

A GUIDE TO PHARMACEUTICAL PATENTS

VOL. I

Editor Carlos M. Correa

South Centre

JULY 2008

THE SOUTH CENTRE

In August 1995, the South Centre became a permanent intergovernmental organization of developing countries. In pursuing its objectives of promoting South solidarity, South-South cooperation, and coordinated participation by developing countries in international forums, the South Centre prepares, publishes and distributes information, strategic analyses and recommendations on international economic, social and political matters of concern to the South. For detailed information about the South Centre see its website www.southcentre.org.

The South Centre enjoys support from the governments of its member countries and of other countries of the South, and is in regular working contact with the Group of 77 and the Non-Aligned Movement. Its studies and publications benefit from technical and intellectual capacities existing within South governments and institutions and among individuals of the South. Through working group sessions and consultations involving experts from different parts of the South, and also from the North, common challenges faced by the South are studied and experience and knowledge are shared.

This “South Perspectives” series comprises authored policy papers and analyses on key issues facing developing countries in multilateral discussions and negotiations and on which they need to develop appropriate joint policy responses. It is hoped that the publications will also assist developing country governments in formulating the associated domestic policies which would further their development objectives.

A Guide to Pharmaceutical Patents was first published in July 2008 by the South Centre. Reproduction of all or part of this publication for educational or other non-commercial purposes is authorized without prior written permission from the copyright holder provided that the source is fully acknowledged and any alterations to its integrity are indicated. Reproduction of this publication for resale or other commercial purposes is prohibited without prior consent of the copyright holder.

South Centre, POB 228, Chemin du Champ d'Anier 17, 1211 Geneva 19, Switzerland.

© South Centre, 2008

ISBN 92-9162-032-7 Paperback
ISSN 1607-5323 Paperback

A GUIDE TO PHARMACEUTICAL PATENTS

Vol. I, July 2008

TABLE OF CONTENTS

VOL. I

PREFACE	<i>xiii</i>
CHAPTER 1 NOVELTY	1
I. INTRODUCTION.....	1
II. INTRODUCING NOVELTY	1
II.1. The Concept of Novelty.....	1
II.2. Absolute and Relative Novelty	2
II.3. Disclosure Issue in Novelty.....	4
II.4. Destroying Novelty	5
II.5. Grace Period.....	16
II.6. Guidelines for Examining Novelty	21
III. NOVELTY IN INTERNATIONAL AGREEMENTS	25
III.1. Novelty with Reference to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)	25
III.2. Novelty under the Patent Law Treaty (PLT) and the Draft Substantive Patent Law Treaty (SPLT).....	26
IV. SOME NOVELTY ISSUES IN PHARMACEUTICAL PATENTS	27
V. CONCLUSION AND RECOMMENDATIONS	38

CHAPTER 2 INVENTIVE STEP.....	39
I. DEFINING THE CONCEPT	39
I.1. Definition.....	39
II. WHAT ARE THE PUBLIC HEALTH ISSUES IMPLICATED?	40
II.1. Special Concerns with Pharmaceuticals and Inventive Step: The Use of Known Elements and Methodologies	41
III. THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY (TRIPS)	43
III.1. What are the TRIPS Requirements?	43
III.2. What are the TRIPS Flexibilities?	44
IV. WHAT ARE THE EXISTING POLICY APPROACHES?.....	44
IV.1. The United States	48
IV.2. The European Patent Office (EPO)	62
V. THE SITUATION IN DEVELOPING COUNTRIES.....	70
V.1. Example of Text and Language from Developing Countries	71
VI. CONCLUSIONS AND RECOMMENDATIONS	74
 CHAPTER 3 INDUSTRIAL APPLICABILITY/UTILITY	 81
I. INTRODUCTION.....	81
II. INDUSTRIAL APPLICABILITY AND UTILITY.....	84
III. TECHNICAL EFFECT UNDER EUROPEAN LAW	87
IV. UTILITY IN US LAW AND PRACTICE.....	89
IV.1. Enablement, Utility and Section 112.....	97
IV.2. Proof and the Issue of More than One Utility	101
V. INDUSTRIAL APPLICABILITY IN EUROPE	106

VI.	CONCLUSIONS AND RECOMMENDATIONS	108
CHAPTER 4 THERAPEUTIC, SURGICAL AND DIAGNOSTIC METHODS.....		109
I.	INTRODUCTION.....	109
II.	THE RATIONALE FOR THE EXCLUSION OF THERAPEUTIC, SURGICAL AND DIAGNOSTIC METHODS	111
III.	THE SCOPE OF THE EXCLUSION.....	115
IV.	THE PATENTING OF A NEW THERAPEUTIC EFFECT	115
V.	CONCLUSION	117
CHAPTER 5 SECOND INDICATIONS.....		119
I.	DEFINING THE CONCEPT	119
	I.1. Definitions	119
	I.2. History of the Concept.....	126
II.	WHAT ARE THE PUBLIC HEALTH ISSUES IMPLICATED?	128
	II.1. Reduction of Access.....	128
	II.2. Biopiracy.....	129
	II.3. Promotion of Traditional Medicine.....	129
III.	THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY (TRIPS)	130
	III.1. What are the TRIPS Requirements?	130
	III.2. What are the TRIPS Flexibilities?	130
IV.	WHAT ARE THE EXISTING POLICY APPROACHES?.....	131
	IV.1. Options on New Uses: Advantages and Disadvantages	132
	IV.2. The United States Patent and Trademark Office	

	(USPTO) and the European Patent Office (EPO): Advantages and Disadvantages.....	136
V.	THE SITUATION IN DEVELOPING COUNTRIES.....	146
	V.1. Countries that Specifically Exclude New Uses.....	147
	V.2. Countries that Specifically Allow New Uses.....	151
VI.	CONCLUSIONS AND RECOMMENDATIONS	153
	BIBLIOGRAPHY	167

LIST OF BOXES

Box 1	Amgen/Erythropoietin.....	30
Box 2	Pfizer/Amlodipine	33

LIST OF ANNEXES AND APPENDICES

Annex I	Model Regulations and Guidelines on Inventive Step.....	76
Appendix I	Table of Developing Country Policies on Second Indications	154

VOL. II

PREFACE	<i>xiii</i>
----------------------	--------------------

CHAPTER 6 SUBSTANCES OCCURRING IN NATURE.....	1
--	----------

I.	INTRODUCTION.....	1
II.	DEFINING A PRODUCT OF NATURE.....	1

III.	THE CONCEPT OF INVENTION AND THE PRODUCTS OF NATURE DOCTRINE	3
	III.1. The Doctrine in the United States.....	7
	III.2. The Doctrine in Europe.....	10
	III.3. Implications	11
IV.	CONCLUSIONS	16
CHAPTER 7 FUNCTIONAL CLAIMS		17
I.	DEFINING THE CONCEPT	17
	I.1. Identifying the Outer Boundaries	17
II.	WHAT ARE THE PUBLIC HEALTH ISSUES IMPLICATED?	18
	II.1. Reduction of Access.....	18
III.	THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY (TRIPS)	21
	III.1 What are the TRIPS Requirements?	21
IV.	WHAT ARE THE EXISTING POLICY APPROACHES?.....	21
	IV.1. The European Patent Office (EPO)	22
	IV.2. The United States Patent and Trademark Office (USPTO).....	26
V.	THE SITUATION IN DEVELOPING COUNTRIES.....	31
VI.	CONCLUSIONS AND RECOMMENDATIONS	33
CHAPTER 8 ENABLING DISCLOSURE.....		35
I.	INTRODUCTION.....	35
	I.1. Meaning of ‘Enabling Disclosure’	36
II.	SUFFICIENT DISCLOSURE IN PRACTICE	40
	II.1. The Issue of Sufficient Enablement	40
	II.2. The Issue of the Person Skilled in the Art.....	48

III.	ENABLING DISCLOSURE IN THE LATEST TECHNOLOGY	55
III.1.	Facilitating Enabling Disclosure in Patents on Micro-organisms	55
IV.	LATEST LEGAL DEVELOPMENTS	57
IV.1.	The Enablement Issue in the Substantive Patent Law Treaty (SPLT)	57
IV.2.	Reform of Patent Law in the USA: The Issue of Enabling Disclosure	59
V.	CONCLUSION AND RECOMMENDATIONS	60
CHAPTER 9 MARKUSH CLAIMS.....		63
I.	INTRODUCTION.....	63
II.	MARKUSH CLAIMS IN EUROPE AND THE USA	65
III.	CONCLUSION	68
CHAPTER 10 SELECTION PATENTS		71
I.	INTRODUCTION.....	71
II.	EVOLUTION OF PRACTICES ON SELECTION INVENTION.....	73
III.	CONCLUSION	80
CHAPTER 11 PRODUCT-BY-PROCESS CLAIMS.....		81
I.	INTRODUCTION.....	81
II.	PRODUCT-BY-PROCESS PATENTS IN THE USA	84
II.1.	Admissibility of PPCs	84

II.2. Infringement.....	93
II.3. PPCs and Drug Registration.....	100
III. PRODUCT-BY-PROCESS PATENTS IN EUROPE	101
IV. PRODUCT-BY-PROCESS CLAIMS IN JAPAN.....	104
V. CONCLUSIONS AND RECOMMENDATIONS	105
BIBLIOGRAPHY	109

LIST OF BOXES AND FIGURES

Box 1 <i>No Fume v. Pitchford</i>	41
Box 2 <i>WL Gore and Associates v. Garlock Inc.</i>	43
Box 3 <i>Biogen v. Medeva</i>	47
Box 4 <i>Kirin Amgen Inc. & Others v. Avantis & Others</i>	52
Box 5 <i>Kirin Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.</i>	53
Box 6 Article 10: Enabling Disclosure SCP/10/4	58
Box 7 Markush Claim Example	65
Figure 1 Genuine Selection Invention	72
Figure 2 Non-Genuine Selection Invention	72

LIST OF TABLES

Table of Legislative, Regulatory and Examination Guideline Approaches	31
--	----

PREFACE

Pharmaceutical products and processes account for a significant part of patents applied for and granted worldwide. As patents confer exclusive rights and lead to increased prices for such products, they are of particular concern in developing countries. In developed countries, patents provide a stimulus to research and development (R&D) in new medicines or in finding new uses or forms of administration of the existing ones. Their social effects on prices in these countries are attenuated by the role that states and social security systems play in securing access to medicines. In developing countries, however, patents do not encourage R&D needed to address the diseases that most affect them, such as malaria and tuberculosis, while the monopolistic rights they confer, and the ensuing pricing policies, deprive a large part of the population of the possibility of receiving the treatments needed. This leads to an ethically unacceptable situation where many people may not receive treatments that are available and which could cure them or save their lives. The case of medicines to treat HIV/AIDS has provided a dramatic example.

