent on ether: “The discovery of the anesthetic properties was considered of such fundamental importance to the public that physicians resented any restrictions on its use”²⁰¹. Nevertheless, the US has steadfastly maintained the potential patentability of methods of medical treatment in the intervening period. More recently, in the early 1990s, American doctors were reportedly scandalised anew over the case of *Pallin v Singer*²⁰², where an attempt was made to enforce a medical method patent. Samuel L. Pallin M.D. was granted a US patent²⁰³ relating to a particular form of incision for use in cataract surgery. Dr Pallin filed suit to prevent others, in the first place Jack A. Singer M.D., from utilising the patented medical technique unless they paid a royalty fee of several thousand dollars per year²⁰⁴. In the event Dr Pallin was unable to press home his claims, not least because significant portions of the patent were invalidated and he eventually agreed not to enforce the remainder. Nevertheless, the uproar from the medical profession was such that legislative action was taken and a new patent exception created to shield medical practitioners (and, for example, the hospital employing them) from patent infringement when carrying out “pure” medical methods²⁰⁵. This exception would therefore cover an act such as making a surgical incision at a particular location but would not cover the use of a patented tool for making that same incision. Neither does the exception cover “the practice of a process in violation of a biotechnology patent”.

An issue that was discussed above in section 2.4 but which is worth highlighting again here is that the balance that the US has chosen with this exception is one which very much reflects its own circumstances. Medical tools and techniques are broadly patentable in the US, intended to encourage as much investment in R&D as possible. The provision of this narrow exception means that those practising the noble art of medicine will not have their professional ethics offended against when carrying out medical treatment techniques, presumably on the assumption that their patients are able to afford the patented tools and interventions that they want to use in that technique (which is obviously not true of all such patients). The situation may be very different in a developing country. There are many reasons why a given patient may not receive the treatment they need but one important element is the price of medicine, and an important factor in that is the patent status of the medicine and whether there is competition between the branded medicine and comparable generic versions. The professional ethics of a medical practitioner in a developing country may be very much offended against if, irrespective of the status of a medical technique *per se*, as the result of a patent issue they *can't* afford to use the tools which they would need to. It is an obvious point, further to the discussion in the section above, that those pushing for US standard IP protection in developing countries should not be surprised that they have received the same or greater uproar from the medical profession (and from the public) in those countries as happened in the US (not that that will likely divert them much - the United States Trade Representative's (USTR) office firmly opposed even its own Medical Practitioner exception in the first place²⁰⁶). No doubt the debate will continue in the US and other OECD countries, with forces pushing strongly both for and against this exception.

The recent review of Australian patent law and policy by the Australian Law Reform Commission (ALRC) examined this American

Medical Practitioner exception, especially in the context of gene patenting²⁰⁷. The relative merits of the American and European approaches were compared, viz allowing medical method patents with an exception for medical practitioners or excluding medical methods from patentability. The ALRC was inclined more toward the US approach as, like the US, Australia permits the grant of medical method patents. The ALRC also indicated that this approach would be the preferable one from the point of view of encouraging R&D investment. One important point noted by the ALRC was that whereas the exclusion from patentability under Art. 27(3)(a) TRIPS only tends to cover medical methods practised on the human or animal body, an exception would have a greater degree of flexibility in being able to target either *in vivo* or *in vitro* techniques. The ALRC noted similar proposals in other jurisdictions, including a proposal from an OECD working party for a patent exception relating to “clinical use”, although difficulties were flagged in terms of distinguishing clinical from commercial use²⁰⁸. Their preliminary conclusion on this issue came in the form of a question rather than a recommendation: “In the absence of a general defence relating to medical treatment, should the Patents Act 1990 (Cth) be amended to enact a new defence to claims of patent infringement based on the use of genetic materials and technologies in diagnostic or therapeutic treatment?”.

In terms of its TRIPS consistency, as the ALRC has also noted, the US was asked by the EC to justify the enactment of this provision during the TRIPS Council review of the American patent law:

“8. Recent amendments to 35 U.S.C. 287, via the inclusion of new subsection (c), provide exemptions from infringement liability, and hence in effect a compulsory and royalty-free licence, to physicians, other licensed medical practitioners and related health care entities including hospitals, universities, medical schools, nursing homes and clinics for the practice of patented medical activities. Please explain how these provisions comply with the TRIPS Agreement (notably Article 31).

The term “medical activity” as used in section 287(c) is defined as “the performance of a medical or surgical procedure on a body”.¹¹ Expressly excepted from the definition of medical activity is the use of a patented machine, manufacture, or composition of matter in violation of the patent; the practice of a patented use of a composition of matter in violation of a patent; or the practice of a process in violation of a biotechnology patent. The exception in 287(c)(1) does not apply to activities in connection with commercial enterprises of operations. The effect of the provision, therefore, is very limited, and is designed to ensure that doctors performing life saving or health enhancing medical or surgical procedures are not inhibited by fear of lawsuits for patent infringement.

Article 30 of the TRIPS Agreement authorizes Members to provide limited exceptions to the exclusive rights conferred by a patent so long as those 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 account of the legitimate interests of third parties. The United States of America believes that the provisions of section 287(c) fall within the limited exception authorized by Article 30 of the TRIPS Agreement.”

It is interesting that the EC chose to characterise this measure in the way that they did, viz, a compulsory and royalty free licence. It is conceptually not significantly different from the EC’s own Pharmacy exception, which it seems uncontentious to describe as a valid patent exception. It is no surprise therefore that the US characterises this Medical Practitioner exception in the same way, as a valid patent exception under Art. 30 TRIPS.

Although it is optional under the TRIPS to grant patents for methods of medical treatment, it would appear that, once that decision is made, there are no reasons to treat an Art. 30 TRIPS exception to the rights under one of these patents any differently from any other exception i.e. more extensive exceptions cannot be provided from those patent rights

which are only optionally granted compared to those which have to be granted. It is therefore again pertinent, given that the US has justified this exception as an Art. 30 TRIPS exception,

to consider how this Medical Practitioner exception compares with the test laid down for a “limited” exception in *Canada-Generics*.

4.11 New Variety Breeding and Farmers Privilege exceptions?

Relevant Policy area: Agriculture / Food

4.11.1 Introduction

The concept of the intellectual property protection of living matter has thrown up a number of challenging issues. Obvious problems arise with the notion of an “invention” when considering living matter, and with issues such as the manner in which living matter is produced, or rather re-produced and with the stability of that reproduction.

The case of the protection of plant varieties in an interesting one inasmuch as it illustrates a number of protection regimes parallel to the patent system but nevertheless sharing similar concerns over the extent of accorded rights and exceptions to those rights.

As the twentieth century moved along, a transition could be observed in how plant varieties were treated. To a great extent, plant genetic resources had been seen as part of the Common Heritage of Mankind, free for all to share. However, regimes of exclusive rights have since developed, whether in terms of private entities holding rights over specific plant varieties, or more broadly, countries being accorded rights over the genetic resources included within their borders.

4.11.2 Private exclusive rights: Sui generis protection systems

As to the first of these, hesitant steps were made in the twentieth century for the intellectual property protection of plant varieties²⁰⁹. Instead of stretching the international patent system to accommodate plants however, the main international instrument of protection that was agreed upon was the Convention relating to the *Union Internationale pour la Protection des Obtentions Végétales* (the “UPOV” convention, 1978, revised 1991). Art. 14 (a) UPOV Convention

accords exclusive rights as follows: “Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorisation of the breeder: (i) production or reproduction (multiplication); (ii) conditioning for the purpose of propagation; (iii) offering for sale; (iv) selling or other marketing; (v) exporting; (vi) importing; (vii) stocking for any of the purposes mentioned in (i) to (vi) above”. Under Art. 19 UPOV Convention the term of these rights is 20 years, or 25 years in the case of trees or vines (it is an interesting and important feature of plant protection systems that the protection accorded often varies depending on the particular type of plant being discussed). Art 15 UPOV Convention provides for “Exceptions to the Breeder’s Right” such that:

- (1) [Compulsory exceptions] The breeder’s right shall not extend to
 - (i) acts done privately and for non-commercial purposes,
 - (ii) acts done for experimental purposes; and
 - (iii) acts done for the purpose of breeding other varieties, and except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties.
- (2) [Optional exception] Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of legitimate interests of the breeder, restrict the breeder’s right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14(5)(a)(i) or (ii).

A clear parallel is seen with the patent system in respect of the mandatory exceptions to the breeder's rights. The exception of Art. 15(1)(iii) is perhaps similar, in terms of the patent system, to the provisions on Art. 31(l) TRIPS, on dependent inventions, i.e. as a compulsory licence matter, rather than an exception *per se*. The optional exception of Art. 15(2), known as the "farmer's privilege" arises from the ability of plants to seed and reproduce. Farmers will certainly benefit from this provision but it is often observed that this is only a just recompense for the contribution that they make to preserving biodiversity. Seed suppliers will clearly not be so well disposed toward this exception as farmers. They reportedly prefer to focus their attention on developing seeds of a hybrid variety which are "naturally" incapable, or less capable, of reproducing, or more recently of a genetically manipulated variety which is "artificially" incapable of reproducing (Genetic Use Restriction Technologies (GURTS)). In either of these latter cases, farmers will have to return to the seed supplier for each new years seeds. Of course, it may be in the more intensively mechanised farming taking place in many countries today that this is the only practical option, gathering seeds for successive years crops not being an "industrially" efficient process, and factors such as market demand, competition and climate change perhaps driving a need to change the varieties grown over a period of some few years. Nevertheless, in some areas this farmers privilege may instead be a matter of food security rather than economic efficiency.

Art 16(1) UPOV Convention provides for the "Exhaustion of the Breeder's Right".

When the TRIPS Agreement was negotiated, no decision was made as to whether such plant varieties ought to be protected under the patent system, or under a system such as the UPOV Convention. Art. 27(3)(b) TRIPS provides:

[3. Members may also exclude from patentability:]

(b) plants and animals other than micro-organisms, and essentially biological

processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Although the UPOV Convention is perhaps the leading *sui generis* arrangement, it is not the only one. A Model Code prepared by the Organisation for African Unity (OAU) provides for an alternative model, strictly rejecting patenting as an alternative (Art. 9 Model Code). A commentary on the OAU Model Code indicates that:

African countries are increasingly rejecting UPOV 1991, as it has proved to be a tool for allowing foreign monopolies over local biodiversity. The OAU's Model Law thus includes Plant Breeders' Rights formulated so that Africa's long tradition of community innovation and breeding is not undermined by the new norms of commercial breeding and innovation, largely by foreign interest groups and/or for foreign markets. This meets the obligations of TRIPS 27 3(b) for a *sui generis* option, while not undermining the obligations under the CBD to the majority of Africa's population.

Where patents over living matter are concerned, generally speaking, patents are regarded as being more restrictive than such *sui generis* systems in terms of such crucial matters as farmers being able to save their seeds and breeders being able to breed new varieties from protected varieties. However, there is no reason why a "Farmer's Privilege" exception and a "New Variety Breeding" exception to patent rights might not be contemplated, for example:

Countries that have, or wish to develop, biotechnology-related industries may wish to provide certain types of patent protection in this area. If they do so, specific exceptions to the exclusive rights, for plant breeding and

research, should be established. The extent to which patent rights extend to the progeny or multiplied product of the patented invention should also be examined and a clear exception provided for farmers to reuse seeds²¹⁰.

4.11.3 States' exclusive rights: the 1992 United Nations Convention on Biodiversity (CBD)

Particularly since achieving independence, many developing countries have been concerned about their ability to assert sovereign control over natural resources such as oil, gas and mineral deposits. A more recent development relates to their ability to assert sovereign control over the resources associated with their biodiversity i.e. their genetic resources. Where States are accorded exclusive rights it is interesting to compare the very similar issues arising, as with any exclusive rights regimes, over the extent of the rights and exceptions to the rights²¹¹. The United Nations Convention on Biodiversity (CBD) provides that, Art. 15(1): "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with national governments and is subject to national legislation". A tension therefore arises between the rights of the States Parties, accorded control over these resources, and private parties wishing to explore and exploit these resources. This important issue, and subsequent developments involving for example the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) need not be reviewed here but it is sufficient to note that concerns have been raised, in like fashion with those of the patent system, to ensure that reasonable exceptions, for example, permitting research are provided²¹².

4.11.4 European Biotech Directive: Farmers Privilege exception

A European Directive of 1998 dealt with the legal protection of biotechnological inventions. One example of a Farmers Privilege exception is provided in the UK implementation of this Directive, Section 60(5) of the UK 1977 Patents Act:

An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if -

- (g) it consists of the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, where there has been a sale of plant propagating material to the farmer by the proprietor of the patent or with his consent for agricultural use;
- (h) it consists of the use of an animal or animal reproductive material by a farmer for an agricultural purpose following a sale to the farmer, by the proprietor of the patent or with his consent, of breeding stock or other animal reproductive material which constitutes or contains the patented invention.

Under Schedule A1 to this Patents Act the operation of the plant related exception is subject to particular conditions including a limitation of eligibility to only 25 named plant species and groups (including for example Oats, Barley, Rice, Rye and Wheat). Most interestingly perhaps is the fact the operation of the exception is made subject to *compensation* such that Farmers who are not "small Farmers" must pay "equitable remuneration" which is (Schedule A1, sections 3 & 4): "...sensibly lower than the amount charged for the production of protected material of the same variety in the same area with the holder's authority".

This example of a patent exception with remuneration will be discussed again below.

There is no such counterpart to Schedule A1 in the animal related exception.

4.11.5 Developing countries

Developing countries have been long concerned about these policy issues, given both the need to assure food security for their populations and the importance of agriculture as a commercial sector in their economies. As noted above however they may often be treated as a matter for *sui generis* protection systems rather than patent matters. However, examples of related patent exceptions are not hard to find.

Under Article 53 of Decision 486 of the Andean Pact (comprising Bolivia, Colombia, Ecuador, Peru and Venezuela: see, for example, the TRIPS Council review of Peruvian patent legislation), a non-plant New Variety Breeding exception, albeit with some limitation, is provided:

[...a patent owner may not prevent third parties not having his consent from engaging in the following acts in relation to a patent:]

- (e) where the patent protects biological material that is capable of being reproduced, except for plants, using that material as a basis for obtaining a viable new material, except where the patented material must be used repeatedly to obtain the new material.

Under Brazilian law, a New Variety Breeding exception limited in a different way is provided (along with an implementation of a related exhaustion provision):

Article 43: The provisions of the previous article do not apply:

- (v) Third parties who, in the case of patents related to living matter, use, with no economic purposes, the patented

product as the initial source of variation or propagation for obtaining of other products; and

- (vi) Third parties who, in the case of patents related to living matter, use, market or sell a patented product that has been lawfully introduced onto the market by the patentee or its licensee, provided that the patented product is not being used for commercial reproduction or propagation of such living matter.

It may be that the limitations on these exceptions are intended to keep the covered activity restricted to non-commercial activity, for the reasons noted above having regard to the alternative of compulsory licensing (or at least compensation)^{213?}

It would appear that Kenya has provided an exception which is aimed in a similar way, albeit directed at the end product.

Limitation of Rights

58.—(6) The rights of the patent shall not extend to variants or mutants of living forms or replicable living matter that is distinctively different from the original for which patents were obtained where such mutants or variants are deserving of separate patents.

4.12 Teaching exception

Relevant Policy area: General

At least some elements of an exception for

teaching purposes are provided in the Brazilian, Indian and Argentinian Experimental Use exceptions, discussed above.

4.13 “Catch-all” provisions

Another important issue is the manner in which new exceptions can be adopted. For most Members it will likely be a matter of explicit legislative activity, or perhaps somewhat speculative development through case law. However, there are perhaps alternative routes for the adoption of new exceptions. For example, Argentina has a provision which permits the delegation of authority to adopt new exceptions:

Article 41

The National Institute of Industrial Property may, at the reasoned request of a competent authority, introduce limited exceptions to the rights conferred by a patent. Such exceptions shall not unjustifiably prejudice the exploitation of the patent or do unjustified harm to the legitimate interests of the owner thereof, due account being taken of the legitimate interests of third parties.

Egypt has a general provision in its legislation repeating the terms of Art. 30 TRIPS, presumably permitting new exceptions to be adopted as a matter of case law.

The following shall not be considered as infringements of that right when carried out by third parties:

- (6) Any other acts by third parties, provided that they shall not unreasonably hamper

the normal exploitation of the patent, and shall not be unreasonably prejudicial to the legitimate interests of the patent owner, taking into consideration the legitimate interests of others.

It is interesting to note, in the light of the discussion in section 3 above of the importance of the term “limited” in Art. 30 TRIPS in the *Canada-Generics* decision, that this provision apparently omits the term.

4.14 Incidence of use of exceptions to patent rights

It is obviously important, from a global policy perspective, to know which countries have availed themselves of which exceptions, and to have an idea of how broad or narrow they are likely to be. However, it is submitted that another important issue which has received rather less attention than either of these two issues, is that of the incidence of use of the exceptions that countries do have.

Where the economic activity in a given developing country is at a very low level, there will perhaps be little incentive for patent holders to bring suits for patent infringement. As the level of activity grows however, there will come a point where it will be judged worthwhile. For the larger, more sophisticated and wealthy developing countries, patent infringement suits may be brought either in terms of protecting the domestic market, or in terms of cutting off the supply of manufactured products, for example pharmaceutical products, from that country to others. This is obviously a matter of great concern from, for example, a public health perspective. For developed countries, there will be considerable incentive to bring suit. The more likely litigation is, the more important patent exceptions are likely to be. Where the boundaries of a patent exception are clear, that exception may be used *implicitly* by those sheltering in the safe harbour it affords. However, where the boundaries are not clear and/or where the patent holder believes the activity being carried out is not covered by the exception, they may sue, and the exception may be used *explicitly* as a defence to patent infringement.

Monitoring the incidence of use of exceptions, for example in reported case law (for those countries that do report case law), may give an interesting insight into the state of the underlying economy. For example, as has been touched on above, for those developing countries with significant technical capabilities, it might be expected that litigation over the Experimental Use and Regulatory Review exceptions may be beginning to take place as the boundaries of the exception are explored. By contrast for poor developing countries, especially LDCs, there may be little such activity. Litigation over the Prior Use exception might be expected as the financial stakes in the domestic market of growing developing countries rise. For those countries where biotechnological agriculture forms an important part of a growing economy, litigation over the Farmers Privilege or New Variety Breeding exceptions might be expected. It would be interesting for policy makers and other observers to have access to such information, in terms of making judgements about how the patent system mandated under the TRIPS Agreement is working out.

It is surprising therefore that so little systematic information on the topic of the incidence of patent litigation in developing countries and the use of patent exceptions seems to be available. Although there are some sources of information, including case law reports, they tend to be rather *ad-hoc*. Entities which are in habit of collecting information about the patent system such as Patent Offices tend not to focus too much on post-grant matters. It would seem that perhaps

the most likely repository of this information, WIPO, does not have any systematic data either. This may well be understandable in terms of the difficulty of collating the information. It is striking that, when the US asks for information on patent enforcement as part of the TRIPS Council review of Members' legislation ("Please provide statistical information related to civil copyright, trademark, geographical indication, industrial design, patent, integrated circuit layout-design, and trade secret enforcement for 2000, including the number of cases filed; injunctions issued; infringing products seized; infringing equipment seized; cases resolved (including settlement); and the amount of damages awarded"; there is an equivalent for criminal matters.)²¹⁴, the answer has quite often been that no such data is collected, or that the data is collected but for some reason not available.

Pending a more full enquiry on this topic though, a few pointers can be gleaned from high level reports on the incidence of patent litigation in a few given developing countries.

For example, it is interesting to note the significant number of patent cases that are now being filed in China. Although the following figures include patents, utility models and design rights, it is remarkable to note that some 12580 cases classified as involving a "patent right" were received for first instance trial in the local courts in China between 1998 and 2004, of which 12058 have been concluded²¹⁵. As has been noted above, specific case law on, for example, the Chinese Experimental Use and Prior Use exceptions has been reported and analysed, and journals dedicated to intellectual property developments in China will no doubt continue this work. This must be taken as a clear indication, as if any were needed given the impact that the Chinese economy is now having on the world, that intellectual property in China has already passed through a developmental threshold such that the financial consequences of where the boundaries of patent exceptions are drawn do matter and are worth litigating over. It is therefore even more important for Chinese policy makers to get the balance right.

Brazil is another interesting example:

"In the past five years, the number of new court actions aimed at enforcing patent rights has substantially increased. While in 1997, 80 new patent actions were filed before the Brazilian Courts, in 1999 there were 200 new filings and in 2001 more than 100. These numbers are substantially higher when compared with the last decade...There are several reasons for an increase in court actions, including the development of the local market, the significant improvement of the economic situation of the country, the enactment of the new Industrial Property Code (IPC) in 1997 and the TRIPS Agreement. In fact, these new legal tools for enforcing patent rights in Brazil are definitely encouraging patent holders to litigate for the protection of their rights and for claiming monetary compensation for infringement. This new tendency is also leading the Brazilian Courts to be more thorough when analysing patent infringement cases. For instance, in 2001, the Brazilian Courts in 83% of the decided cases found the patents at issue valid and infringed where the patent owners were foreign companies. This percentage shows that the Brazilian Courts take a very pro-patent view when deciding patent infringement cases".²¹⁶

The case of India is also interesting but perhaps for a different reason, the incidence of litigation on patent exceptions being seemingly very low. Unlike China and Brazil, India took full advantage of the TRIPS Agreement transitional provisions allowing it to put off patenting pharmaceutical products until 1st January 2005. It is therefore arguable that there may have been somewhat less pressure to need to use patent exceptions such as the Experimental Use exception as the full rigour of medicine patents, which is one of the most important areas of patent protection in developing countries, had not yet descended. At their 2003 TRIPS Council review, India responded to the US statistical information question as follows:

“Statistical information in respect of injunction, infringements, seizures, cases resolved, etc. are not maintained by the IP Offices in the country since they fall under the purview of the Civil and Criminal justice system and are administered in various different courts in the country. This information is not compiled centrally.”

Given that India has now moved to a new regime, it is no surprise that India has recently adopted a Regulatory Review exception. No doubt the incidence of patent litigation, and the importance of patent exceptions, will increase across all technical fields (potentially including, for example, computer software, depending on how the Indian provisions in this area develop or are applied) as the Indian economy continues to grow. Indian companies are not notably shy of litigating in, for example, the US market.

A number of other Members responded to the US statistical information question in much the same way, for example: Ghana (“The current Copyright Law provides civil, criminal and arbitration settlement remedies for copyright infringement. The stakeholders as well as the Copyright Office and the Law enforcement agencies ensure that the law is enforced. However data in this area is yet to be compiled.”), Kenya (“Although a number of cases were filed in court in the year 2000, the

exercise of compiling the requested statistics is not yet complete. The requisite information will be provided as soon as the information is available.”), Nigeria (“Still liaising with relevant government agencies for statistical details.”) and Sri Lanka (“The statistic information is not available for the time being. The incidence of infringement is very low.”)

Others however did provide some data, for example: Jamaica (“Approximately four cases involving copyright issues were initiated in the Supreme Court in 2000 and about two cases related to trademark infringements were initiated in the Supreme Court.”) and the Philippines (“The Task Force on Anti-Intellectual Property Piracy of the Department of Justice reported that for the year 2000, there were a total of four hundred fifty-one cases filed and acted upon, of which 85 cases or 18.81% were filed in Court and on-going trial, 75 cases or 16.61% were dismissed, 97 or 21% were still being investigated while 194 cases or 43% were referred to prosecution offices for various reasons including that they are not intellectual property right violation cases.”)

Naturally there are resource limitation issues involved in many of these cases, not to mention best use of those limited resources. Nevertheless, this issue must surely merit further investigation.