This book is intended to provide policy makers with information and guidance about some important aspects relating to the patenting of pharmaceutical inventions. This theme was chosen on the basis of three main considerations.

First, the adoption of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement represented a resounding victory for the international pharmaceutical industry, as it included an obligation to provide patent protection for pharmaceutical products. However, the Agreement did not include specific rules on all aspects relating to the grant of patents. The determination of how the patentability criteria are applied, the form and breadth of claims and the extent of disclosure are some of the core flexibilities available under the TRIPS Agreement. While there is a number of important post-grant flexibilities, such as parallel imports and compulsory licenses, which have been extensively

explored in the literature,¹ much less effort has been made to identify from the perspective of developing countries the room available to grant a patent or not and to determine the scope of protection. These are crucial aspects of a patent policy which this book explores in some depth.

Second, not only do pharmaceutical patent applications account for a large proportion of total patent applications, but the grant or not of a patent in this field may have important implications for public health. While the number of new chemical entities developed per year has declined dramatically in the past ten years, there is a proliferation of patents on salts, ethers, esters, polymorphs, isomers and other variants of known drugs as well as on formulations and combinations thereof. This type of patents, often called “evergreening” patents, is strategically used to block generic competition. The essential point made in this book is that in many cases such patents could not have been granted if adequate standards to assess the patentability requirements had been applied.

Third, many patent offices have developed practices for assessing patent applications following the advice received from patent offices of developed countries or the World Intellectual Property Organization (WIPO), without proper consideration of such countries’ development needs. This book is premised on the concept that patentability criteria and the scope of protection should be determined, as a basic component of a patent policy, having in view the conditions and objectives of the country concerned. In the absence of a defined government policy on the delicate issues raised by patent protection, the policy is finally made by the patent offices or the courts. Health ministries and other departments, as appropriate, should be able to participate in the crafting of that policy.

The book contains notes prepared by Ravi Srinivas, Santanu Mukherjee and Dalindyabo Shabalala as part of the research undertaken, under my supervision, at the South Centre in the context of a project on intellectual property rights, innovation and development, funded by the Rockefeller Foundation. The notes expand on and supplement the

¹ See, for example, C Oh and S Musungu *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines* (World Health Organization – South Centre Geneva 2006).

previous South Centre publication *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (Geneva 2000). However, they do not pretend to cover exhaustively all the issues raised by the patenting of pharmaceuticals. They only provide information about how some of such issues are dealt with in developed countries and how much room for manoeuvre is left to developing countries in adopting their own approaches. The aim of the notes is to facilitate the adoption of informed patent policies in developing countries in line with the objective of promoting access to pharmaceutical products for all.²

Although a significant portion of the analysis made in the notes is based on the law and jurisprudence of developed countries, this is not to suggest that their practices are to be automatically followed in developing countries but to show their rationale, limitations and how these countries have designed the patent policies to suit their national interests. The reading of the notes, which address several horizontal issues about patentability (applicable to inventions in the pharmaceutical industry and other sectors of technology) should be supplemented with that of *Guidelines for the examination of pharmaceutical patents: developing a public health perspective, Working Paper* (the World Health Organization (WHO), the International Centre for Trade and Sustainable Development (ICTSD) and the United Nations Conference on Trade and Development (UNCTAD), available at www.ictsd.org, Geneva 2006), which deals with certain types of claims particularly relevant to pharmaceuticals.

It must be borne in mind that there is no single “patent system” and that governments can, within the limits imposed by the applicable international obligations, pursue the solutions that are better adapted to their own needs. The notes contained in this book show the diversity of solutions adopted at the national level (for example with regard to the criterion of industrial applicability/utility) and even within the same country (for example the reading of the product-by-process claims in the United States of America (USA)), the evolution that has taken place in some developed countries towards increased protection (for example the Markush claims in the USA), the application of public interest limits

² See the Doha Declaration on the TRIPS Agreement and Public Health (4th World Trade Organization Ministerial Conference November 2001), available at www.wto.org

(for example in relation to “selection” patents), and the use of legal fictions (such as in the case of the admissibility of patents on “second indications”).

Chapter 1 (S. Mukherjee) elaborates on the concept of novelty, the differences in its regulation in national laws and the acts that may destroy it and consequently prevent the granting of a patent. It examines, in particular, the issue of novelty as applied to pharmaceutical inventions. Developing countries are recommended to apply a concept of “absolute” novelty and to avoid the adoption of legal fictions that unnecessarily expand the space for patenting of pharmaceutical products.

Chapter 2 (D. Shabalala) contains a detailed study of the way in which the standard of inventive step/nonobviousness has been applied in the USA and by the European Patent Office (EPO). It shows that the required level of inventive step/nonobviousness may vary, as it is not determined by the TRIPS Agreement, and that developing countries may opt for the standard that best suits their level of technological development and public policies, including in the area of pharmaceuticals. The experiences in the application of such standards allows interesting lessons to be drawn for developing countries. As a general rule, they should adopt a notion of a qualified “person skilled in the art” and ensure that patents are granted only when a real contribution to the state of the art has been made.

Chapter 3 (R. Srinivas) studies practice in the application of the standard of industrial applicability/utility in developed countries and its implications for the patentability of pharmaceutical inventions. In particular, it considers what degree of knowledge about the therapeutic effects of a product is required to obtain a patent thereon. Developing countries are recommended to apply an industrial applicability standard which avoids the patenting of early or speculative developments that may deter further innovation and production.

Chapter 4 (R. Srinivas) deals with therapeutic, surgical and diagnostic methods. It makes it clear that most countries do exclude such methods from patentability, consistent with the exemption allowed by article 27.3(a) of the TRIPS Agreement. Such methods lack

industrial applicability and may be deemed non-patentable even in the case of an explicit exemption in countries where such standard is applied. Developing countries are advised not to allow for the patentability of therapeutic, surgical and diagnostic methods. Among other advantages, this solution permits the refusal of applications on “second indications” of known drugs, which are equivalent to applications on therapeutic methods.

A review of the patentability of “second indications” of known drugs is undertaken in Chapter 5 (D. Shabalala). This chapter considers four possible options for dealing with the scope of pharmaceutical product patents and with protection of the new use of known products. It considers thoroughly the premises on which patentability of such uses has been accorded in developed countries and the practice of some developing countries (such as India) where patents on second indications are refused. The TRIPS Agreement, in fact, does not require WTO members to recognize those patents. Developing countries are recommended to make full use of this TRIPS flexibility and to exclude patents on new therapeutic uses of known medicines within the framework of policies aimed at promoting follow-on innovation and access to drugs.

Chapter 6 (R. Srinivas) explores the differences between “discovery” and “invention” in the context of the discussion about the patentability of substances occurring in nature. It examines how the dividing line between those two concepts has blurred in some jurisdictions. This chapter makes it clear that developing countries can adopt their own approaches on the matter, as the TRIPS Agreement mandates the grant of patents only with regard to “inventions”, the definition of which is left to the discretion of WTO members. The chapter recommends developing countries to stick to a rigorous concept of invention and to exclude the patenting of substances occurring in nature.

Chapter 7 (D. Shabalala) studies the problems posed by “functional” claims (that is, those describing what an invention does rather than what the invention structurally is) and their limited admissibility even in developed countries. The analysis in this chapter also addresses the applicability of what is known as the “doctrine of

equivalents” and how it may influence the interpretation of functional claims in cases of alleged infringement. Developing countries are recommended to require the description of pharmaceutical products in structural terms and to admit functional language only in very limited and well defined circumstances.

Chapter 8 (S. Mukherjee) deals with another important aspect relating to the assessment and grant of patents: the level of disclosure required to ensure reproducibility of the invention by a person skilled in the art. It considers the practice relating to “sufficient enablement” in the USA and by the EPO. It recommends developing countries to adopt strict requirements of disclosure in order to ensure that patents properly fulfil their informational function. It also warns such countries against supporting the harmonization of rules that may restrain their current space to determine their policies on the matter.

Chapter 9 (S. Mukherjee) deals with a particular type of claim common in the chemical and pharmaceutical fields: the “Markush claims”. These claims may cover thousands or even millions of compounds that share some common characteristics. The admissibility of Markush claims raises issues of sufficient disclosure, since normally the applicant has only empirically obtained and tested a few of the potential embodiments of the invention. Developing countries are advised to apply a strict requirement of disclosure which ensures that patents are granted only with regard to the embodiments of the invention that have actually been obtained by the applicant.

Chapter 10 (S. Mukherjee) discusses a related issue, the “selection patents”, which are often based on previous Markush claims. The admissibility of selection patents is controversial as the members selected from a larger group are already known and, hence, they lack novelty. The chapter reviews the practice in developed countries and suggests a restrictive approach to the subject. As in the case of other issues considered in the notes, there is nothing in the TRIPS Agreement or other international treaties obliging countries to accept such patents.

Chapter 11 (R. Srinivas), finally, addresses another particular form of claim: the product-by-process claim wherein a product is claimed on the basis of the method used to obtain it. This chapter

examines in detail the practices in developed countries and the divergent interpretations that have arisen with regard to the infringement of such claims. While clarifying that there are no international mandatory rules on the matter, the chapter recommends that if developing countries accept such claims, they should be limited to cases where the product cannot be otherwise described.³ In addition, such claims should be deemed to be infringed only when the same method of production is employed.

The notes included in this volume have been edited by D. Shabalala and later reviewed for consistency in the arguments and presentation within the context of the South Centre's Innovation and Access to Knowledge Programme (IAKP).

Carlos M. Correa
January 2008

³ For instance, the Chinese patent office has adopted the modality of product-by-process claims to protect traditional medicines, since their characteristics generally make it difficult precisely to determine their active components. See *Patent Application as Indicator of the Geography of Innovation Activities: Problem and Perspectives*, Xuan Li and Yogesh Pai, Paper prepared for Joint Session between South Centre and the World Institute for Development Economics Research of the United Nations University (UNU-WIDER) at Southern Engines of Global Growth: China, India, Brazil and South Africa (CIBS) at WIDER, Helsinki, Finland, 7–8 September 2007 (forthcoming South Centre research paper 2008).

CHAPTER 1

NOVELTY

I. INTRODUCTION

This chapter will deal specifically with the novelty issue in pharmaceutical patents. It is divided into four sections. In *Section II*, the “novelty” requirement which forms an essential part of the patent system is introduced and information on the novelty issue in the present international state of affairs is provided. This section also provides a distinction between absolute and relative novelty, and discusses the different aspects of novelty in detail, highlighting issues such as disclosure, how novelty is destroyed, grace period and different patent examination practices.

The paper then moves to *Section III* which elaborates on novelty in international agreements. *Section IV* provides details of pharmaceutical patents and the policy approaches followed in different major jurisdictions and the standard practice in some developing countries. *Section V* draws conclusions and makes some recommendations.