4.15 Conclusions

This brief review of State practice as regards exceptions to patent rights under Art. 30 TRIPS reveals a rich variety of developments.

Exceptions that were well known at the time of the TRIPS Agreement continue to evolve:

- In some cases the scope of an exception has narrowed through judicial decisions, for example, that of the US Experimental Use exception.
- In some cases the scope of an exception has been forced to become more narrow or to remain narrow through, for example, a bilateral dispute such as that between

the US and Argentina which narrowed Argentina’s International Exhaustion exception, or a bilateral agreement such as the Free Trade Agreement between the US and Morocco which required Morocco to maintain only narrow Regulatory Review and International Exhaustion exceptions.

- In some cases the scope of an exception has broadened through judicial decisions, for example, that of the US Regulatory Review exception.
- In some cases the scope of an exception has been broadened through legislation to address economic policy issues,

for example, the Indian and Kenyan International Exhaustion exceptions.

- In some cases, an exception has been broadened through legislation to embrace continuing technological change, for example, the US Foreign Vessels exception being widened to include spacecraft so that US patents will not interfere with the launching of foreign satellites.
- In some cases, due to legal and political developments, an exception has been adopted on the basis of a foreign model, for example, the adoption of a Regulatory Review exception by the EC following the *Canada-Generics* Panel and the expansion of the EC to include Eastern European states.
- In some cases, it is suggested that an exception thought no longer to have much practical utility may become useful again due to technological changes, for example, the Pharmacy exception and somatic genetic and somatic cell therapies.

Whether in respect of a pre-existing exception or a new exception, uncertainty as to the scope of an exception will likely have a negative impact. This may be particularly so where patent

infringement is criminalised, for example as in Brazil. In an optimal case, a country's patent legislation would be periodically reviewed to ensure that its present form is continuing to operate in the best interests of the country, as is, for example, the case in China. Discrete policy review processes may also be undertaken to address just one problematic area, as in the case of the Australian Law Reform Commission and the Experimental Use and Medical Practitioner exceptions. Monitoring the incidence of use of these patent exceptions may be expected to yield interesting insights into underlying economic and technological changes in developing countries and would assist such a review process. However, this is difficult at the present time however given the lack of systematic empirical data.

New exceptions, to solve new policy problems (typically resulting from the expansion of patentability into a new field) have also been adopted. These new exceptions are summarised in Table 3:

It is particularly interesting that the European implementation of the Farmers Privilege exception includes an element of compensation.

Table 3

Exception to patent right	Nature of policy problem addressed
Business Method Prior Use	Prior users of business methods should be treated fairly vis-à-vis patent holders.
Medical Practitioner	Freedom for medical practitioners to carry out medical treatments
Farmers Privilege	Need for farmers to be able to harvest and re-sow their own seeds
New Variety Breeding	Need for breeders to be able to use present varieties as a basis from which to breed new varieties
Teaching	Freedom to teach students

5. SOLVING POLICY PROBLEMS WITH PATENT EXCEPTIONS IN THE FUTURE?

5.1 Introduction

This concluding section examines the policy space likely now available for Members to adopt new exceptions, in the light of the arguments presented on *Canada-Generics* in Section 3 and the practice of Members reviewed in Section 4. Factors tending to increase that policy space, in particular the possibility of providing compensation under an exception, and factors

tending to decrease that policy space, for example bilateral or multilateral TRIPS-plus agreements, are discussed. Finally, by way of conclusion, a process is suggested for policy makers considering solving a present or future policy problem with an exception under Art. 30 TRIPS.

5.2 Factors permitting a more broad scope of Art. 30 TRIPS exceptions?

What is the proper dividing line between matters that ought to be treated as exceptions to patent rights and matters that ought to be treated as ground for a compulsory licence? Is there such a proper dividing line?

A classical conception of the difference between an exception to patent rights and a compulsory licence might focus on the issues of permission, and compensation. Where an act falls under an exception to patent rights, it is usually the case that no permission, whether from the patent holder or the government, is required for that act to be carried out, and no compensation is due to the patent holder. By contrast, where an act is carried out under a compulsory licence, permission has to have been gained from the government, insofar as a compulsory licence has had to have been applied for, and granted, and “adequate compensation” is due to the patent holder. In the conception of the EC, at least as expressed early on in their representations in *Canada-Generics*, patent exceptions are to be reserved for *de minimus* matters, and compulsory licences for more substantial interferences in the patent holders rights. Is this a reasonable distinction though?

In fact, it seems that it is not possible to make such a clear distinction. Arts. 30 and 31 TRIPS are not explicit on when a matter ought to be treated under one, or the other provision. Art 31 TRIPS applies to situations of “other use” than

Art. 30 TRIPS, but without explicit delineation of one or the other this is not very helpful. It might be argued that where Art. 31 mentions a matter explicitly, for example, making special provision for public non-commercial use, that strongly suggests, or even demands, that that matter be treated under that Article, but this is only an inference rather than an explicit requirement.

An interesting example of an exception which blurs the distinction between these two categories is the Prior Use exception. As noted above, this exception has been referred to as a “statutory licence” rather than a classical exception. It certainly does not entail any compensation. The Regulatory Review exception is another intriguing example of an exception that lies on the border between these two articles. Given the degree of straightforwardly commercial impact on the patent holder that occurs under the Regulatory Review exception, it would be easy to make the case that this matter should be treated under a compulsory licence regime, rather than as an exception. And yet, it is a valid exception. No permission is needed from the government once within the safe harbour of the exception. Crucially, although patent holders were “compensated” in the US with an extension of patent term, this is not a necessary element for the Regulatory Review exception to be valid. So, no compensation need be paid to the patent holder for the activity under this exception either.

If there are exceptions which appear to be licence-like in form, is it conceivable to go a step further and posit an exception where compensation is to be paid (in the sense of royalty payments rather than, for example, the patent term extension seen in Hatch-Waxman or other such measures). The difference between this form of exception and a compulsory licence would be rather narrow, turning largely on the need or otherwise to go through the process of gaining permission. In fact there is no conceptual bar to designing a patent exception which entails compensation to the patent holder. This is of course demonstrated in concrete fashion with the European Farmers Privilege exception discussed in the previous section where Farmers (who are not “small Farmers”) have to pay equitable remuneration.

So, in the future, it may likely be the case that a new exception could be designed which does require the payment of compensation, which might very well allow a broader scope of activity, or a more commercial scope of activity, in terms of offsetting the impact on the patent holder,

than an exception which is not compensated. Conceptually there is little difference between monitoring whether the acts of a third party fall within the scope of a patent exception and whether they fall within the scope of a patent licence. It is not the case, for example, that the Regulatory Review exception is rendered unworkable by being an exception rather than a licence. There will be actionable infringement if the activity falls outside either an exception or a licence.

No doubt there are situations where the adoption of an exception to deal with a given matter could be seen as a sidestepping of the provisions of Art. 31 TRIPS, in bad faith. An example might be if perfectly ordinary compulsory licensing activity were implemented under a compensated Art. 30 TRIPS mechanism. In other cases, there may well be perfectly good policy reasons for wishing to obviate the requirement that the compulsory licence process of seeking, and gaining, permission is undertaken and one example is touched on below.

5.3 Factors forcing a more narrow scope of Art. 30 TRIPS exceptions?

5.3.1 “Non-violation” complaints

The issue of whether or not “non-violation” complaints (under Art. XXIII:1 (b) GATT) ought to be admissible in respect of the TRIPS Agreement is still the subject of some debate. Such a complaint does not involve an explicit violation of a provision of the Agreement but rather involves the “legitimate expectations” of a Member as to what that provision ought to “deliver”. It is clear however that if a dispute of a non-violation character were able to be brought to the WTO in respect of a TRIPS matter such as the issue of patent exceptions under Art. 30 TRIPS, this would very likely have the effect of further constraining Members’ ability to craft exceptions without fear of challenge from other Members²¹⁷.

5.3.2 Bilateral “TRIPS-plus” agreements: Free Trade Agreements?

It is perfectly possible for two Members to

enter into a bilateral agreement under which they bind themselves to provide higher levels of patent protection than called for by the TRIPS Agreement i.e. they reduce the amount of policy flexibility that they retain under the TRIPS Agreement. A good example of such a mechanism is the bilateral Free-Trade Agreement (FTA). As has already been noted in a number of places above, the United States has recently been negotiating such bilateral FTAs with other Members, both developed and developing, with Chapters on intellectual property rights at a TRIPS-plus level

Although the general language in these FTAs on the tests for acceptable exclusions remains that of Art. 30 TRIPS, there are a number of other specific provisions which have a bearing on patent exceptions. For example, the US is limiting FTA Parties to its own view of a Regulatory Review exception including a bar on exporting any product made for testing and

a requirement for a patent term extension. Furthermore, the US is limiting FTA Parties to its own view of the exhaustion of rights, barring the unrestricted International Exhaustion exception that a Member might otherwise have decided to adopt.

Although not a patent exception matter *per se* it is worth noting again that some of the most obviously TRIPS-plus language in these FTAs relates to the issue of data exclusivity. As noted above, such an approach requires exclusive rights lasting a period of years to be provided for, for example, the clinical trial data submitted to a regulatory authority by an originator when they are registering their product. Even if the relevant patent has expired, or even if there never was a relevant patent, such data exclusivity rights will alone delay the marketing of a generic medicine until they have expired, for example 5 or 10 years after the registering of the originator medicine. Severe concerns have been voiced at the impact that these provisions will have on public health in developing countries in terms of constructing a new mechanism, above and beyond the patent system, to delay the introduction of generic competition.

5.3.3 Multilateral “TRIPS-plus” agreements: International patent harmonisation?

Another type of relevant TRIPS-plus agreement would be that of a new multilateral instrument aimed at “harmonising” international patent law at a higher level than the TRIPS Agreement²¹⁸. The impetus for such harmonisation tends to come from patent holders, for whom a more uniform international approach to patent matters would be very helpful. However, it necessarily implies replacing the policy freedom available under the TRIPS Agreement, such as it is, with more of a “one size fits all” approach, which may be damaging to the interests of developing countries. Efforts continue at WIPO, for example, to negotiate a Substantive Patent Law Treaty (SPLT). The issue of exceptions to patent rights was at least originally on the table for negotiation under this process. It now seems though that the differences of opinion between parties are such that future discussions will have to continue to focus on a much smaller set of issues than originally conceived, and indeed it may be that the whole process grinds to a halt.

5.4 A new exception to solve the “paragraph 6 problem”?

It is perhaps true to say that, with one notable exception, there has not been much of a clamor among Members since the Canada- Generics Panel Report for new exceptions to be invented to meet their policy needs. In general, for example as with the high profile debate over “access to essential medicines”, it has been compulsory licensing that has occupied the centre stage. The notable exception relates to the problem identified in paragraph 6 of the Doha Declaration on TRIPS and Public Health.

As discussed above, the Doha Declaration on TRIPS and Public Health (the “Declaration”) was a landmark event for the interpretation of the TRIPS Agreement. One issue however was sufficiently contentious that no solution could be found at the time and paragraph 6 of the

Declaration reflected instead a characterisation of the problem and an instruction to the TRIPS Council to find a solution:

“6. We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002”

Although every Member has the same right to grant a compulsory licence for, or make government use of, a patented invention, it is manifestly clear that not all of them have the same domestic resources to be able to

take advantage of those powers. In the area of medicine, for example, the context in which this issue arose, a poor developing country Member (A) would not likely have sufficient domestic pharmaceutical resources to be able to manufacture a generic version of any given patented medicine. The obvious response is to consider the manufacture of the generic product in another Member (B), under a compulsory licence (CL-B) in that Member as well if necessary, and import it for use back into the poor developing country Member under a domestic compulsory licence (CL- A). The problem identified in paragraph 6 of the Declaration was therefore related to a limitation that the TRIPS Agreement threw in the way of such a course of action as regards the compulsory licence in the exporting country (CL-B). Under the provisions of Art. 31(f) TRIPS any such compulsory licence could only be authorised “predominantly for the supply of the domestic market of the Member authorising such use” i.e. the second compulsory licence (CL-B) would have to be predominantly focussed on the domestic supply of the domestic market and only a non-predominant portion could be exported to other Members, such as poor developing ones with health problems.

A number of possible solutions were suggested including, most straightforwardly, a waiver or amendment of Art. 31(f) TRIPS such that the “predominantly” test no longer applied in the relevant circumstances. However, for the purposes of this Paper, the most interesting suggestion was that a patent exception under Art. 30 TRIPS could be designed to solve the problem. Given that the problem identified in the Declaration related to the problems of importing Members, looking straight to Art. 31(f) TRIPS was a leap. There was no good to reason not to look at the full spread of possible solutions that could solve the importing Members’ problem. Significantly, given the position taken a few years before in the *Canada - Generics* case, it was the EC that first formally proposed the Art. 30 TRIPS solution at the TRIPS Council²¹⁹. By contrast the US was strongly against any proposals for considering the use of an Art. 30 TRIPS exception.

There were a number of compelling policy reasons pointing to Art. 30 TRIPS as the optimal solution to the problem insofar as it would most closely put the importing Members in the same position as a Member with domestic manufacturing capacity. However the full political weight of the US was ranged against the use of Art. 30 TRIPS. In terms of the legal position, opinions were expressed both for and against²²⁰. There were clear and complete analyses supporting the legal soundness of utilising an exception under Art. 30 TRIPS to solve this problem. Professor Fred Abbott, among others, compared the metes and bounds of the proposed exception with the tests of Art. 30 TRIPS, both as interpreted in the *Canada - Generics* Panel and beyond (that is to say in the light of criticism that the Panel had erred in adopting, for example, the narrow interpretation of “limited” that they did, as discussed above) to reach a conclusion that:

“The express text and context of Article 30, particularly in the light of paragraph 4 of the Doha Declaration, allows Members to authorize the making and export of patented public health related products to address unmet health needs in countries without the financial resources to provide access to medicines for all.”²²¹

Professor Abbott also made clear that it was in any case within the power of the WTO Ministerial Conference or General Council, on the recommendation of the TRIPS Council, to make an “authoritative interpretation” of Art. 30 TRIPS (i.e. not bound by a Panel or Appellate Body report) such that the exception in question would undoubtedly comply with its requirements.²²²

Naturally the fact that the EC had suggested the use of Art. 30 TRIPS had also lent great weight to the proposal. In the end though, the political factors weighed heavily and the solution adopted, the so-called “August 30th (2003)” decision adopted by the WTO General Council, looked instead to amending Art. 31(f) TRIPS. Members reached agreement in December 2005 to amend the TRIPS Agreement

to reflect this outcome, intended to take effect from 1 December 2007.

Implementation of the August 30th mechanism in national or regional law has begun, for example in Canada, Norway and the EC. This process of implementation has however engendered a replay of some of the more contentious issues of the original negotiations, as those favouring a restrictive mechanism have tried to put back in restrictions at a national or regional level which they failed to have included at

the WTO level. If it turns out that the August 30th mechanism, which is complex enough to begin with at the WTO level, has been crippled through additional substantive or procedural limitations at the national or regional level, then it may be necessary to turn again to alternative mechanisms to solve the problem. Specifically, although a mechanism based on Art. 30 TRIPS was not utilised for the August 30th mechanism, this possibility is still there for use in the future.²²³

5.5 A suggested process for considering the adoption of new Art. 30 TRIPS exceptions?

Where a policy maker is considering solving a policy problem through the adoption of a new exception to patent rights (based on Art. 30 TRIPS), how are the preceding sections to be summarised in terms of an effective policy process? The following process is suggested:

1. The first step is to ensure that the policy problem which is being considered *is* amenable to solution in terms of an *exception to patent rights*. This seems an entirely obvious point to make but it is an important one nevertheless. A patent exception will only be an effective solution to policy problems caused by the existence or exercise of patent rights.
2. The second step is to consider whether an exception which is already provided for in national law could solve the problem. Perhaps the exception has simply not been identified by those working on the policy problem. Perhaps it has never been used before. If so, comparison with the practices of other countries could help to illuminate its utility. If the country is a member of an international community, such as the Commonwealth, it will likely be the case that the practices of other Commonwealth members could be examined. However, caution has to be employed in the application of precedents from developed countries in such a community in terms of their different policy circumstances.

National regulations or other guidance could be issued to operationalise the exception. Alternatively, it could be that an exception which already exists in national law could be modified to solve the problem.

EXAMPLE: If a sophisticated developing country (likely on or near the equator) with a “standard” Foreign Vessels exception were wanting to consider entering the commercial satellite launching business, consideration ought perhaps to be given to whether or not foreign constructed satellites brought to the country for launching could be seized if they infringe a national patent. As a precaution, policy makers in that country ought perhaps to consider expanding the Foreign Vessels exception to include “spacecraft”, following the US and Malaysian models (section 4.6 above)?

3. If there is no appropriate exception existing in national law, then one could adopted from elsewhere. In terms of “legal transplantation”, it is usually easier to adopt a legal measure from another country in the same legal family, or legal community, as in the step above. However, patent exceptions are perhaps more “stand-alone” than many other legal measures, so the net could be spread more widely. Exceptions in foreign countries, in international model codes, or analogies to exceptions in other intellectual property

systems could all be considered. Again, the imported exception could also be modified.

EXAMPLE: The European Farmers Privilege exception relating to the ability of Farmers to save seed from their harvest to re-sow has been imported from a parallel sui generis intellectual property rights system relating to plant varieties.

4. If there are no appropriate models of exceptions already in existence then a new exception will likely have to be designed. In designing a new exception, it is important to recall that under the Canada-Generics decision (see section 3.5.3 above) although account ought to be taken of the non-discrimination provisions of Art 27.1 TRIPS, well founded differentiation between different technical fields (as distinct from perjurative discrimination) is permissible under Art. 27.1 TRIPS. This means that patent exceptions under Art. 30 TRIPS can be crafted to deal with specific problems in specific technical fields. This is perhaps self-evident given the many exceptions discussed in this report that deal with a specific technical field but there is also ample evidence from specific regimes in the neighbouring field of compulsory licensing, such as the ex-officio licences for medical products in France (recently explicitly amended to include diagnostics after the debacle over the BRAC1 and BRAC2 patents covering breast cancer tests)²²⁴ and the compulsory licensing provisions relating to clean air and atomic energy in the US.²²⁵ In terms of designing a new exception there are perhaps at least three different options:

- (i) A new exception could be designed by analogy to an existing exception. If the new exception can be seen to be very similar to an existing exception which is accepted as being valid then the acceptance of that new exception will likely not be too problematic.

EXAMPLE: A recent policy proposal was made to permit countries facing the threat of pandemic diseases to be able to import

and stockpile generic versions of patented medicines in case they ever needed to be used, instead of having to purchase the patented version of the medicine straight away²²⁶. If the generic medicines did ever actually have to be used though, then the proposal requires that adequate compensation be paid to the patent holder. In this way, it is suggested, governments will be more likely to prepare for such diseases whilst still ensuring that patent holders would be properly remunerated if the medicines ever needed to be used. If a policy maker were considering utilising a patent exception to implement this policy proposal, consideration could perhaps be given to using the Chicago exception (sections 2.6 and 4.7 above) as a basic model? Under the Chicago exception generic parts to maintain aircraft making international flights can be imported and stockpiled for use at any time during the life of the patent, without any compensation to the patent holder. Compensation can however be built into a patent exception (section 5.2 above).

EXAMPLE: There is a great deal of concern among the Free and Open Source Software community about the threat that “software patents” pose to the continuing use and growth of this alternative and highly successful model of software development. Some countries are maintaining an exception to patentability for such inventions, although there is continuing debate over where to draw the line between patentable and unpatentable. Clearly for this community it will be preferable to maintain a situation where software “as such” remains unpatentable. Should software “as such” become patentable however, consideration could perhaps be given to a patent exception which might render immune from patent infringement all those working on Free or Open Source software projects, and their software.

The European Pharmacy exception (sections 2.4 and 4.5), or the American Medical Practitioner exception (section 4.10) (respectively rendering immune

from patent infringement pharmacists and the medicines they produce and medical practitioners carrying out medical methods) could perhaps be considered as a basic model?

EXAMPLE: Proposals have been discussed for a Humanitarian Use exception (or conceived with an equivalent term given possible difficulties surrounding the term "humanitarian"). Notwithstanding the widespread adoption of a Private and Non-Commercial Use exception, an alternative and more broad approach is to limit the rights of the patent holder to commercial activity (section 2.1), thereby potentially enabling a degree of not-for-profit activity to be carried out under a de facto or explicit exception.

- (ii) A wholly new exception could be designed which arguably fits within the Canada-Generics tests, outlined above in section 3. Although the Canada-Generic tests have been criticised in this Paper, it is true to say that are the leading precedent at the moment. Irrespective of whether or not it is reasonable to be confined to these tests, if it could conceivably be demonstrated that the new exception is very likely to meet them then acceptance of the new exception, although perhaps harder than

in the previous case, may be achievable.

- (iii) If a wholly new exception is needed to solve the policy problem in hand, but is one which would likely not meet the Canada-Generics tests, especially the "limited" test, then the next step, in the light of section 3.4.5, is to design the new exception in such a way that it fits within a more reasonable interpretation of Art. 30 TRIPS than that provided in Canada-Generics. This would be, for example, one which takes account of all the pre-existing exceptions and which takes account of the Doha Declaration on TRIPS and Public Health. This new exception could likewise be broadened even further if an element of compensation were due to be paid to the patent holder. In either case, acceptance of the new exception might be somewhat difficult. No doubt this would be ameliorated if a group of countries were designing the exception for joint adoption. Alternatively, the exception could be adopted and if another Member challenges it, then preparations could be made, on the basis of the comparative and international law exercise undertaken to determine the more reasonable interpretation, to defend the exception before a new Panel.