II. INTRODUCING NOVELTY

II.1. The Concept of Novelty

“Novelty” is one of the essential requirements for an invention to qualify for patent protection. As per this requirement, a patent application for an invention needs to be “novel” or new before the date of filing of a patent application.⁴ A novel invention is one which has

⁴ CM Correa *Protection and Promotion of Traditional Medicine Implications*

not been previously disclosed in any form or, in other words, was not available as “prior art”. Thus the invention “... needs to be quantitatively different from what has been disclosed previously; that is, that the technical information disclosed by the patent is not already available to the public”.⁵

McCarthy’s *Desk Encyclopaedia of Intellectual Property* states: “Novelty is opposite to ANTICIPATION. For example, an invention that is ‘anticipated’ by the disclosure of a prior art patent or publication lacks ‘novelty’.”⁶ To prove that there is no novelty in an application, the prior use is to be in a manner wherein access to the information concerned would allow a third party to execute the invention without significant further research.⁷ Hence, novelty is established to confirm the claim of the applicant that he or she was the first to make the invention and it qualifies under the requirements set for the granting of a patent.⁸

II.2. Absolute and Relative Novelty

According to present practice, novelty can be *absolute* which means that it is universally new (new throughout the world) or *relative* which means it is new only within a restricted area (for example within a country). A detailed description of the two types of novelty will clarify the distinction between the two.

Absolute Novelty: The practice of absolute novelty is actually based on the foundational notion of patent law, that only inventions which are absolutely new should be patented. Hence, if a claimed

for Public Health in Developing Countries (South Centre, Geneva 2002) p. 40.

⁵ L Bently and B Sherman *Novelty in Intellectual Property Law* (Oxford University Press Oxford 2001) p. 413.

⁶ JT McCarthy, RE Schechter and DJF McCarthy *Desk Encyclopedia of Intellectual Property* (3rd edn The Bureau of National Affairs Inc. Washington DC 2004) p. 406.

⁷ CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) Part IV.1.

⁸ RP Merges, PS Menell and MA Lemley *Intellectual Property in the New Technological Age* (2nd edn Aspen Law & Business New York 2000) p. 131.

invention already existed in the public domain anywhere in the world in one form or another, it could no longer qualify as a new invention (for the purpose of acquiring patent rights) because that would exclude the general public from what was already in existence.⁹ As such, the practice of absolute novelty balances the interests between public rights (through availability of incremental innovations in the public domain) and private rights of inventors.

Relative Novelty: In the case of relative novelty, the novelty is usually restricted to within the country, where only local knowledge can destroy such novelty. Effectively, therefore, if an inventor discloses something outside the country, it will still be considered to be unknown inside the country. So, in practice, even when something is not new or novel (globally), it will be considered novel within the particular jurisdiction and accorded monopoly rights via patents. This might be considered as a way to extend monopoly rights unduly, but those in favour argue that whereas absolute novelty obstructs exploitation of foreign technology in the local market, relative novelty allows more diffusion of technology through technology importation.¹⁰ This is based on the notion that absolute novelty does not allow "... modification and refinement ..." of foreign technology.¹¹

It is important to note that a patent monopoly is granted to the inventor as an incentive for the invention or, in other words, for the value added: "The patent system was conceived to reward the inventor for contributions to the pool of existing knowledge. The criteria used to define what is new are key determinants of the scope of possible limitations to the free access and use of technical knowledge and products in the public domain."¹² Naturally, it would be against the purpose of the patent system to follow a practice of novelty that

⁹ WS Thompson 'Reforming the Patent System for the 21st Century' (1993) 21 *AIPLA Q. J.* 171, p. 176.

¹⁰ D Jiang-Schuerger 'A Topic on Harmonization: Relative and Absolute Novelty' (2001) 64(1) *China Patents & Trademarks* 57, p. 60.

¹¹ J Otieno-Odek 'Public Domain in Patentability after the Uruguay Round: A Developing Country's Perspective with Specific reference to Kenya' (1995) 4 *TUL. J. Int. & Comp. Law* 15, p. 22.

¹² CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) Part IV.1.

extended beyond its expected boundaries, but the practice varies from one country to another.

II.3. Disclosure Issue in Novelty

The patent system is based on providing incentive to the inventor by granting restricted monopoly rights on one hand and by encouraging dissemination of knowledge on the other through the disclosure of the invention. In accordance with a popular view, “A patent is a contract between the inventor and society where the inventor receives a temporary monopoly at the cost of disclosure”.¹³ Hence as a standard requirement, a patent application must disclose the information known to him or her to perform the invention on which the patent is claimed.

This disclosure of the patent makes the invention available to the public and so any person interested in the invention can do further research based thereon. Furthermore, the disclosure clause is also essential so that after the expiry of the patent, the invention can be made and used by others. This fulfils the criteria of the dissemination of knowledge and furthering research in science and technology. To achieve this aim, the domestic law on patents should have a provision requiring a detailed description of the invention that would sufficiently allow the local expert to learn from the invention.

In the USA, this is a requirement under 35 USC § 112 whereby the patentee needs to describe the invention in such a manner that any ordinary person skilled in the art can read and understand the invention in such a manner that he or she can work the invention.¹⁴ Under the requirements of the EPO, a similar requirement is laid down under article 63 of the European Patent Convention (EPC) which states: “The application must disclose the invention in a manner that is sufficiently clear and complete for it to be carried out by a person skilled in the art.”

¹³ U Kaiser and T Rønne ‘A Danish view on Software Related Patents’ (Discussion Paper 2004–05 Center for Economic and Business Research 2004) p. 5.

¹⁴ RP Merges, PS Menell and MA Lemley *Intellectual Property in the New Technical Age* (2nd edn Aspen Law & Business New York 2000) pp. 131–132.

It must not be ignored that if the disclosure requirement is not strictly applied, in a manner which balances public and private interest, it may become just a formality. A proper disclosure practice would require the applicant to provide sufficient details so that each embodiment of the invention applied for can be reproduced by a person skilled in the art.¹⁵ Hence, the “enablement” requirement would mandate disclosure of each embodiment in a case where several embodiments are claimed.

Here it must be noted that the EPO and other patent offices do not make it obligatory for the disclosure to include specific information on ways/methods of obtaining all possible variants within the claim definition. “One approach applied by some patent offices, is to permit more generalized claims for those inventions constituting a substantial technical contribution. Thus, ‘pioneer’ inventions — those that open a whole new technical field — may be entitled more generality in their claims than mere ‘follow-up’ inventions — those that only constitute improvements or ‘minor’ innovations.”¹⁶

II.4. Destroying Novelty

As mentioned earlier, in some countries there are various factors that destroy novelty wherever it takes place, whereas in other countries (actually a minority nowadays) novelty is destroyed only if these factors take place inside the country.¹⁷ Further, the destruction of novelty caused by anticipation varies in different jurisdictions; in some, a “single source” anticipation rule applies, as in the USA.¹⁸ In such practice, the invention is anticipated only in cases where the claimed invention is disclosed in a single reference of prior art.¹⁹

¹⁵ CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) Part VI.

¹⁶ Ibid.

¹⁷ SP Ladas *Patents, Trademarks, and Related Rights National and International Protection* (Harvard University Press Cambridge 1975) Vol 1, p. 287.

¹⁸ DS Chisum and MA Jacobs *Understanding Intellectual Property Law* (Times Mirror Books, Legal Texts Series, New York 1992) pp. 52–53.

¹⁹ Ibid.

In the United Kingdom (UK) the present law²⁰ is based on the requirements under the EPC. Hence, in the UK novelty in a patent application requires that the claimed invention "... must not be found at the priority date in any 'matter (whether a product, a process, information about either, or anything else) which has at any time been made available to the public (whether in the UK or elsewhere) by written or oral description, by use, or in any other way'".²¹ As in most other patent jurisdictions, an invention loses its novelty and becomes available in the public domain if there is an "enabling disclosure" or in other words if the public is informed about such invention (because it has already been worked or practised)²² prior to the filing of the patent.²³

It is impossible to predict the nature of the information that needs to be disclosed for a chemical compound to be worked or practised because it is not possible to specify, in advance, what type of format the prior art needs to adopt to destroy novelty. This varies in each case and depends on the particular invention under examination.²⁴ Historically, the British patent system gave much importance to prior use in considering the novelty issue in patent applications. This was mainly because the approach was developmental, with an intention to introduce more inventions into local manufacturing.²⁵ Under the previous UK law,²⁶ even when "prior publication" was sufficient to disqualify novelty in a patent application, "prior use" was critical. Hence, in some cases even secret use (not deliberate), which in practice did not reveal

²⁰ 1977 Patent Act.

²¹ W Cornish and D Llewellyn *Novelty in Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (5th edn, Sweet & Maxwell London 2003) pp. 174–175.

²² See House of Lords judgement in which it reconfirms that the prior art must provide clear information about the patentee's claims on the invention – *Merrell Dow Pharmaceuticals v. Norton* [1996] RPC 76, 89 (HL).

²³ L Bently and B Sherman *Novelty in Intellectual Property Law* (Oxford University Press Oxford 2001) p. 422.

²⁴ *Ibid.*

²⁵ W Cornish and D Llewellyn *Novelty in Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (5th edn, Sweet & Maxwell London 2003) p. 176.

²⁶ 1949 Patent Act.

the invention, was considered sufficient to invalidate an application due to lack of novelty.²⁷

In an interesting case (decided under the previous law) before the House of Lords, it was held that even when the prior art in a patent did not reveal any information relevant for the applied patent, or in other words about the secret or uninformative use, the applied patent lacked novelty. Bristol-Myers' application for a patent on an ampicillin compound²⁸ was claimed to have been anticipated because Beecham (another pharmaceutical company) had made small quantities of such ampicillin (although without knowing about Bristol-Myers' invention).²⁹

Under the present law, the issue of prior use is no longer treated with the strictness it used to be under the previous law: "Under the new law, novelty is concerned with the patent system as a source of information, not as a stimulus to use nor as protection to those who have already used the invention. The prior user who does not reveal his invention is confined to a limited measure of protection against being held to be an infringer. While prior use was a distinct objection, it was not open to an inventor of a secret process first to use it until it became a success and then to patent it at the most advantageous moment."³⁰

The issue of secrecy was interpreted by the House of Lords in *Merell v. Norton* under the new law.³¹ In this case, the claimant Merell Dow owned a patent (held since 1972) for a pharmaceutical drug (antihistamine terfenadine), used in treating hay fever and allergies. After the drug was taken by the patient, it metabolised (transformed) inside the body to produce certain metabolites (products). At the end of this patent, the claimant identified the particular metabolite having the

²⁷ W Cornish and D Llewellyn *Novelty in Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (5th edn, Sweet & Maxwell London 2003) p. 176.

²⁸ Derivative of the antibiotic penicillin.

²⁹ *Bristol-Myers Co (Johnson's) Application* [1975] RPC p. 127.

³⁰ W Cornish and D Llewellyn *Novelty in Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (5th edn, Sweet & Maxwell London 2003) pp. 176-177.