ENDNOTES

- 1 Gervais, "The TRIPS Agreement: Drafting History and Analysis", Sweet & Maxwell, 2003, section 2.292.
- 2 Jessel M.R. in *Frearson v. Loe* (1878) 9 Ch. D. 48. More broadly at that time, "...if a person makes use of a patented process and obtains the product, not for the purpose of commercial profit, he is not guilty of infringing the patent", Johnson & Johnson, "The Patentee's Manual: A Treatise on the Law and Practice of Patents for Inventions", Longmans, Green & Co, 1890, p.267. The Canadian government made use of Jessel M.R.'s reasoning and its "neither using or vending of the invention for profit" test in the *Canada - Generics* dispute, discussed below in section 3.
- 3 Ladas, "Patents, Trademarks and Related Rights: National and International Protection", Harvard University Press, 1975, Volume 1, p. 413.
- 4 See Industrial Property, October 1988, "Committee of Experts on the Harmonisation of Certain Provisions in Laws for the Protection of Inventions", Fifth Session (Geneva, June 13 to 17, 1988), ("Expert Committee Report"), pp. 358 *et seq.*
- 5 Given that this harmonisation attempt in WIPO was a failure but that success was achieved within the context of the GATT/WTO TRIPS Agreement, it is ironic to note that attention has now switched back to WIPO to try to negotiate further harmonisation, at a higher level even than that achieved in the TRIPS Agreement. These discussions are not progressing smoothly however and it would appear that many developing countries are resisting this application of "forum switching" to narrow the policy space provided under the TRIPS Agreement. This is discussed below in section 5.3.2.
- 6 Union des Industries de la Communauté européenne (UNICE).
- 7 See Expert Committee Report, *ibid*, p. 364. Also quoted in Benyamini, *ibid*, p. 266.
- 8 A. Benyamini, "Patent Infringement in the European Community" , Vol 13, IIC Studies, VCH Verlag, Weinheim, 1993, pp. 265-266.
- 9 Concrete examples in the form of the relevant UK provisions will be provided in this section. It should be noted however that, under Section 130(7) of the UK Patents Act 1977, these UK provisions are "so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of...the Community Patent Convention...". The aim of the (Luxembourg) Community Patent Convention (CPC) was to harmonise European patent law in a more fundamental manner than the European Patent Convention (1973) had. However, although the CPC was signed in 1975 it was never ratified. Nevertheless, a number of its provisions, for example Art. 27 CPC providing for exceptions to patent rights, are regarded as reflecting a high degree of consensus among European States. Accordingly, the UK provisions may be taken as reasonably representative of European thinking on this issue, and given the influence of European thinking on international patent matters, must be of wide interest.
- 10 Note the comments of Jessel M.R. above and later e.g. "Manufacture or use purely for experimental purposes does not constitute an infringement; if an inventor wishes to improve upon an invention covered by an earlier patent owned by A, he is entirely free to conduct any bona fide experiment for the purpose...", Meinhardt, "Inventions, Patents and Monopoly", Stevens & Sons, 1950, p. 180.
- 11 See, for example, David Gilat, "Experimental Use and Patents", Vol. 16, IIC Studies in Industrial Property and Copyright Law, Max Planck Institute for Foreign and International Patent, Copyright and the Competition Law, Munich. Weinheim, VCH Verlagsgesellschaft mbH, 1995. See more recently Cornish, "Experimental Use of Patented Inventions in European Community States", IIC, Vol. 29, No. 7 / 1998. See also the Correa Experimental Use exception comparative law review and the Australian Law Reform Commission report discussed below in section 4.3.
- 12 Cornish, *ibid* p. 752, notes that "Until the last two decades, when that Article [Art. 27(b) CPC] began to be incorporated into national law, the scope of any exception to patent infringement for experimentation was in most systems ill-defined; in some certainly, it was confined to the private and personal use of a scientific experimenter. The changing nature of research among industrial competitors and in academic-industrial relationships has led to a step-wise expansion of the experimental use exception and this was apparently the intention of the governments which negotiated the CPC. No longer is any exception confined to the strictly non-commercial, because frequently scientific curiosity operates in conjunction with the desire to turn successful work to account...".
- 13 See Correa study, *ibid*, section 4.3.
- 14 The United States provides inventors with a 12-month "grace period" during which time an inventor may fully disclose their invention, for example in trials or during negotiations, before filing their patent

application without adversely impacting their right to obtain the grant of a patent for that invention in terms of its novelty. However, since the vast majority of the rest of the world views novelty in “absolute” terms and does not provide such a grace period as an exception to the novelty requirement, if an inventor does fully disclose their invention under the US provisions, they will be unable to obtain the grant of a valid patent in most countries outside the US. Provision for such a “grace period” (in the context of the debate over “first to file” vs “first to invent”) is perhaps the most contentious difference of opinion outstanding between the US and the EC on patent matters.

- 15 This is again based on the widely accepted view of novelty as “absolute”. The situation was different in the UK under the previous 1949 Patents Act, for example, where the secret prior use was permitted to be used as a ground to invalidate the patent. The Prior User exception therefore puts the patent holder in a better position that they would have been under this previous view. A limitation on the likely incidence of such prior use arises taking this novelty issue into account. Presumably only a certain amount of activity can take place without the activity becoming public. If the activity of the prior user was on such a scale that it did become public, and was such as to disclose the invention to the public, then it would not be possible for a later inventor to obtain a valid patent.
- 16 Simon Thorley et al, “Terrell on the Law of Patents”, Sweet & Maxwell, 15ed, pp. 236-237.
- 17 Ladas, *ibid*, p.414.
- 18 A variation on this theme is providing for the continuation of use that began during a period of time where a patent had lapsed, for example, as a result of a failure to pay the requisite renewal fees, as provided for in Section 28A(4) of the UK Patents Act 1977.
- 19 Terrell, *ibid*, p. 236.
- 20 Aldous J. in *Helitune v. Stewart Hughes* [1991] F.S.R. 171 at 206, referenced in Terrell, p. 235.
- 21 “Considerable divergences in various national laws are found in regard to inventions relating to chemical processes and products, pharmaceutical products and medicines and foodstuffs. The reason why special stipulations are needed with regard to these three categories of inventions is obvious. Monopolies for medicines and foodstuffs are against public interest, and a monopoly for a new chemical product as such would prevent the manufacture of such product by another method, to the serious disadvantage of national industry”, Jan Vojáček, “A Survey of the Principal National Patent Systems”, Prentice Hall Inc., New York, 1936, p. 18.
- 22 n.b. This paper uses “medical method” as a shorthand for, for example, medical, diagnostic and surgical methods.
- 23 See e.g. Graham Dutfield, “Intellectual Property Rights and the Life Science Industries: A Twentieth Century History”, Ashgate, 2003.
- 24 Least Developed Members have an extended transitional period till 1 January 2016 during which time they need neither grant patents for pharmaceutical products, nor even enforce those that they may have granted. See, paragraph 7 of the WTO Doha Declaration on TRIPS and Public Health.
- 25 New Shorter Oxford Dictionary, see e.g. “extemporaneous”, “extemporary”, “extempore”.
- 26 Bengt Domeij, “Pharmaceutical Patents in Europe”, Kluwer Law International, 2000, p. 310.
- 27 As suggested by Preeti Ramdasi (ICTSD) however, and to the extent that potentially patented pharmaceutical products might be involved, it is perhaps also interesting to consider whether or not this exception could have some relevance to the field of traditional medicine in developing countries, for example Indian Ayurveda or Traditional Chinese Medicine.
- 28 As discussed below in section 3, in *Canada-Generics* the EC described the exception as “mainly historic”.
- 29 Doris Thums, “Patent Protection for Medical Treatment - A Distinction Between Patent and Medical Law”, IIC, Vol. 27, No. 4/1996, p. 441.
- 30 See Expert Committee Report, *ibid*, p. 364.
- 31 See Expert Committee Report, *ibid*, p. 364.
- 32 See Expert Committee Report, *ibid*, p. 364.
- 33 For example, “There are broad exemptions for ships, aircraft and other vehicles of countries belonging to the Industrial Property Convention [Paris Convention] and for aircraft if countries belonging to the Chicago Convention. Similar exemptions have existed for many years now, without giving rise to

dispute...”, Clark et al, “Encyclopedia of UK and European Patent Law”, Sweet & Maxwell, London, section 4-309.

34 Ladas, *ibid*, pp. 416-417.

35 This provision mentions “territorial waters”. Under Art. 3 of the 1982 Law of the Sea Convention, the maximum extent of a coastal states territorial waters is specified to be 12 nautical miles. Under Art 77(1) of the same Convention, coastal states are accorded significant rights over their continental shelf and, for example, under UK law, the provisions of this exception are extended under Section 132(4) of the UK Patents Act to use taking place on the continental shelf. There are difficult questions remaining as to the treatment of, for example, oil rigs under this exception. It is noted that this provision specifies “hovercraft” as a type of vehicle. For further extension to, for example, spacecraft, see below, section 5.6.

36 Ladas, *ibid*, p. 418.

37 *Stena Rederi Aktiebolag v Irish Ferries Ltd* [2003] R.P.C. 36.

38 European patent (UK) No. 0648173. An argument that the Foreign Vessels exception could not be utilised in this case since the patent claim related to the whole vessel rather than devices “in the body” of the vessel was rejected.

39 *Anthony J Cali v Japan Airlines Inc* 380 F. Supp 1120 (1974), affirmed on appeal but not reported.

40 US Code, Title 35, Part III, Chapter 28, § 272.

41 *Stena Rederi Aktiebolag v Irish Ferries Ltd* [2003] R.P.C. 36. at page 676, line 30 *et seq.*

42 *National Steel Car, Ltd v Canadian Pacific Railway, Ltd.* 2004 US App LEXIS 1346, 03-1256 (Fed Cir January 29 2004). It was held that a Canadian railroad car could qualify as a Foreign Vehicle for the purposes of the exception. One commentary upon the case (www.ropesgray.com) indicates that “The Federal Circuit then noted “a concern to leave the channels of international commerce, or more accurately the vessels and vehicles that pass through these channels, free from the excessive burdens that would result if such vessels or vehicles had to conform to the patent laws of all nations that the vessel or vehicle visited during its lifetime.” It therefore determined that “the definition of entering ‘temporarily,’ as the word is used in Section 272, is entering for a period of time of finite duration with the sole purpose of engaging in international commerce”.

43 In one or the more entertaining sounding examples of patent litigation, that of the *Carrying Carts for Plants* case, “a German court has held that, where the defendant loses control of a vehicle within the jurisdiction, that vehicle has not entered the country temporarily (...”Pflanzen-Transportwagen” [Germany] noted (1990) 21 IIC 99)”, referred to in CIPA Guide to the UK Patents Act, section 60.16. Unfortunately the spectacle this report raises of a patent infringing wheelbarrow packed with foliage, rocketing off wildly down a hill just over the border, with a hapless gardener in hot pursuit, all under the merciless gaze of a patent attorney, is too good to be true. “Losing control” in this context refers to the fact that, after entering Germany, a third party was utilising the Carts before subsequently returning them to their foreign owner.

44 There are a number of places in the world where international ferry routes must surely represent a more lucrative market than purely domestic routes. In Europe, the English Channel, the Irish Sea, the North Sea, the Baltic Sea, the Bay of Biscay and the Mediterranean (including e.g. the Adriatic etc) are all heavily plied by international ferry traffic.

45 Ladas, *ibid*, p. 419.

46 See, for example, Zylicz, “International Air Transport Law”, Utrecht Studies in Air and Space Law, Martinus Nijhoff Publishers, 1992, Chapter VIII, “The Chicago System of Public International Air Law” for an introduction.

47 See the website of the International Civil Aviation Organisation at www.icao.int.

48 Graham McBain (ed), *Aircraft Liens & Detention Rights*, Sweet & Maxwell,, (looseleaf, latest 19-06-05).

49 Implemented through The Aircraft (Exemption from Seizure on Patent Claims) Order 1977 (S.I. 1977 No. 829).

50 *Roche Products Inc. v. Bolar Pharmaceuticals Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984).

51 US Code, Title 35, Part III, Chapter 28, § 271(e)(1).

- 52 Although the US seemed content to have it on record that such activities could be regarded as falling under the “experimental use” exception, “The delegation of the United States of America also wishes to draw attention to the practice in its country whereby a person other than the patent owner, who wished to obtain a license to market a medicine covered by a patent, was permitted to use a patented invention, where the patent term was nearing expiration, in order to develop the information necessary to support the license application. It sought clarification that such a use of a patented invention would be considered to be a use for experimental purposes which could be excepted under Article 302(2)(ii) and, to this end, proposed that the following sentence be added to note c., on page 44 of the English text of document HL/CE/V/2: “The development of data solely for submission to a governmental agency to obtain approval for marketing after a patent had expired would be an acceptable ‘experimental purpose’.”, Expert Committee Report, *ibid*, p. 364.
- 53 Jacques Gorlin, “An Analysis of the Pharmaceutical-Related Provisions of the WTO TRIPS (Intellectual Property) Agreement”, 1999, p. 30.
- 54 Terrell, *ibid*, p. 225, “Limited licence”. A particularly interesting example of this is provided in Heath & Petit, “Patent Enforcement Worldwide”, Hart Publishing 2005, “The Enforcement of Patent Rights in Japan”, p. 347 at footnote 74: “In Tokyo High Court, 29 November 2001, 34 IIC 821 (2003) - *Acycrobil*, the defendant had obtained marketing approval for a generic drug containing the same active ingredient as the one described in the plaintiff’s patent. Marketing approval would expire unless the products were actually brought on the market within six months from the date of marketing approval. The defendant thus purchased the plaintiff’s pharmaceuticals containing the active ingredient, distilled the latter and used this basic substance for producing the generic drugs. As the patentee had received the economic benefits deriving from the patent by the act of first marketing, he could no longer control further acts of commercial exploitation by the purchaser. The action was thus dismissed”.
- 55 Terrell, *ibid*, pp. 226-227, “Repairing”.
- 56 Nuno Pires de Carvalho, “The TRIPS Regime of Patent Rights”, Kluwer Law International, 2002, p.227.
- 57 Gorlin, *ibid*, pp. 30-31.
- 58 There are even broader conceptions of international exhaustion that do not rely on the patent holders consent but also embrace, for example, products placed on the market under a compulsory licence, where the patent holder has at least received adequate compensation.
- 59 A European patent application may be filed which, following examination by the European Patent Office, may lead to the grant of a European patent. However, this system is merely one of convenience of handing application and examination. The grant of such a European patent in fact leads to separate patents in each European country which has been designated in the European patent application. Despite years and years of discussion, disagreement over translation issues has so far prevented agreement on a unitary European Community patent.
- 60 Case 15/74 *Centrafarm v. Sterling* (1974) ECR 1147.
- 61 The case law on this issue dealing with a number of important practical elements of the application of the doctrine is quite extensive. Broadly speaking, in the European conception of exhaustion it is the notion of “consent” which plays a central role. Hence a product put on the market by a (voluntary) licensee is treated in the same way as if the patentee had placed the product on the market himself. By contrast, if a product were placed on the market under a compulsory licence the doctrine would not apply. In the context of medicines, issues such as price controls are also important. For a relatively recent review of the legal and business state of play on parallel importation in Europe (at least from the perspective of a multinational pharmaceutical company advisor) see Philip Grubb, “Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy”, Oxford University Press, 4th ed, pp. 462-466, “Parallel Importation”.
- 62 Following the *BBS v Racimex & Japanese Auto* decision (H-7(o) No. 1988 (July 1 1997) Supreme Court of Japan). See, for example, “Parallel Imports of Patented Products Permissible in Japan”, IP Asia, August 1997, which notes the potential practical difficulties of enforcing such conditions in terms of labelling the products.
- 63 Consideration of the six year limitation period is interesting as an example. Art. 41.2 TRIPS provides that “Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time limits or unwarranted delays”. Presumably it is possible to justify such a six year time limit on the basis that it is “fair and equitable”? But what if a Member decided instead that, taking account of a desire to reduce the amount of patent litigation that might be entertained, it would set a time limit of one year?

- 64 *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank* 51 USPQ2d 1081 (Sup. Ct. 1999).
- 65 For example, Grubb, *ibid*, p. 176: "In view of the fact that state universities such as the University of California are among the most prolific users of the patent system, and do not hesitate to enforce their own patents, it is totally unjust that should have immunity from suit themselves. Proposals have been made in Congress for legislation to bar state universities from suing other parties for infringement unless they waive their own immunity, but as of 2004 no such law has been passed".
- 66 An outline history of the provisions is provided in the Panel Report at section 4.21, p. 35 *et seq.* Canada's justification for taking action as a matter of patent law rather than e.g. as a price control matter is provided at Panel Report section 4.20, p. 40 *et seq.*
- 67 The US Regulatory Review exception explicitly recites the ability to import, see 35 USC § 271(e)(1).
- 68 This important difference between the US and Canadian provisions arose, Canada explained, since the US was large enough for generic manufacturers to consider manufacturing products just for the US market, whereas the Canadian market was not sufficiently large: "'Pre-expiration testing' exceptions that had the effect of confining all activities to a single country were of little use to countries that, unlike the United States, depended on international trade to obtain generic products." (Panel Report, section 4.38, p. 79). Indeed, Canada asserted that "In order to be consistent with the first paragraph of the Preamble to the TRIPS Agreement and with the overarching objective of the WTO Agreement set out in its Preamble quoted above, a properly crafted "pre-expiry exception" had to take into account foreign regulatory approvals in order that the objective of removing impediments to international trade could be sustained" (Panel Report, section 4.38, p. 82). Canada expanded on this theme of the creation of a trade barrier through only permitting domestic testing, unfairly shielding American generic manufacturers in their testing activities against competition from foreign entities capable of carrying out such testing activities at Panel Report, section 4.38, p. 83 and section 4.41, p. 93.
- 69 Although Canada argued that it paralleled a requirement of the US FDA that a generic manufacturer had to demonstrate three production runs at commercial scale before marketing authorisation could be given (Panel Report section 4.21, p. 38). This was seemingly denied by both the EC and the US (Panel Report section 4.22, p. 46).
- 70 Note though, "In answer to a question from the Panel, however, Canada has taken the position that the exception will be construed also to allow the "sale" of patented ingredients that have been ordered by a producer who is stockpiling the final patented product - for example, with regard to pharmaceuticals, sales by fine chemical producers of active ingredients ordered by the generic producer" (Panel Report, section 7.7, p. 148).
- 71 See e.g. "...Thus the overall time required for a generic manufacturer to develop its submission and to complete the regulatory review process ranges from three to six-and-a-half years...", Panel Report, section 2.5, p. 5.
- 72 Canada observed that: "Without the limited exceptions (particularly the regulatory review exception) patentees would benefit from an additional gratuitous and often lengthy period of de facto protection - equal to the time required for a competitor manufacturer to prosecute its application for regulatory approval - which was neither contemplated by domestic law nor required by the TRIPS Agreement", Panel report, section 4.21 (c), p. 40. This leads to what has been perceived to be an asymmetric result that, whereas the shortening of the patent holders term due to the regulatory delays involved in the first marketing of the patent holders product is regarded as a natural phenomenon to be borne by the patent holder, a delay in bringing a later generic product to market caused by the interaction of the patent holders rights during the patent term and the generic companies need to obtain regulatory approval for that product, is regarded as pernicious. To "compensate" patent holders some Members have therefore enacted extensions to the patent term hand-in-hand with permitting generic companies to obtain regulatory approval during the patent term. However, although the EC and others had argued for such a *quid pro quo* extension to be included during the TRIPS Agreement negotiations this was rejected, and accordingly there is *no* obligation under the TRIPS Agreement to provide for such a patent extension in return for providing a Regulatory Review exception (unlike e.g. Art. 1709(12) NAFTA), as discussed in the Panel Report. Canada characterised the EC bringing this dispute as an attempt to "... win through litigation the windfall period of protection that they could not secure by negotiation." (Panel Report section 4.11, p. 17).
- 73 The other members of the Panel were Mihály Fisor (Previously Assistant Director General of WIPO) and Dr Jamie Sepulveda (Director General of Mexico's National Institute of Public Health). See e.g. Frederick Abbott, "Tribute to Robert E. Hudec", *Journal of International Economic Law*, Vol. 6, No. 3, September 2003, p.734.

- 74 The UK Statute of Monopolies 1624 is an early example: “In 1624 Parliament sought to declare these exercises of royal prerogative [the granting of monopolies by the King or Queen] void. The Statute of Monopolies which it enacted suggests not only the growing significance of trade in the country’s economy and the beginnings of the long political campaign to favour competition at the expense of monopoly, it also shows the readiness of the political forces represented in Parliament to challenge policies of convenience to the Crown”, Cornish, “Intellectual Property: Patents, Copyrights, Trade Marks and Allied Rights”, Sweet & Maxwell, 4th ed, p. 111.
- 75 Art. 7 TRIPS, *Objectives*, 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*. (emphasis stressed by Canada).
- 76 Canada noted that, Panel Report footnote 40, “Article 31.1 forms part of the “customary rules of interpretation of public international law” within the meaning of Article 3(2) of the *WTO Understanding on Rules and Procedures Governing the Settlement of Disputes* (1994) and this applies to the interpretation of the TRIPS Agreement pursuant to Article 64.1 thereof: *United States - Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, at p.17. The EC noted the same, in more extensive fashion, at Panel Report footnote 153.
- 77 Panel report s. 4.12, p. 18.
- 78 Panel report s. 4.13, p. 19.
- 79 Panel report, section 4.30, p. 53.
- 80 Panel report, section 4.30, p. 50.
- 81 Panel report section 4.40, p. 84.
- 82 It may be recalled that patents themselves are an exception to the broader rule against monopolies.
- 83 Panel Report section 4.40, p. 84.
- 84 WT/DS114/R. The text of the Panel Report is laid out in a way which reflects the fact that the EC and Canada provided successive rounds of argumentation, developing their arguments in response to the others as they did so. Where reference is made to the Panel Report in the following, this explains why similar points may have references at very different section and page numbers.
- 85 Panel report, section 4.14, p. 21.
- 86 Panel report section 4.37, p. 76.
- 87 Panel report section 4.37, p. 77.
- 88 Panel report section 4.15, p. 28. A general reference to the history of TRIPS negotiations on proposals for exceptions was provided by Canada at footnote 41.
- 89 Panel report section 4.30, p. 56.
- 90 Panel report section 7.27, p. 154.
- 91 Panel Report section 4.30. p. 57.
- 92 Panel Report, p.59. See also e.g. “...Section 55.2(1) of the Canadian Patent Act did not only allow all the activities mentioned in the text to be carried out by somebody who had himself the intention to use the substances for preparing his application for marketing approval, but allowed such activities as manufacturing, importing and selling for anybody, if only the results of these activities were eventually intended to be used by somebody else for his application to a marketing approval authority in any country of the world...”, Panel Report section 4.4, p. 11.
- 93 Panel Report, p. 57.
- 94 Panel Report p. 56. The astute observer will note that this list only adds up to four rights, rather than five. It is not clear what happened to the right of the patentee to prevent others from “making” the invention in this EC calculation.
- 95 Panel report section 4.37, p. 73.
- 96 Panel Report p. 54, “...any person who, in good faith, before the filing date [...] and within the territory where the patent produces its effect, was using the invention or was making effective and serious

preparations for such use; any such person shall have the right, for the purposes of his enterprise or business, to continue such use or to use the invention as envisaged in such preparations...", quoting from Wegner, *Patent Harmonization*, London, Sweet & Maxwell, p. 115.

97 Panel report p. 55.

98 Panel report p. 85.

99 See sections 2.3 and 4.4.

100 Panel Report, section 4.36, p. 70.

101 Panel report, footnote 76, p. 32.

102 Panel Report section 5.36, p. 139.

103 Panel Report section 5.6, p. 99 and section 5.8, p. 102.

104 Panel Report section 5.8, p. 102.

105 Panel Report, section 7.26, p. 154.

106 Panel Report section 7.47, p. 159.

107 Note, for example, Canada's response to a question asked by the Panel, "...The excepting provision set out the circumstances in which an otherwise unauthorised use would not attract infringement liability in Canada. The circumstances were focused on the presence of a valid Canadian patent and the potentially infringing uses of the invention that might be required in order to make a viable submission to a competent regulatory authority. The excepting provision was not therefore concerned with the frequency with which the circumstances might arise...", Panel Report, footnote 50, pp. 22-23.

108 "By allowing the activities referred to in Section 55.2(1) of the Canadian Patent Act with a view to obtaining marketing approval in any country in the world, the extent of such activities and their duration during the patent terms were totally open-ended and completely outside the control of the Canadian authorities...Consequently, very significant quantities of the products protected by the patent could be used, manufactured, imported and sold without the consent of the patent holder at any time during the patent term", Panel Report, section 4.23, p. 46.