³¹ *Merell Dow Pharmaceuticals v. Norton* [1996] RPC 76 (HL).

antihistamine property and isolated it, following which it secured a patent on this particular metabolite. This effectively meant that the second patent actually covered the metabolite which produced antihistamine effects by ingestion of the terfenadine. The usage of this new metabolite also had an advantage over the previously patented drug; it had fewer side effects than the previous one. Merrell Dow brought infringement action against Norton, claiming that the defendant was infringing its patent by facilitating the making of the patented metabolite by supplying terfenadine.³² Norton counterclaimed that novelty in the second patent was lost due to prior use, since terfenadine was used by volunteers in clinical trials before the priority date of the patent.

The matter was heard by Lord Hoffman in the House of Lords where, in a landmark judgement, the reverse-infringement test was rejected. According to him, the use of an invented product can become part of the state of the art only if it discloses the necessary information to make it. He stated in his decision that even when the invention existed before the priority date by virtue of the secret use (by volunteers in the clinical trial), this did not result in destruction of the novelty. He stressed the fact that the invention was nothing but a piece of information that was not available to the public. In this case, usage of the drug by the volunteers did not disclose the information required to destroy novelty.³³

In the European Union, novelty gets destroyed in line with the EPC. The novelty requirement under the EPC is found in article 54 (1) which states, “An invention shall be considered to be new if it does not form part of the state of the art” and (2) which states, “The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use or in any other way before the date of filing of the application.” It can be said that if the invention in the patent claim is generally available on the priority date, it is not novel.³⁴ Hence, novelty can be destroyed if the state of the art were already a part of any previous patent or the state of the art (invention)

³² L Bently and B Sherman *Novelty in Intellectual Property Law* (Oxford University Press Oxford 2001) p. 425.

³³ *Ibid.*

³⁴ B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 132.

was communicated to the general public through mechanical reproduction, sale, printing, manuscript copy, lecture/presentation or any other other mode of communication.

The issue of losing novelty was decided by the Enlarged Board of Appeal in G/92 which overturned an earlier decision of the Board of Appeal in T 93/89. In its decision the Enlarged Board of Appeal stated that if an invention were available to a person skilled in the art, then it would be considered as belonging to the state of the art. Here the decision also mentioned that the skilled person did not need to have any special reason for arranging for the investigation of a product generally available on the priority date.³⁵

In its decision, the Board also added, “Where it is possible for the skilled person to discover the composition or the internal structure of the product and to reproduce it without undue burden, then both the product and its composition or internal structure become state of the art. There is no support in the EPC for the additional requirement referred to by Board 3.3.3 in case T 93/89 ... that the public should have particular reasons for analysing a product put on the market, in order to identify its composition or internal structure. According to article 54(2) of the EPC the state of the art shall be held to comprise everything made available to the public. It is the fact that direct and unambiguous access to some particular information is possible, which makes the latter available, whether or not there is any reason for looking for it. ... It may be added that a commercially available product per se does not implicitly disclose anything beyond its composition or internal structure. Extrinsic characteristics, which are only revealed when the product is exposed to interaction with specifically chosen outside conditions, e.g., reactants or the like, in order to provide a particular effect or result or to discover potential results or capabilities, therefore point beyond the product per se as they are dependent on deliberate choices being made. ...”³⁶

In another case decided in 1990, scientists from the National Institutes of Health (NIH)³⁷ had claimed that since their research was

³⁵ Ibid. p. 133.

³⁶ G 1/92, OJ EPO 1993, p. 277.

³⁷ The NIH is a part of the US department of Health and Human Services and is the primary Federal agency which conducts and supports medical research.

funded by the NIH, they were bound to distribute the new (“unique”) biological material to the general public if they were asked to do so (although these biological micro-organisms were not deposited). The patent applicant claimed that such an act made the biological materials publicly available (which was sufficient to destroy novelty). However the Board of Appeal did not consider this as destruction of novelty since the NIH regulated the release of new biological material in a manner that such release could be restricted.

The decision stated, “As becomes apparent from the paper ‘NIH policy relating to reporting and distribution of unique biological materials produced with NIH funding’ ... investigators are reminded that unique or novel biological materials and their products are considered to be inventions and therefore are subject to the various laws and regulations applicable to patents. Accordingly, the NIH requires that grantees and contractors adhere to grant regulations and contract clauses, respectively pertaining to the reporting of inventions to the NIH. In addition and of equal importance, nowhere is there any obligation on the NIH to ensure that the biological material necessary to carry out the inventions in the present case is cultured and kept alive. Finally, the Board notes that NIH policy of releasing biological material developed within NIH research programmes may be changed at any time in such a manner that the release of newly developed biological material could be restricted in any way whatsoever.”³⁸

In yet another case³⁹ it was decided by the Board of Appeal that novelty was destroyed due to prior art. In this case the applicant had claimed novelty in its patent application for human growth hormone, but an earlier patent (filed in 1983) which had claims of generally serviceable method for manufacturing proinsulin, was invoked as a prior document. This prior patent application had also stated that other proteins such as human growth hormones could be manufactured by the same method (although it did not elaborate further on this). The Board of Appeal decided that the previous patent was sufficient for a person skilled in the art to make the human growth hormone with the help of the previous patent.⁴⁰

³⁸ T 815/90, OJ EPO 1994, p. 389.

³⁹ T 158/91 of 30 July 1991.

⁴⁰ B Domeij *Novelty in Pharmaceutical Patents in Europe* (Kluwer Law

In the USA, Title 35 USC Sections 101 & 102 provides details on novelty and how it is destroyed. 35 USC § 101 mentions that the invention should be new and states: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.” The conditions pertaining to novelty and loss of the patent right due to destruction of novelty are elaborated in 35 USC § 102 as follows: “A person shall be entitled to a patent unless:

- a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
- b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
- c) he has abandoned the invention, or
- d) the invention was first patented or caused to be patented, or was the subject of an inventor’s certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for the patent in this country on an application for patent or inventor’s certificate filed more than twelve months before the filing of the application in the United States, or
- e) the invention was described in
 - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under article 21(2) of such treaty in the English language, or (This language represents the text of § 102(e) as amended by the 21st Century Department of Justice Appropriations Authorization Act, Pub. L. 107 – 273 [H.R. 2215] (Nov. 2, 2002) §13205 (titled “Domestic Publication of Patent Applications Published Abroad”) (amending Subtitle E of title IV [the American Inventors Protection Act of 1999] of the Intellectual Property and Communications Omnibus Reform Act of 1999, as enacted by section 1000(a)(9) of Public Law 106-113).

f) he did not himself invent the subject matter sought to be patented, or

g) (1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person’s invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or

(2) before such person’s invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.”

Reading the above subsections of 35 USC § 102 will show that actually subsections (a), (e) and (g) are related to novelty because they are related to events before the date of invention and it is subsections (b) and (d) which specifically relate to novelty destruction or, as termed under US law, “critical date”.⁴¹ A careful reading of 35 USC § 102 makes it clear that the United States Patent and Trademark Office (USPTO) needs to prove that the novelty in a patent application has been destroyed in order to refuse the application. For this reason, if the prior art in a patent or a particular journal article or any other disclosed information is to be used to prove lack of novelty, it should essentially fall into the subsections detailed earlier.⁴²

The issue of novelty being destroyed by prior art is perhaps the most often contested issue in patent law. The issue of anticipation is often contested because the claim of anticipation as a means to challenge is based on evidence which itself might be challenged.⁴³ In yet another case⁴⁴ decided more recently, the Federal Circuit affirmed that the prior art that was claimed to have destroyed novelty did not actually anticipate the patent claim. In this case the Federal Circuit reiterated that the prior art would anticipate the patent claim if the reference disclosed all of the limitations of the claim (either expressly or inherently).⁴⁵

⁴¹ JM Mueller *An Introduction to Patent Law* (Aspen Publishers New York 2003) p. 95.

⁴² *Ibid.* pp. 93–94.

⁴³ *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ.2d (BNA) 1051 (Fed. Cir. 1987). This case was decided by the Federal Circuit in 2000 on appeal from the District Court (Central District Court of California), where the jury had found that there was not sufficient evidence (written description) supporting asserted claims, that was anticipated under § 102. The Federal Circuit affirmed the District Court’s decision since there was substantial evidence in support of the jury’s verdicts of no anticipation and sufficient written description.

In:

http://www.ipo.org/Content/ContentGroups/In_the_Courts/Federal_Circuit_Opinions/20004/Union_Oil_Co_Of_California_v_Atlantic_Richfield_Co_.htm (11 January 2006)

⁴⁴ *Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings* 370 F.3d 1354, 71 USPQ.2d (BNA) 1081 (Fed. Cir. 2004).

⁴⁵ LM Sung and JE Schwartz *Patent Law Handbook 2004–2005* (Thomson

The most debated and often criticised issue in the US patent law relating to the loss of novelty is its treatment of printed publication which is clearly provided under 35 USC § 102 (a) and (b). The law states in clear and simple language that if the claimed invention was already published "... in a printed publication ..." in the USA or abroad, "... or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States", it will be considered to be in the public domain. However, the criticism lies particularly in the treatment of prior knowledge obtained through usage or sale or information that is known but never published in a written form (for example traditional knowledge), because it destroys novelty only if disclosed within the boundaries of the USA.

There have been different explanations as to why such a geographical bar has been placed on prior art. One view is that "The statute probably reflects a historical notion, translated into an evidentiary presumption, that 'personal' activities (such as an individual's knowledge or use or sale of an invention in a foreign country) require greater effort to disseminate to US citizens than do domestic activities".⁴⁶ It is also argued that search and use of knowledge in a foreign country will impose an unfair burden on US inventors.⁴⁷ It is difficult to accept such arguments since today transmission of knowledge has broken all territorial barriers. Further, corporate inventors are interested in exploring options in foreign countries.

There is, in fact, a countering argument that this approach is taken specifically to promote importation of a technology from abroad without imposing any extra cost.⁴⁸ There is a tendency to link this issue of geographical limitation on novelty and non-obviousness with what is known as the Intellectual Property Clause of the US Constitution. Article 1, Section 8, clause 8 provides that to promote arts and science ("promoting the progress of the useful arts"), the US Congress is

West 2004) p. 65.

⁴⁶ Ibid., p. 100.

⁴⁷ Ibid.