109 See section 4.7 below.

110 Panel Report section 4.35, p. 66.

111 Although even in this case, Canada argued that: "- The EC had noted that learned commentators had said that subsequent practice must be "concordant, common and consistent". The EC took this as meaning that practice must be "common to all the parties". In the case of a multilateral agreement, such a standard would be extremely difficult, if not impossible, to satisfy. However, the standard was not as exacting as the EC contended. In *Alcoholic Beverages*, the Appellate Body had held that "concordant, common and consistent" meant a "sequence of acts or pronouncements which is sufficient to establish a discernible pattern implying the agreement of the parties" regarding the interpretation of the treaty. The emergence of a discernible pattern did not depend on the universal adoption of a practice. On the contrary, the discernible pattern standard was only intended to require the identification of something more than an "isolated act". - The EC had argued that there could be no discernible practice, because the TRIPS Agreement had only been in force for a short period of time. This contention ignored the fact that not all periods of time were of equal significance. The immediate aftermath of the conclusion of a treaty like the TRIPS Agreement was, in reality, more important than the longer term, because Members were obliged, within a relatively short period of time, to ensure that their domestic legislation met their new obligations. It was in the immediate aftermath that a treaty like this generated both legislative activity and documents like the US Statement of Administrative Action, when the parties were actively engaged in the exercise of interpreting the new agreement and putting it in their own words, and closely reviewing the legislative activity of other Members. Far from being irrelevant, the implementation period had a vital importance far exceeding what might transpire later on. - The EC had said that, since it had contested Canada's practice, there was no agreement on the matter. However, the reference in Article 31.3 of the Vienna Convention did not deal with the specific subject-matter of a dispute, but with patterns of conduct from which assumptions about the meaning of a provision could be inferred. In every dispute taken to an international tribunal, there was a difference of opinion about the specific subject of the litigation, but that did not mean that there could be no relevant subsequent practice. If it did, Article 31.3 would be ruled out of consideration in every contentious matter, precisely in those circumstances in which it was intended to be of assistance. Consequently, all that the fact of the EC's disagreement meant was that the EC's position was inconsistent with a pattern of conduct on the part of other Members - including member States of the EC for that

matter - which established implicit agreement about the meaning of the relevant TRIPS provisions.”, (Panel Report, section 4.41, pp. 88-89).

- 112 As to Art. 31(3)(b) VCLT and such “subsequent practice”, see e.g. Aust, *Modern Treaty Law and Practice*, Cambridge University Press, 2000, p. 195, “It is not necessary to show that each party has engaged in a practice, only that all have accepted it, albeit tacitly”. Aust quotes the widely known example of such a tacit acceptance in the matter of Art. 27(3) of the United Nations Charter and the manner in which, through the practice of the United Nations Security Council, “concurring votes of the permanent members” came to be interpreted as “not objecting”.
- 113 de Carvalho, *ibid*, p. 227.
- 114 For an outline see e.g. UNCTAD-ICTSD, “Resource Book on TRIPS and Development”, Cambridge University Press, 2005, Chapter 23, or Abbott, *ibid*.
- 115 Panel Report section 7.82, page 168.
- 116 Panel Report section 4.14(iv).
- 117 *ibid*.
- 118 Referred to in the following unusually careless terms: “Obviously the Patent Section of the TRIPS Agreement did not stipulate any legal right for a *counterfeit generic* producer to effectively have a share of the market on day one after patent expiry” (italics added), Panel Report, page 58.
- 119 Panel report, page 86.
- 120 October 2002 ruling of Thai Central Intellectual Property and International Trade Court on Bristol Myers Squibb’s didanosine (ddI) patent.
- 121 Panel report footnote 139.
- 122 Panel report footnote 439.
- 123 “The decision rendered by the Panel in *Canada - Generic Pharmaceuticals*, which was not appealed, is certainly the most important analysis of the TRIPS Agreement to date. It was evident from the inception of the proceedings that the case was significant because it addressed a subject matter of intense interest in the field of medicines...There were critical issues of public health policy and access involved, and a great deal of money at stake...The main determination was to approve Canada’s regulatory review exception. This was a major step in safeguarding public health interests because such an exception reduces the lead time to market for generic pharmaceuticals”, Frederick Abbott, “Tribute to Robert E. Hudec”, *ibid*. Professor Abbott does however criticise certain aspects of the decision in this article including the findings on Art. 27.1 TRIPS and the narrow interpretation of “limited”. I am very grateful to Professor Abbott for sharing his insights into the origin and outcome of the Canada-Generics dispute.
- 124 For example, “The most noteworthy single development in the first five years of WTO dispute settlement was the flowering of the Appellate Body. The role it would play in the WTO system was quickly put to the test as the first 12 panel reports were appealed. From the outset, the Appellate Body established itself as an activist tribunal. It modified 10 of the reports, effectively reversing one of them.”, William J. Davey, “The WTO Dispute Settlement System: The First Ten Years”, *Journal of International Economic Law*, 2005, 8(1), 17-50.
- 125 India - Patent Protection for Pharmaceutical and Agricultural Chemical Products (“India-Mailbox”), WT/DS50/AB/R, 19 December 1997.
- 126 WT/MIN(01)/DEC/2, 14 November 2001.
- 127 See UNCTAD-ICTSD Resource Book, *ibid*, pp. 700-701, “The principle of evolutionary interpretation”, referring to i.a. the WTO *Shrimp-Turtle* dispute on this issue.
- 128 The author wishes to thank Knirre Sogaard (ICTSD) for her invaluable assistance in carrying out this review. Another review of interest is that of Phil Thorpe, “Study on the Implementation of the TRIPS Agreement by Developing Countries”, Study Paper No.7, UK Commission on Intellectual Property Rights, 2002. Yet another is the Correa review discussed below. Another important source of data is the WTO TRIPS Council review of each Members IP legislation, see e.g. http://www.wto.org/english/tratop_e/trips_e/intel8_e.htm. For a country-by-country summary of enacted legislation see also e.g. <http://www.wipo.int/about-ip/en/ipworldwide/country.htm>.
- 129 The case of the Commonwealth and the community of countries linked by their adoption of the English Common Law is well known, as is the case of the French speaking countries. The same is true of a number of other European countries as well though. See, as just one example, Christoph Antons, “The

Development of Intellectual Property Law in Indonesia: From Colonial to National Law", IIC, Vol. 22, No. 3/1991.

- 130 Ladas, *ibid*, p. 413.
- 131 See Dr Ida Madieha bt Abdul Ghani Azmi, "Patent Law in Malaysia: Cases and Commentary", Sweet & Maxwell Asia, 2003. It is clear however that, although persuasive, UK provisions and precedents do not prevail over Malaysian statutory provisions. For example, *ibid* p. 167, "Due to long reverence to UK laws and precedents, many view that computer programs are not patentable in Malaysia, in line with the UK approach. Such viewpoint, is obviously not supported by the statutory provisions themselves and is not tenable. The correct view should be that computer programs are patentable in Malaysia".
- 132 See, for example, Folarin Shyllon, "Intellectual Property Law in Nigeria", IIC, Vol. 21, p. 140 *et seq* for a history of Nigerian patent law from 1900 to the present day. Previously, till 1970, the grant of patents in Nigeria also depended on a system of re-registration of granted UK patents but, for obvious reasons, this was not regarded as an adequate arrangement for Nigerian inventors when the country began to develop more quickly. Shyllon notes that, *ibid* p. 143, "The [1970] Act is modelled on the draft law prepared in 1965 by the United Bureau for the Protection of Intellectual Property (BIRPI), WIPO's predecessor. It has been suggested that by adopting BIRPI, Nigeria did not proceed on any policy consideration, since at that time Nigeria was still to formulate a national economic policy with regard to its industrial and technological development. Rather it adopted the model law simply because the then Acting Registrar of Patents actively participated in the deliberations, resulting in the draft model law".
- 133 See, for example, Ivan B Ahlert, "New Brazilian Industrial Property Law", IIC, Vol. 28, No.5, 1997. Ahlert is a Former Chairman of the Patent Commission of the Brazilian Intellectual Property Association.
- 134 Ahlert, *ibid*, indicates that "The reservation as to acts resulting in prejudice to the economic interests of the patentee substantially limit the exception. It should be noted that no expression of the type "substantial" or "significant" is used before "prejudice" ["damage"], leading to the interpretation that any prejudice should be considered as making the unauthorised third party liable to prosecution for infringement".
- 135 Carlos Correa, "The International Dimension of the Research Exception", AAAS/SIPPI Paper, January 2004.
- 136 See Australian Law Reform Commission, "Gene Patenting and Human Health", Discussion Paper No. 68, February 2004. The final report, "Genes and Ingenuity: Gene Patenting and Human Health" was released in August 2004. Another review was carried out by the Australian Advisory Council on Intellectual Property (ACIP) with a paper released in December 2004 detailing a number of different options for an Australian Experimental Use exception.
- 137 Patents Act 1990, Act. No. 83 of 1990.
- 138 *ibid* Section 118.
- 139 *ibid* Section 119. See, for example, McKeough, Stewart & Griffith, "Intellectual Property in Australia", LexisNexis Butterworths, 2004, pp.402-403 for further patent exceptions provided for in the Australian patent legislation including use of an invention during a period when the patent has lapsed and use of a pharmaceutical invention where the term of the relevant patent has been extended.
- 140 Based on *Frearson v Loe*, quoting Jessel MR, *ibid*.
- 141 *ibid*.
- 142 *ibid* p. 408, section 14.131.
- 143 New Zealand (1953 No 64 as amended, 1972 No 91, 1976 No 112, 1992 No 81, 1994 No 122, 1996 No 139, 1999 No 119, 2002 No 72).
- 144 *ibid* Section 68B.
- 145 Frankel & McLay, "Intellectual Property in New Zealand", LexisNexis Butterworths, 2002, p. 352, "The exclusive rights of the patentee are not found in the body of the Patents Act 1953. The schedules of the Patent Regulations 1954 provide the forms in which a patent may be granted in New Zealand. These forms grant to the patentee, "his agents or licensees and others the right to make, use, exercise and vend the said inventions within New Zealand and its dependencies for the term of the patent."
- 146 It should be noted in passing that this does not necessarily impact compliance with the TRIPS Agreement. Art 1.1 TRIPS provides that "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice". So long as the relevant rules are capable of being adequately enforced, then it will not much matter whether they are provided

for in the text of the Patent Act *per se* or elsewhere. This can of course make matters difficult though in terms of ascertaining what provisions are in force in a given country if they are provided for other than in the patent legislation.

- 147 This review of the Experimental Use exception is only part of a broader review relating to the patenting of genes and the impact on human health. A specific concern of the ALRC was whether or not a specific provision could be formulated to address the problem of facilitating the experimental use of the subject matter of gene patents. No clear cut answer is given on the impact of Art. 27.1 TRIPS in terms of the particular application of an exception targeted at activities under gene patents: "It may be possible to craft a broader research use exception that is specific to some defined subset of gene patents, so that the provision does not discriminate by field of technology in terms of TRIPS. However there would need to be strong arguments to justify differentiating a relevant category of gene patents from patents in other fields of technology". The ALRC also touched on the possibility of enacting a specific Private and Non-commercial Use exception (which it found to be of little use except in the notional task of protecting end-users who likely wouldn't be sued anyway) and a proposed exception for medical practitioners (as discussed below in section 5.10).
- 148 307 F3d 1351 (Fed Cir 2002).
- 149 Azmi *ibid* pp. 411-422.
- 150 The present Chinese Patent Law was adopted at the 4th Meeting of the Standing Committee of the Sixth National People's Congress on March 12, 1984, amended in accordance with the Decision of the Standing Committee of the Seventh National People's Congress on Amending the Patent Law of the People's Republic of China at its 27th Meeting on September 4, 1992, and amended again in accordance with the Decision of the Standing Committee of the Ninth National People's Congress on Amending the Patent Law of the People's Republic of China adopted at its 17th Meeting on August 25, 2000. A third process of review of the patent legislation is currently underway. The journal "China Patents & Trademarks" contains invaluable information as to the history, present and future of Chinese Intellectual Property law.
- 151 Yin Xintian, "The Newly Revised Chinese Patent Act - A Brief Introduction", IIC, Vol. 24, No. 2, 1993.
- 152 Referred to as the "Opinions on Several Issues Relating to Patent Infringement Adjudication (for Trial Implementation)" note, or the "Counterclaim Based on Not Being Deemed an Infringement" note.
- 153 Wu Yuhe, "Experimental Use Exemption in Clinical Trials of New Drugs", China Patents and Trademarks No. 2, 2003.
- 154 See Ahlert, *ibid*, p. 656, "Although not expressly mentioned, the above item [Art 43(ii)] should be interpreted as limiting the exception to non-commercial or non-profit activities. This can be inferred from the passage "for experimental purposes" which, construed in a restrictive manner as it should be, is to be understood as *exclusively* for experimental purposes. Yet, as a general rule, the use should be limited to the experimentation necessary to ascertain the veracity of the specification and the reproducibility of the invention as opposed to the continuous use of the patented invention, which latter should not be admitted as *experimental* for the purpose of the above provision." This is a rather more narrow view of the exception than might be expected to be taken at the present day in the light of comments as to the broadening of the exception that has taken place, for example in Europe, over the last decade.
- 155 See e.g. Pravin Anand & Gitanjali Duggal, Halsbury's Laws of India, Volume 20(2), Intellectual Property II, LexisNexis Butterworths, New Delhi 2005, section [185.1734].
- 156 State Street Bank & Trust Co. v. Signature Financial Group Inc. 149 F.3d 1368 (Fed. Cir. 1998).
- 157 35 U.S.C. § 273 (2001), provided for under the American Inventors Protection Act 1999.
- 158 *Intercontinental Specialty Fats Sdn Bhd v Asahi Denka Kogyo KK* [2000] 4 MLJ 775 (HC), discussed in Azmi, *ibid*, p. 432 *et seq* (although the Prior Use exception was not found to be applicable in this case).
- 159 Noted in Shyllon, *ibid*, p. 150.
- 160 For example, Xu Zhongqiang, "Looking into Issue of Prior Use Right", China Patents & Trademarks, No. 1, 2005, p. 54 *et seq* noting Judgement No. Guiminzhongzi 3/2002 of the Guangxi Higher Peoples Court (although it appears, in this case, that it was only a *utility* model patent that was being litigated).
- 161 Ahlert, *ibid*, p. 661, "The prior user is entitled to continue his activities in Brazil; however he must do so under the same conditions of use existing prior to the time of the date of the filing of the patent application by a third party. In other words, the prior user must not, in principle, exceed the amount