⁴⁸ D Jiang-Schuerger 'A Topic on Harmonization: Relative and Absolute Novelty' (2001) 64(1) *China Patents & Trademarks* 57, p. 61.

authorised to grant exclusive rights to inventors for a limited period of time. An argument based on a superficial reading of this particular section of the Constitution would seem to be that the geographical bar on novelty and obviousness is legitimate because it would allow an alleged invention in the USA to be patented even when it is known and used in another country. Such monopoly right would benefit US citizens by providing them with access to technology previously not known to them.⁴⁹ However such an argument does not hold ground since “From the earliest days, the Intellectual Property Clause has been understood to prohibit the grant of patents (1) to non-inventors and (2) for inventions in the public domain, even if the grant of a patent might have expedited the introduction of beneficial technology within the US borders”.⁵⁰

Such a provision in the US law has resulted in a serious problem of extending monopoly over public domain only because it was either not available in printed form or it was not available for sale or use in the USA. One of the live examples is claiming patents over available biodiversity materials although they should actually fail the novelty test because they have been known for a very long time. This issue came up, among other cases, with the neem patent wherein a US-based multinational corporation named W.R. Grace obtained different patents on pesticide (both the products and the method of producing them) derived from the neem tree.⁵¹ The neem tree had been known for its pesticide properties for centuries and so there was a great furore over the patent. In response to pressure from activists, the patent was re-examined by the USPTO but it was decided that novelty had not been destroyed because foreign knowledge and usage did not destroy novelty

⁴⁹ MA Bagley ‘Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World’ (2003) 87 *Minnesota Law Review* pp. 679, 684.

⁵⁰ To stress this point Bagley points out that “the First Congress had deliberately excluded patents of importation from U.S. law in the first patent act, even though such patents would have provided incentives for intrepid entrepreneurs to import much needed technology from England, France, and other locales, to the fledging nation”.

⁵¹ The botanical name of the neem tree is *Azadirachta Indica*, which is derived from the Persian words *Azad darakht* or “free tree”. For further discussions see Vandana Shiva, ‘Free Tree’, *Hindusthan Times Online*, 9 June 2000.

in the USA.⁵² It is worth noting that on a similar claim for revocation of the patent on neem at the EPO, the European patent was revoked because the claims were considered not to be novel.

II.5. Grace Period

It has been discussed above how a patent applicant might lose his or her chance of patenting an invention if it had been disclosed to the public by different means. In most cases, business units interested in working any particular invention would prefer to test the invention and find out how it works, mainly to assess its value in the market. However, if such testing is done (mainly in a manner accessible to the general public) it can destroy the novelty in the invention. Sometimes the inventor might be interested in placing his invention in a trade fair or other exhibition to attract prospective assignees or licensees. Even in that case the invention will be open to disclosure in such a manner that the novelty can be destroyed. To deal with such essential disclosure of a novel invention, many countries provide the patentee with a grace period during which such disclosures will not destroy novelty. The grace period “enables those applicants who are forced to make their invention public before having filed it to avoid the negative effects of such a disclosure”.⁵³ Hence, if a disclosure is made for such specific reasons during the grace period, the state of the art is not taken into consideration as destroying novelty. As a result of this, the inventor can test or display (including working) of the invention in public before the patent application is filed.

An empirical study was done in 1998 by the Max Planck Institute for Intellectual Property Rights in five member states of the European Economic Community covering 120 scientists and researchers in 19 research institutes, to assess the importance of having “grace period”. “... [T]he survey showed that 41.66% of those interviewed considered the introduction of a novelty grace period as ‘indispensable’ and 53.34%

⁵² Re-examination certificate, US Patent No. 5124349 (issued on 20 October 1998).

⁵³ H Bardehle ‘Grace Period – Benefit for applicants or risk for competitor’ in GE Dannemann and MT Wolff (eds) *Global Perspectives of Contemporary Intellectual Property Issues* (J Sholna Rio de Janeiro 1999) p. 46.

as ‘desirable’. Only 5% of those interviewed considered such a move ‘not necessary’. A majority of 58.33% preferred a twelve-month period, 30% a six-month period and only 5.83% considered a longer period necessary, while remaining largely convinced that a period of 6 or 12 months would substantially improve the current situation.⁵⁴ The International Federation of Inventors’ Association (IFIA) presented their position on the issue of grace period before the European Commission, reiterating their stand in support of a 12-month grace period.⁵⁵

It is necessary, however, to make sure that such grace period is not extended in a manner that benefits the patentee disproportionately. The proponents of a grace period usually raise the following arguments:

- a) The reader of an article describing an invention who wants to copy the invention as fast as possible not only has to wait for the publication of the possible patent application that was filed before the appearance of the article, usually 18 months from the date of priority, until he knows whether a corresponding patent application exists. Additionally, in order to copy without risk the period of waiting is extended to include the grace period as well.
- b) Without an established grace period it is relatively easy for industrial companies to prohibit scientists employed by them an early disclosure of their inventions. However, if there was a grace period, scientists could oppose this prohibition of an early disclosure of their inventions with the argument that a disclosure does not affect the patentability of a later patent application filed within the grace period.⁵⁶

⁵⁴ J Straus *The Significance of the Novelty Grace Period for Non-Industrial Research in the Countries of the European Economic Community* (Commission of the European Communities, Luxembourg 1988, QFA EUR 1127.1 EN) VI.

⁵⁵ Dr F Moussa *Statement in favour of the grace period* (presented at the hearing of the European Commission on the grace period, Brussels 5 October 1998). In: http://www.invention-iffia.ch/byFaragMoussa_GracePeriod.htm (11 January 2006)

⁵⁶ H Bardehle ‘Grace Period – Benefit for applicants or risk for competitor’ in GE Dannemann and MT Wolff (eds) *Global Perspectives of Contemporary Intellectual Property Issues* (J Sholna Rio de Janeiro 1999) p. 48.

At present there is no international agreement governing grace periods and thus, while some countries allow it, others do not, while some adopt different grace periods.

In Germany and the UK, the practice was to allow a grace period of six months. However, with the EPC coming into effect a grace period was no longer allowed and Germany had to remove the provision for a six-month grace period from its national law.⁵⁷ Often there is confusion regarding article 55 of the EPC wherein some consider the provision as a grace period (perhaps because the period is six months, as in those European countries which had the provision in their domestic law when they joined). On the contrary, however, a detailed study of the article will make it absolutely clear that it is not a grace period but a special concession provided for legitimising disclosure as a safeguard against possible abuses.⁵⁸

In Japan, the grace period is for six months but the practice of disclosure to affect grace period is different from that in Europe. The disclosure by publication for consideration of the grace period needs to be more specific. In such a case, publication or any written presentations will be considered to be a disclosure if they are from organisations that are sanctioned by the director general of the Japanese Patent Office (JPO). Further, the grace period will cover only the disclosures made by the inventor or his or her assignee, and thus third-party disclosure will not be allowed.⁵⁹ Section 30 of the Japanese

⁵⁷ *Ibid.* p. 47.

⁵⁸ Article 55 of the EPC states, "(1) For the application of article 54, a disclosure of the invention shall not take into consideration if it occurred no earlier than six months preceding the filing of the European patent application and if it was due to, or in consequence of: (a) an evident abuse in relation to the applicant or his legal predecessor, or (b) the fact that the applicant or his legal predecessor has displayed the invention at an official, or officially recognized, international exhibition falling within the terms of the Convention on international exhibitions signed at Paris on November 22, 1928, and last revised on November 30, 1972." It must be noted that the Strasbourg Convention 1963 also provides a special exclusion to "International Exposition" from disclosure if the inventor or his/her assignee filed the patent application within six months of such exhibition.

⁵⁹ ML Kotler and GW Hamilton 'A Guide to Japan's Patent System' (US

Patent Law limits public disclosures which can qualify for a grace period to a restricted few, which includes experiments conducted by the inventor, presentations made in printed publications and presentations made through electronic media.⁶⁰

In the USA the grace period is for twelve months from the date of disclosure (also referred to as the “critical date”).⁶¹ This grace period exempts acts of disclosure by the patent applicant or a third party through commercially exploiting the patent, describing it in a printed publication, placing the invention in the public domain or using it publicly and offering the invention for sale.⁶² It must not be overlooked that the USA follows a policy of “first to invent”; hence, taking advantage of the grace period, individual inventors or small and medium sized enterprises can establish themselves as the first inventor.⁶³ The provision for grace period in the US law is exclusively at a domestic level and does not apply to foreign applications.⁶⁴

It is quite clear that there is no standard practice for treating grace period, and even when the grace period is the same in some jurisdictions, there are differences in treating it. Such differences can

Department of Commerce Office of Technology Policy Asia – Pacific Technology Program, November 1995) p. 29. In: <http://www.technology.gov/Reports/JapanPatent/pages.pdf> (11 January 2006).
⁶⁰ R Maruyama ‘The Grace Period: A Japanese Perspective’ in *Rethinking Intellectual Property: Biodiversity and Developing Countries, Extraterritorial Enforcement, the Grace Period and other issues: Proceedings of the 2000 High Technology Summit Conference, University of Washington, Seattle* (University of Washington CASRIP Symposium Publication Series No. 6 Seattle July 2001) p. 260.

In: <http://www.law.washington.edu/casrip/Symposium/Number6/Maruyama2.pdf> (11 January 2006)

⁶¹ 35 USC § 102 (b).

⁶² JM Mueller *An Introduction to Patent Law* (Aspen Publishers New York 2003) p. 104.

⁶³ Intellectual Property Advisory Committee (IPAC) UK *The Patent Office Consultation on a Patent Grace Period* In: <http://www.intellectual-property.gov.uk/ipac/std/observations.htm> (11 January 2006)

⁶⁴ H Bardehle ‘Grace Period – Benefit for applicants or risk for competitor’ in GE Dannemann and MT Wolff (eds) *Global Perspectives of Contemporary Intellectual Property Issues* (J Sholna Rio de Janeiro 1999) p. 49.

cause problems and unnecessary complications, mainly when patents are filed cross border. For example, if an applicant applies for a patent for the same invention in another country where there is no provision for grace period, he might lose novelty. This can be a serious problem and can only be addressed if the grace period is calculated not from the date of application at the national patent office but with reference to priority under the Paris Convention.⁶⁵

Some countries have undertaken other ways of addressing the problem: "... the applicable Brazilian patent law of May 14, 1996, in its Art. 12 includes the rule that the disclosure of an invention by the inventor that is followed by the filing of a corresponding patent application 12 months later at the least shall not be taken into account, the twelve-month term being calculated retroactively from the date of application or the date of priority. Thus, it is an 'international grace period'. Additionally, in Art. 45 the Brazilian patent law provides a rule that grants the right of prior use to a user in good faith, but not to a user who obtained the information necessary for the prior use by knowledge that goes back to an inventor in the sense of the above mentioned Art. 12 who filed a patent application within the grace period."⁶⁶

⁶⁵ Article 4 B of the Paris Convention states, "Consequently, any subsequent filing in any of the other countries of the Union before the expiration of the periods referred to above shall not be invalidated by reason of any acts accomplished in the interval, in particular, another filing, the publication or exploitation of the invention, the putting on sale of copies of the design, or the use of the mark, and such acts cannot give rise to any third-party right or any right of personal possession. Rights acquired by third parties before the date of the first application that serves as the basis for the right of priority are reserved in accordance with the domestic legislation of each country of the Union. C. (1) The periods of priority referred to above shall be twelve months for patents and utility models, and six months for industrial designs and trademarks. (2) These periods shall start from the date of filing of the first application; the day of filing shall not be included in the period."

⁶⁶ H Bardehle 'Grace Period – Benefit for applicants or risk for competitor' in GE Dannemann and MT Wolff (eds) *Global Perspectives of Contemporary Intellectual Property Issues* (J Sholna Rio de Janeiro 1999) p. 49.

II.6. Guidelines for Examining Novelty

The guidelines for examination of patents by relevant patent offices, is not substantive law but are intended to help the examining officials to maintain consistency in the examination. They are based on the patent law of the land and are basically administrative rules to implement the law (and as such they do not have the force of law). They contain, however, rules which the examiners should follow in assessing patent applications. Some examples are provided below.⁶⁷

II.6.1. Guidelines for examinations in the United States Patent and Trademark Office (USPTO)

It has already been mentioned above that the issue of novelty is covered in 35 USC § 102. The guidelines for examination of patents by the USPTO lay down that each claim for novelty in the patent application should be described in written form in detail. It elaborates as follows:

- a) Rejections based on publications and prior patents resulting in lack of novelty – “Any invention described in a printed publication more than one year prior to the date of a patent application is prior art under Section 102(b), even if the printed publication was authored by the patent applicant.” Such rejections cannot be overcome by affidavits and declaration dates, foreign priority dates, or evidence that the applicant himself invented the subject matter.⁶⁸
- b) Rejections based on public use or sale – This can be applied jointly or severally, hence if there is public use without any sale or there is a secret sale without any offer for sale or any other public communication, it will still evoke the restriction as provided in the law. It is important to note that one single case of public use is sufficient to destroy novelty and it does not require more than one

⁶⁷ For a set of specific guidelines on the matter, see CM Correa, *Guidelines for de examination of pharmaceutical patents: developing a public health perspective* (WHO-ICTSD-UNCTAD Geneva 2006).

⁶⁸ 2133.02 of the Manual of Patent Examining Procedure as revised on 2 May 2004.

article (although a number of articles would only strengthen the case). Such public use can be of a commercial nature or non-commercial use.⁶⁹

Even when the public use is initiated by a third party and not by the inventor, it will bar the patent. If the inventor allows another person to use the invention without any restriction or “obligation of secrecy to the inventor ... The presence or absence of a confidentiality agreement is not itself determinative of the public use issue, but is one factor to be considered along with the time, place, and circumstances of the use which show the amount of control the inventor retained over the invention ... Any “non secret” use of an invention by someone unconnected to the inventor, such as someone who has independently made the invention, in the ordinary course of a business for trade or profit, may be a “public use”.⁷⁰

In the case where the invention was the subject matter of a sale⁷¹ or offer for sale one year before the filing of the application, and this disclosed the claims in any manner, the patent application will be rejected for lack of novelty. Such sale, whether it is a conditional sale or a non-profit sale, will result in rejection of the patent. At the same time it should not be overlooked that an assignment will not necessarily lead to rejection of the application since it is not sale of the invention but sale of rights only. Further, to be considered a sale, the buyer must not be related to the seller or offerer of sale in a manner that the seller is in control of the buyer.⁷²

⁶⁹ 2133.03 (a) of the Manual of Patent Examining Procedure as revised on 2 May 2004.

⁷⁰ Ibid.

⁷¹ Here sale means “... a contract between parties wherein the seller agrees ‘to give and to pass rights of property’ in return for the buyer’s payment or promise ‘to pay the seller for the things bought or sold’”.

⁷² 2133.03 (b) of the Manual of Patent Examining Procedure as revised on 2 May 2004.

The offer for sale is sufficient to evoke the restriction, acceptance of such offer is not needed, and so even if the offer is rejected or not received or not delivered, or if the seller did not have the goods “on hand” at the time of offer, this would not make any difference. It is also to be noted that even if the inventor were not aware of the sale, it will still be sufficient to reject the application. In a case where the invention was sold by a third party (without the consent of the inventor and even when the third party acted independently of the inventor) who had obtained the invention from the inventor, it would not be a defence for the inventor. For consideration of sale, it is essential to produce objective evidence of the offer to sell or the sale and in such case, “non-prior art publications can be used as evidence of sale before the critical date.”⁷³

- c) The invention should be complete at the time of sale or offer for sale or public use, that is it must be ready for patenting in order to be a bar to the patent, although the invention might not be ready for sale or for commercial marketing.

II.6.2. Guidelines for examination in the European Patent Office (EPO)

The EPO provides guidelines for substantive examination of patents in Part C in chapters I to VI. Specific provision on the guidelines on examination of novelty is provided in chapter IV in paragraph 7.⁷⁴

This paragraph provides the following:

- a) An invention is novel if it does not form part of the state of the art. It is not permissible to combine separate items of prior art together or to combine separate items belonging to different embodiments described in one and

⁷³ Ibid.

⁷⁴ EPO *Guidelines for Examination in the European Patent Office*. In: http://www.european-patent-office.org/legal/gui_lines/pdf_2005/part_c_e.pdf (11 January 2006)

- the same document, unless such combination has specifically been suggested. In the case that the primary document explicitly refers to another document to provide further details, this document will be considered to be a part of the document containing such reference (but only if the document referred to was available to the public on the publication date of the document containing the reference). Any matter explicitly disclaimed (with the exception of disclaimers which exclude unworkable embodiments) and prior art acknowledged in a document, insofar as explicitly described therein, are to be regarded as incorporated in the document.
- b) In the case where there is any express reference (either direct or indirect) to the claimed subject matter in any document (including any features implicit to a person skilled in the art in what is expressly mentioned in the document), the novelty will be considered lost.
 - c) The relevant date of the prior document should be considered as the publication date, if the document is published, and, in the case of priority art, date of filing or priority date as applicable.
 - d) Generic disclosures usually do not take away the novelty of any specific case that falls within the terms of that disclosure but at the same time the specific disclosure destroys novelty of a generic claim covering that disclosure.
 - e) In the case of lack of novelty due to prior document, it might be direct or indirect. This means that it might be explicitly stated in the document or it might be implied in a manner that a person skilled in the art would inevitably know that it is obvious. Such objection would arise where there can be no reasonable doubt as to the practical effect of the prior teaching. Situations of this kind may also occur when the claims define the invention, or a feature thereof, by parameters. It is possible that the relevant prior art mentions a different

parameter or it might not mention any parameter; in such cases, if the applicant can substantiate that difference exists with respect to the parameters, then the disclosure as to destroy novelty could be questioned.

- f) The examiner should consider that regarding the subject matter of claims directed to a physical entity, non-distinctive characteristics of a particular intended use should be disregarded. Hence not only explicit but also implicit details will be considered. Further, the use of a known compound for a particular purpose (second non-medical use) which is based on a technical effect should be interpreted as including that technical effect as a functional technical feature, and is accordingly not open to objection under Art. 54(1), provided that such technical feature has not previously been made available to the public.

III. NOVELTY IN INTERNATIONAL AGREEMENTS

III.1. Novelty with Reference to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The Paris Convention does not state anything on novelty. The TRIPS agreement, being an integral part of the World Trade Organisation (WTO) Agreement, came into existence in 1995 when the WTO was established. The agreement requires member countries to provide both product and process patents in all fields of technology. According to the agreement, the claimed invention needs to be “new”.⁷⁵ The agreement does not specify how novelty is to be treated, nor does it bind the

⁷⁵ Article 27 (1): “Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application (Footnote omitted). Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”

member countries to follow a set pattern (for example first to invent, first to file or absolute novelty or relative novelty).

III.2. Novelty under the Patent Law Treaty (PLT) and the Draft Substantive Patent Law Treaty (SPLT)

The Patent Law Treaty (PLT) aimed in the 1980s at introducing a harmonized patent system. However there was no consensus as to the basis of such harmonization and the issues that were to be taken up. This became obvious during the Diplomatic Conference in 1991, where the USA and the European countries remained divided on the filing method (first to file versus first to invent) and the grace period. The matter was brought up again in WIPO in 1995 and the PLT was adopted in 2000.⁷⁶ However, the treaty did not cover the substantive issues such as treatment of novelty, inventive, step, and so on, but limited itself to procedural aspects. The discussions on these issues were taken up under the draft Substantive Patent Law Treaty (SPLT).⁷⁷

Given the resistance that the harmonization of substantive patent rules met among developing countries, and the differences among developed countries themselves, in the tenth session of the Standing Committee on the Law of Patents (SCP) of WIPO the USA, Japan and the EPO submitted a joint proposal which focused on harmonization in the SCP of four issues, namely prior art, grace period, novelty and inventive step, as a matter of first priority. According to this submission, once there was an international agreement on these issues, two other issues, sufficiency of disclosure and genetic resources, could be taken up in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). In this proposal, there was some consensus among this trilateral working group about adopting a limited “grace period”.⁷⁸

⁷⁶ PLT In: http://www.wipo.int/treaties/en/ip/plt/trtdocs_wo038.html (11 January 2006)

⁷⁷ WIPO (Substantive Patent Law Harmonization) In: www.wipo.int/patent/law/en/harmonization.htm (11 January 2006)

⁷⁸ European Patent Office *Trilateral Working Group - Substantive Harmonization of Patent Law (SPLT): The European Perspective* (European Patent Office September 2003).

A group of 14 developing countries led by Brazil submitted a “Friends of Development” proposal which stressed that all the six issues be given equal importance, and they also proposed a “Development Agenda” which included issues such as transfer of technology, anti-competitive practices, safeguarding of public interest flexibility and specific clauses on principles and objectives. WIPO members were divided at this point and since there was no possibility of consensus, the General Assembly of WIPO directed the Director General of WIPO to undertake informal consultations so that the date of the next SCP could be decided and the matter taken up.

Discussions at the most recent sessions of the SCP seem to suggest preference for a system which would include a first-to-file method, absolute novelty and a short grace period (probably six months), among many other issues concerning novelty. However, the negotiations on the SPLT are stalled. For good reasons,⁷⁹ developing countries continue to be reluctant to lose the flexibilities they currently enjoy under the TRIPS Agreement to deal with the right to patent and patentability issues.