of products manufactured, or otherwise the level of the activities concerning the patented invention, which can basically be a product or a process', continuing at p. 663, "It is to be noted that the above article does not contain similar provisions to WIPO's Draft Treaty as regards the situation in which a person is still making arrangements or preparing to exploit the invention at the time of filing the patent application by a third party. Therefore, this situation does not entitle this person to prior user rights".

- 162 Heath & Petit, *ibid*, p. 463.
- 163 IP/Q3/BRA/1, 24 February 2004.
- 164 42 U.S.C. § 2547(k).
- 165 *Hughes Aircraft Company v. United States of America*, US Court of Federal Claims, 16th August 1993 (29 USPQ 1974, p. 2000 et seq). See e.g. Dieter Stauder, "Patent Infringement in Outer Space - from Ships to Space Ships", Journal of the Chartered Institute of Patent Agents, 1995, pp. 520-527.
- 166 *ibid*.
- 167 Decree 15.110 enacted 24 May 1946 (ratified Law 13.891).
- 168 Civil Aviation Code R 123-8.
- 169 s. 15(1) of the Civil Aviation Act (Ch. 394 Laws of Kenya).
- 170 The contributor from the Phillipines helpfully confirms that they are not aware of any cases in the Phillipines on this provision.
- 171 Strictly speaking the entry from the US contributor does not explicitly reference the Chicago Convention, unlike all the other countries, but reads instead "We are not aware of any laws in the US that permit an aircraft to be detained for patent infringements".
- 172 IP/Q3/NOR/1, 22 January 1998.
- 173 A footnote to Art. 51 TRIPS ("Suspension of Release by Customs Authorities") may also be noted in connection with Art. 6 TRIPS, reading, "It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the rights holder, or to goods in transit".
- 174 Ghana confirmed that only national exhaustion is provided for in its TRIPS Council Review, IP/Q3/GHA/1, IP/Q4/GHA/1, 9 February 2004.
- 175 Ahlert, *ibid*, p. 658.
- 176 Brazilian Industrial Property Code, Article 184 (ii): [A crime is committed against a patent of invention or a utility model patent by he who: (ii) Imports a product that is the subject matter of a patent of invention or of a utility model patent or is obtained by a means or process patented in this country, for the purposes mentioned in the previous item, and that has not been placed on the external market directly by the proprietor or with his content. Penalty - detention of 1 (one) to 3 (three) months, or a fine.
- 177 Ahlert, *ibid*, pp. 659 - 660.
- 178 Art. 61 TRIPS leaves open the option of criminalising patent infringement.
- 179 Noted in Shyllon, *ibid*, p. 150.
- 180 Tshimanga Kongolo, "Towards a New Fashion of Protecting Pharmaceutical Products in Africa - Legal Approach", IIC, Vol. 2/2002, p. 191.
- 181 Kongolo *ibid* p. 196.
- 182 Necessarily, the same regime applies in the US.
- 183 Available at: <http://www.moroccousafta.com/pdf/15-ipr.pdf>
- 184 See http://www.ustr.gov/Document_Library/Fact_Sheets/2004/US-Morocco_Free_Trade_Agreement_Access_to_Medicines.html
- 185 S.K.Verma, "Exhaustion of Intellectual Property Rights and Free Trade - Article 6 of the TRIPS Agreement", IIC, Vol. 29, No.5/1998, p. 552 et seq.
- 186 Sigrid Dörmer, "Dispute Settlement and New Developments Within the Framework of TRIPS - An Interim Review", IIC, Vol. 31, No. 1/2000, p. 29, "No Application of Art. 4 TRIPS to the EU". See also e.g. UNCTAD-ICTSD Resource Book, *ibid*, p. 108.

- 187 IP/Q3/EEC/1, 22 October 1997.
- 188 *Smith Kline & French Laboratories Ltd v Salim (M) Sdn Bhd* [1989] 2 CLJ 228 (HC), discussed in Azmi, *ibid*, p. 436 *et seq*.
- 189 Universal's "The Patents Act 1970 as amended by The Patents (Amendment) Act 2005", Universal Law Publishing Co. Pvt. Ltd., New Delhi, 2005, section 107A.
- 190 Document WT/DS171/3.
- 191 Thorpe, *ibid*.
- 192 In the *Klinische Versuche I & II* decisions.
- 193 Directive 2001/83EC as amended by Directive 2004/27/EC.
- 194 *Merck KGaA v. Integra Lifesciences I, Ltd*, 125 S. Ct. 2372, No. 03-1237 (June 13, 2005).
- 195 Heath & Petit, *ibid*, p. 463.
- 196 Meng Fanhong, "Patent Infringement in Drug Registration", September 2005, (www.kingandwood.com), "For instance, in GlaxoSmithKline Inc. vs Southwest Synthetic Pharmaceutical Factory in 2000, the Chongqing No. 1 Intermediate People's Court held indirectly that by producing patent drugs for the purpose of clinical testing, the infringing party Southwest Synthetic Pharmaceutical Factory caused damages to the interests of the patentee. The court judged that the defendant shall compensate the plaintiff for its losses."
- 197 For example see Wu Yuhe, *ibid* and Meng Fanhong, *ibid*.
- 198 None was acknowledged at the TRIPS Council review of the Ghanaian patent law in 2004.
- 199 Thorpe, *ibid*.
- 200 See http://www.ustr.gov/Document_Library/Fact_Sheets/2004/US-Morocco_Free_Trade_Agreement_Access_to_Medicines.html
- 201 See e.g. "Symposium on Medical Patents", Journal of the Patent Office Society, May 1934, Vol. XVI, No. 5, p. 434. Despite the fact that this symposium took place over seventy years ago, the institutions present (including the US Patent Office and the US National Institute of Health) and the views expressed would be familiar to those involved in the debate today,
- 202 36 USPQ 2d 1050 (1995).
- 203 No. 5, 080, 111.
- 205 In what seems to have been a strategy doomed to fail, Dr Pallin reportedly indicated that these royalty fees were not levied for financial gain *per se* but were intended to secure the professional respect of his peers given that the relevant journal had declined to publish his paper.
- 201 35 U.S.C. §287(c)(1)
- 206 ALRC report, *ibid*, section 22.36.
- 207 ALRC report, *ibid*, Chapter 22.
- 208 OECD Working Party on Biotechnology - Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies (2002), referred to in ALRC report, *ibid*, p. 608.
- 209 A fine introduction is provided in Dutfield, *ibid*, Chapter 7, "Plant Breeding, the Seed Industry and Plant Breeders' Rights".
- 210 UK CIPR Report, *ibid*, Recommendation, p. 66.
- 211 The present author is currently completing a study comparing the 1982 Law of the Sea Convention and its implementation of the concept of the Common Heritage of Mankind with the patent system and global biomedical R&D models.
- 212 See e.g. Zakir Thomas, "Common Heritage to Common Concern: Preserving a Heritage and Sharing Knowledge", Journal of World Intellectual Property, Vol. 8, No. 3, May 2005, pp. 241-270. See also e.g. UNCTAD-ICTSD Resource Book, *ibid*, Chapter 21.
- 213 It has been argued that the UPOV New Variety Breeding exception should be made subject to compensation, see e.g. Dutfield, *ibid*, p. 192.

- 214 See http://www.wto.org/english/tratop_e/trips_e/intel8_e.htm.
- 215 Specifically, in terms of cases filed in the local courts per year during this period, these are to be broken down as follows: 1998 (1162), 1999 (1485), 2000 (1596), 2001 (1597), 2002 (2081), 2003 (2110) and 2004 (2549).
- 216 Joaquim Eugenio Goulart & Ivan Ahlert, "The Enforcement of Patent Rights in Brazil" in Heath & Petit, "Patent Enforcement Worldwide: A Survey of 15 Countries, Writings in Honour of Dieter Stauder", IIC Studies in Industrial Property and Copyright Law, Hart Publishing, Oxford, 2005. p. 452.
- 217 See e.g. UNCTAD-ICTSD Resource Book, *ibid*, pp. 668-677 and 680-682.
- 218 See e.g. Musungu & Dutfield, "Multilateral agreements and a TRIPS-plus world: The World Intellectual Property Organisation (WIPO)", Quaker United Nations Office TRIPS Issues Paper no. 3, 2003.
- 219 Concept Paper Relating to Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Communication from the European Communities and their Member States, IP/C/W/339, 4 March 2002.
- 220 For an opposing view see e.g. Bourgeois & Burns, "Implementing Paragraph 6 of the Doha Declaration on TRIPS and Public Health: The Waiver Solution", Journal of World Intellectual Property, Vol. 5, No. 6, 2002.
- 221 Frederick M. Abbott, "Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health", Quaker United Nations Office (QUNO) Occasional Paper No. 9, February 2002, p.5.
- 222 *ibid*, section V.
- 223 Paragraph 9 of the August 30th Decision provides that "This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement."
- 224 Nouvel article L613-16 (Loi n° 2004-800 du 6 août 2004 art. 18 Journal Officiel du 7 août 2004)
- 225 See 42 USC § 7608 ("Mandatory Licensing" under US Clean Air Act) and 42 USC § 2183 ("Nonmilitary utilisation" under US Atomic Energy provisions).
- 226 " But there is a better way of thinking about the management of emergency medical stockpiles - one that would change the incentives to protect us from anthrax, avian flu, severe acute respiratory syndrome and other emerging public health threats, at least for medicines that already have commercial markets for other uses. The proposal is to permit governments to acquire medicines freely for stockpiles from generic suppliers, on the condition that if the medicines were used to treat people, the patent owner would receive royalties. This makes it much cheaper to acquire the stockpiles but also increases the value of the patented invention, as long as there is some probability that the emergency use will occur. The price of medicines is related to their expected benefit. But this assumes a nearly 100 per cent probability that someone will actually use them. In the case of stockpiles, on the other hand, there is often a fairly low probability of use. Indeed, the lower the risk of the emergency, the lower the expected benefit of the stockpile. As long as the prices for the medicines are above marginal costs and the patent owner insists on a price related to the price of the drug when used, stockpiles will be small. But if governments could freely obtain stockpiles at marginal costs, with only a liability to remunerate the patent owner in the event of use, the incentives to match costs and benefits will be far more efficient.", James Love, Financial Times, October 28th, 2005.

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