IV. SOME NOVELTY ISSUES IN PHARMACEUTICAL PATENTS

Novelty in pharmaceutical compounds is usually categorised under three types: “... combination preparations comprising two or more known pharmaceutically active ingredients; new drug delivery systems or galenic forms (for example a new kind of tablet giving a controlled rate of release of drug when swallowed); and compositions comprising a compound not previously used as a drug, together with any conventional pharmaceutical carrier or excipient”.⁸⁰

In:

http://www.aipla.org/Content/ContentGroups/Meetings_and_Events1/International_Symposia1/EPOTrilateral.pdf (11 January 2006)

⁷⁹ See, for example, CM Correa and S Musungu *The WIPO Patent Agenda: the risks for developing countries*, Working Paper No. 12, South Centre Geneva 2002. In: <http://www.southcentre.org/publications/wipopatent/toc.htm>

⁸⁰ PW Grubb *Chemical Inventions in Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law Practice and Strategy*

The novelty issue as applied to pharmaceutical patents is crucial from the perspective of public health and access to medicines. If a country follows relative novelty in pharmaceutical patents, it will not be able to restrict patent applications on inventions which are already in the public domain. As a result, even those patent applications that do not have even one new essential feature to add to what is already in the state of the art might succeed and a patent may be granted.

In many cases, pharmaceutical companies base their research on traditional medicines. Often there is no written record of such medicines since they have been passed on through ages from one generation to the next.⁸¹ Using the components available in these medicinal plants to produce drugs, and then applying for patents on these drugs on the pretext that they are new (since there is no written record of any sort), is an extension of the patent monopoly beyond its mandate and an ethically questionable solution.

Pharmaceutical patents generally depend heavily on chemical substances that may be precisely defined structurally. In such cases, the novelty requirement in product patent applications actually becomes "... an assessment of two substances ...". So if there is the slightest difference in these substances, the product will be considered to be novel.⁸² The issue of novelty in patents is closely related to 'inventive step' and in pharmaceutical patents this is crucial. For example, in a case where there are equivalent alternatives, "If the skilled man has an exact notion of the significance of a feature in the state of the art, equivalent alternatives beyond the scope of the definition are to be deemed new. The critical issue in the assessment of patentability will then be inventive step."⁸³ It is crucial that patent offices examine closely applications for pharmaceutical patents so that patents are not granted in cases where the product is disclosed in prior art. It is obvious that to qualify for a patent, the invention should be structurally different from the earlier product in the state of the art.

(Clarendon Press Oxford 1999) p. 215.

⁸¹ NR Farnsworth 'Screening Plants for New Medicines' in EO Wilson *Biodiversity* (National Academy Press Washington D.C. 1988) pp. 83, 95.

⁸² B Domeij *Novelty in Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 131.

⁸³ *Ibid.*

In a decision where the patent application was for monoclonal antibodies, the process of manufacturing these antibodies was held patentable. In this case, it was not possible to distinguish them by their structure from naturally-occurring antibodies, and so the way they were manufactured was considered. The application was allowed even when the end product was not new.⁸⁴

Two recent pharmaceutical cases have been subject to considerable discussion and debate. One is the Amgen/Erythropoietin case which was interpreted differently by different courts in different jurisdictions. The other case is the Pfizer/Amlodipine case which was first decided in favour of the defendant at the US District Court of New Jersey and then reversed on appeal by the US Federal Circuit. This case is important specifically since in this case the court determined the generic pharmaceuticals' ability to compete with branded drugs in case of patent term extension. The two cases are examples of how interpretation of novelty is crucial in the pharmaceutical patent sector. The two cases are discussed in Boxes 1 and 2 below.

⁸⁴ T 130/90 of 28 February 1991. See chapter 11 on product-by-process claims.

Box 1
Amgen/ Erythropoietin

This case was first brought by Amgen (Thousand Oaks, CA) against Transkaryotic Therapies (TKT; Cambridge, MA) and Aventis Pharma (previously Hoechst Marion). [For further details see Debra Robertson, 'First round to Amgen in EPO battle' 18 *Nature Biotechnology* 2000 (p. 483) and 19 *Nature Biotechnology* 2001 (p. 188).]

The case was regarding the patent application for a glycoprotein produced by the kidney to enhance red blood cell production, called 'Erythropoietin' (E). This E is a hormone used for treating anaemia, kidney failure and other pathological states and is an active component in Amgen's popular drug 'Epogen'.

Amgen alleged that TKT infringed five of its US patents on E on which it enjoyed process patents over the process of preparing a biologically active E as well as the host vertebrate cells in which E can be produced. The claimed process described the production of the E product Epogen by expression of the cloned human E cDNA sequence by placing the simian viral DNA promoter (SV40) adjacent to the target gene in vertebrate or mammalian cell lines.

The defendant argued that the Amgen patent did not disclose enough for a person skilled in the art to be able to know how the E is produced in human cells. Further, it was already known (before the priority date) that this hormone could be extracted from urine (a natural source) and then purified. The patent claim was over E produced by recombinant technology (recombinant E), wherein it was clear from the patent claims that some of its properties were the same as in the naturally occurring E. The defendant argued that because its E is made by activating a cell's endogenous E gene, Amgen's patent claim over E in vertebrates or mammalian host cells does not encompass human cells.

The ruling was made in favour of Amgen on the basis that the defendant's human cells would not make E without human involvement and, according to the judge, the E produced by the defendant was not naturally existing. It was within the scope of Amgen's patent, and hence the defendant was considered to be infringing Amgen's patent.

Continued ...

... continued

In Europe Amgen has only one patent (unlike in the USA where it had five) which covers both the E as well as the process to make it. The dispute was first heard at the Royal Courts of Justice in London and from there it went on appeal to the House of Lords. Remarkably, the House of Lords decided that the patent application lacked novelty as the E hormone could be extracted from naturally occurring human urine and then purified. Hence, the decision went against Amgen and the infringement under Protocol 69 of the EPC was not upheld. [For further details see *Kirin Amgen Inc. and Others v. Aventis (Hoechst Marion Russel Ltd.) and Others*, Protocol on the interpretation of Art. 69 (2004) UKHL 46].

The matter was before the Board of Appeal of the EPO where the EPO made its elaboration as follows. A new process of production does not imply that the product was new. “[T]he fact that a product is referred to in a claim as being the result of some process, does not automatically mean that the product is novel even if it is beyond dispute that the process referred to is new. The purpose of the reference to the process was to exclude those products which in the prior art were not obtained by the process. If, on the evidence available, the process appears capable of producing every product meeting the characteristics of the product of the prior art, the reference to the process is not a limitation for the purpose of considering novelty. The process feature in a product claim can only be relied on for establishing novelty over the prior art, where use of that process necessarily means that the product has a particular characteristic and the skilled person following the teaching of the specification would inevitably achieve the characteristic, would be aware of that characteristic and would discard any products not having it.” [For further details, see T 412/93 of 21 November 1994, discussed in detail in Bengt Domeij *Novelty in Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 144].

Continued ...

... continued

It is interesting to note that the applicant provided other sets of alternative claims to prove novelty but could not succeed. In one set of alternative claims the applicant tried to redefine the claim by stating that the recombinant E was not identical to the one isolated from urinary sources. “No novelty, however, was found to exist now either, because, with such a claim formulation, the burden of proving any differences between recombinant and natural E would develop entirely on a third party, which was found to make the claims unclear. The claims were contrary to Art. 84 EPC. It was too laborious and difficult for a third party to judge what was protected solely in the light of what was not protected, that is what could be isolated from natural sources.” In another failed attempt to define the claim in a manner to prove that the claimed invention was different from the natural product, it stated that the claimed E had an average carbohydrate composition that differed from the “... human E isolated from urinary sources”. The Board was still not convinced since no values were given either for the naturally occurring E or for the recombinant E. As a result the infringement motion was not upheld.

Box 2
Pfizer/ Amlodipine

In this case the dispute was regarding the US pharmaceutical company Pfizer Inc.'s patent (909) a drug ("Norvasc") for high pressure, an anti-hypertensive, anti-ischemic drug containing amlodipine and its acid addition salts as its active ingredient. Pfizer had obtained US Food and Drug Administration (FDA) registration for besylate salt of amlodipine although it had submitted clinical data obtained using both besylate salt and maleate salt of amlodipine.

Pfizer got an extension of the patent term from 2003 to 2006 under the Hatch-Waxman Act. Under the provisions of this Act such extensions are allowed, to compensate the patent owner for the regulatory delay in obtaining FDA approval for a drug or a salt of a new drug.

The Indian pharmaceutical company Dr. Reddy's Laboratories filed an application, "paper NDA" proposing to market amlodipine as the maleate salt for the uses for which Pfizer had obtained FDA approval. The defendant relied on Pfizer's safety and efficacy data for the drug Norvasc (which was approved by the FDA) and did not challenge Pfizer's amlodipine patent but alleged that the extension of the patent term is applicable for only the besylate salt since this is the registered product of Pfizer. Further it argued that amlodipine is a different active ingredient from the amlodipine besylate; hence there was no patent for amlodipine maleate or other derivative salts.

To prevent Dr. Reddy's generic product from entering the market, Pfizer sued Dr. Reddy's Lab in the US District Court of New Jersey alleging infringement of its patent. The district court decided the case in favour of Dr. Reddy's Lab on the basis of US Patent Law Section 156 (b) wherein the court opined that this particular section posed limitation on the rights derived under the patent term extension to the specific form of approved product, which in this case was amlodipine mabesylate.

Continued ...

... continued

Aggrieved by the decision, Pfizer challenged it before the US Court of Appeals for the Federal Circuit. Pfizer argued that it had submitted clinical data for both amlodipine maleate and besylate but had selected besylate because it is easier to manufacture in tablet form.

The Federal Circuit read 35 USC Section 156 (f) since it defines the term “drug product” as the active ingredient of a new drug that includes any salt or ester of the active ingredient whether as a single entity or in combination with another active ingredient. The court opined that if Dr. Reddy’s Lab. was permitted to rely on the safety and efficacy of Pfizer’s test data regarding Norvasc, then the Pfizer product could not be considered to be different from that of Dr. Reddy’s Lab. Finally the Federal Circuit ruled that the active ingredient is amlodipine and this can be administered as besylate or maleate salt, they are the same, and hence Dr. Reddy’s Lab. had infringed Pfizer’s patent.

In *Pfizer v. Apotex* (2007), however, the Court of Appeals for the Federal Circuit (CAFC) invalidated Pfizer’s patent covering Norvasc arguing, inter alia, that Norvasc is amlodipine besylate and that, at the time of the invention, amlodipine was known, as was the use of besylate anions. The CAFC considered that the alleged unpredictability of the properties of the besylate did not result in nonobviousness.

Patenting of diastereomers or enantiomers has become common in the past two decades.⁸⁵ For instance, a case before the EPO dealt

⁸⁵ Bengt Domeij discusses stereochemistry and provides some details on diastereomers and enantiomers. He states, “Diastereomers occur in a situation where a molecule has more than one asymmetric (chiral) atom. A situation of this kind involves several possible three-dimensional structures in molecules having the same number of the same kind of atoms. The structural differences between the diastereomers are usually material for the biological properties of substances and also for other properties.” The study of spatial or three-dimensional shapes of molecules relating to atoms in space is called

with novelty of the diastereomer in a patent claim over chlorophenoxy imidazol dimethyl butanol. In the particular case the Board of Appeal had granted the patent, affirming the novelty of the invention.⁸⁶ In this application the claims included only one of the four possible isomers (the threo form) and had a mucolytic effect wherein the isomer was defined through its melting point (158–159°C) among other things. Although there was a prior document disclosing chlorophenoxy imidazol dimethyl butanol with an identical formula, the melting point in this case was 145–147° C. Hence, the Board presumed that there were two diastereomers which were structurally different.⁸⁷

In another case before the Board of Appeal of the EPO, the novelty of enantiomers⁸⁸ was considered. Although the chemical substance referred to in the prior document had an asymmetric carbon atom, it did not specify any of the two conceivable enantiomers. The application referred to one of the two enantiomers, a mixture containing 80 per cent D-form, having higher activity than the racemate.⁸⁹ In its

stereochemistry. See B Domeij *Novelty in Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) pp. 146–148. See also JM Daniels, ER Nestmann and A Kerr ‘Development of Stereoisomeric (Chiral) Drugs: A Brief Review of Scientific and Regulatory Considerations’ (1997) 31 *Drug Information Journal* p. 639.

⁸⁶ T 12/81, OJ EPO 1982, p. 296.

⁸⁷ B Domeij *Novelty in Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) pp. 146–148.

⁸⁸ “If two molecules containing the same number of atoms of the same kind are also each other’s mirror image, they are called enantiomers (the R and S configuration; sometimes they are also called + or – or else dextro or levo (D/L)). They contain an asymmetric carbon atom which forms a chiral centre. A mixture in which the two enantiomers are included in equal proportions – which is the normal result of a chemical manufacturing process – is called a racemic mixture or a racemate.” “Using racemic solutions in pharmaceuticals without any further reflection means using a mixture of an active substance and a substance which is often inactive or in some cases even toxic. The presence of the differences in biological effect is due to pharmaceutical receptors as a rule also being asymmetric ... Nowadays authorities approving new pharmaceutical products for sale are tending more and more often to stipulate that the applicant shall have investigated whether a racemic mixture of a pharmaceutical product can be separated and only the most active isomer used.” *Ibid.*, p. 149.

⁸⁹ *Ibid.* pp. 146–149.

decision the Board of Appeal allowed the application since it found that novelty existed. It stated that although it would be considered “obvious” if a prior document did not clarify whether the L or the D form were being referred to in the race mixture, in this case the question was whether novelty already existed at the time when the application referred to a different mixture of enantiomers rather than a race mixture.⁹⁰ This is also the practice in the USA.

Given that the existence of single enantiomers and their different effects are known to a person skilled in the art, they should generally not be deemed patentable when the race mixture was known. However, processes for the obtention of enantiomers, if novel and inventive, may be patentable.

The case of “selection inventions” in pharmaceutical patents moves away from the traditional concept on the novelty issue. In standard practice, novelty disclosure includes what is known in the priority document. But in a selection invention, “... the legal position is modified through the principle that a generic reference in the state of the art does not necessarily make all individual elements within the disclosure known. In the reverse situation – a known smaller area within a claimed larger one – on the other hand, the larger area always lacks novelty”.⁹¹

In the UK a landmark case established special rules for selection inventions which came to be known as *Farben* rules, wherein it is stated, “(1) there must be some substantial advantage to be secured by the use of the selected members; (2) all of the selected members must possess the advantage (although a few exceptions would not invalidate the patent); and (3) the selection must be in respect of a property which can fairly be said to be peculiar to the selected group”.⁹² However, in such

⁹⁰ T 296/87, OJ EPO 1990, p. 195, “... The Board concludes that this prior art is concerned only with racemates which do not affect the novelty of the D-forms claimed in the contested patent. This assessment must also apply to products according to the contested patent which – as finally claimed – have ‘a content of at least 80% D-form’.”

⁹¹ B Domeij *Novelty in Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) pp. 146–157.

⁹² I.G. Farbenindustrie’s Patents (1930) 47 RPC 239 (Ch.D.)

cases, “if out of a previously disclosed large group of compounds a smaller group A can be identified having a non-obvious advantage, then the compounds in group A should be patentable as a selection invention. If subsequently a second group B is identified, having also that property, then group B may or may not be patentable ...”⁹³

The Board of Appeal of the EPO addressed the issue of selection patents in 1996 in the case T 374/94. Later, in yet another case, the Board dealt with the issue of generic disclosure and what would destroy novelty: “[C]onsideration has not only to be given to the examples of a prior art document but also to whether the disclosure of such a document as a whole is such as to make available to the skilled person the subject-matter for which protection is sought. This means, that the technical teaching of examples of a patent document may be combined with technical information disclosed in its description, provided that the examples concerned are representative for the general technical teaching of this document.”

Regarding assessment of novelty in selection inventions, it is noticed that “... the narrower the selection is in relation to the generic term, the more likelihood there is of the selection being deemed new. A selection in the form of one or two individual substances is more likely to be new than a selection of a wider group of compounds”.⁹⁴

Usually the EPO assesses novelty of selection inventions if there is a continuous, numerically-stated interval in the state of the art, by a special rule which it has established through its case law since 1985.⁹⁵ Later through another case law this was summarised and streamlined as follows: “... the Board had considered that a selection of a sub-range of numerical values from a broader range is possible when each of the following criteria is satisfied: (i) the selected sub-range should be narrow, (ii) the selected sub-range should be sufficiently far removed from the known range illustrated by means of examples, (iii) the

⁹³ PW Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law Practice and Strategy* (Clarendon Press Oxford 1999) pp. 196–197.

⁹⁴ B Domeij *Novelty in Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 159.

⁹⁵ T 198/84, OJ EPO 1985, p. 209.

selected area should not provide an arbitrary specimen from the prior art, that is not a mere embodiment of the prior description, but another invention (purposive selection).”⁹⁶

As further elaborated in Chapter 10, as a general rule selection patents should not be granted if the selected components have already been disclosed or claimed and, hence, lack novelty.⁹⁷ If unexpected advantages of existing products were deemed patentable under the applicable law, the patentability of a selection could be considered when an inventive step is present.⁹⁸

V. CONCLUSION AND RECOMMENDATIONS

The above discussion shows how elastic notions of novelty may broaden the scope of pharmaceutical patents. This may, in turn, cause in some cases unnecessary problems for access to drugs which would otherwise remain in the public domain.

Developing countries should adopt an absolute standard of novelty and consider all types of acts, whether in written form or not, that may destroy it. In particular, in the case of selection inventions, when there is an earlier disclosure of the larger group, it is natural that after the patent period is over, its full scope should fall into the public domain. If a patent were granted on a selection, it would just extend the patent beyond the original period without a new contribution that would justify it.

⁹⁶ T 279/89 of 1 July 1991.

⁹⁷ When a prior claim or document in the prior art includes a range, for instance, in the form of C₁-C₄ or 50° to 75° of temperature, all the comprised possibilities (for example C₂ and C₃; 60° of temperature) should be deemed disclosed and, hence, not patentable as a “selection”.

⁹⁸ The patentability of a selection will proceed in this case if an exception to the principles of novelty were allowed under the applicable law.

CHAPTER 2

INVENTIVE STEP

I. DEFINING THE CONCEPT

I.1. Definition

There are several terms that refer to inventive step and they differ slightly in how they define it. At the core, however, the concern is the distance between what is now known (prior art or state of the art) and the invention claimed by the patent applicant. The size of that gap will vary across jurisdictions and sometimes by industry sector within an economy.

I.1.1. Non-obviousness

Under this concept for determining inventive step, an invention is not patentable if its technical teaching would or could have been discovered in due course by a person with average skills in the respective field. In US practice, courts applying the non-obviousness standard (the US equivalent to inventive step) undertake a three-step factual inquiry, examining:

- 1) the scope and content of the prior art to which the invention pertains;
- 2) the differences between the prior art and the claims at issue;
- 3) the level of ordinary skill in the pertinent art.

The examiner then makes a final determination of non-obviousness by deciding whether a person of ordinary skill could bridge

the differences between the prior art and the claims at issue given the relevant prior art.⁹⁹

1.1.2. The non-obvious solution to a technical problem

The EPO utilizes what is known as the “problem-solution” approach to inventive step. The goal of the method is to determine whether a claimed invention is obvious to a skilled person.¹⁰⁰ The determination of obviousness is a three-step process:¹⁰¹

- 1) Determining the closest prior art;
- 2) Determining the objective problem to be resolved in relation to this prior art by a comparison of the results;
- 3) Determination of the obviousness of the claimed solution in regard to further prior art and general technical knowledge.

This is essentially an additional requirement that not only must the claimed invention be beyond the prior art, it must present an actual technical advance rather than a solution to a problem that already has a solution.

II. WHAT ARE THE PUBLIC HEALTH ISSUES IMPLICATED?

The manner in which patentability criteria are defined and applied is a crucial determinant of the pool of knowledge which is taken out of the public domain. This issue is acutely important for pharmaceuticals. The registration of a large number of patents on pharmaceutical compositions, therapeutic uses, polymorphs, processes and/or forms of administration relating to an active ingredient often permits the owner to

⁹⁹ J Dratler *Intellectual Property Law: Commercial, Creative, and Industrial Property* (Law Journal Press New York 1991) §2.03[3].

¹⁰⁰ B Hansen and F Hirsch *Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law* (Wiley-VCH Berlin 1998) p. 195.

¹⁰¹ *Ibid.*

create a high barrier against competition. If aggressively enforced through strategic, or even “sham”, litigation practices as a tool to discourage competition by local companies, those (secondary) patents may unduly extend the market power conferred by the original patent.¹⁰² Such abuses may be particularly severe in developing countries where there is a lack of, or limited tradition in, controlling such practices under antitrust (or anti-monopoly) regulations.¹⁰³ It is hard to undo the granting of overly broad patents and secondary patents. Once a patent has been granted, it is presumed valid. Challenging parties generally bear the burden of proving that the patent was wrongly issued.¹⁰⁴ Thus the development of both new and generic medicines is discouraged, especially since the larger pharmaceutical companies may be reluctant to invest or collaborate in research into derivative drugs that may be more suited to developing countries, such as single pill or Fixed Dose Combinations (FDC).¹⁰⁵

II.1. Special Concerns with Pharmaceuticals and Inventive Step: The Use of Known Elements and Methodologies

The issue of inventive step arises in several situations that involve claims specific to the chemical and pharmaceutical sectors, such as in the case of polymorphism, analogy processes and optical isomers.

Some therapeutically active ingredients present polymorphic forms, that is, they may crystallize in several different forms, each of which may have different properties that are more or less significant for

¹⁰² See, for instance, the US Supreme Court decision in *Walker Process Equipment Inc. v. Food Machinery & Chemical Corp.*, 382 US 172 (1965) and subsequent case law on antitrust (anti-monopoly) liability when there is an attempt to enforce invalid patents. See, for example, A Chandra ‘Antitrust Liability for Enforcing a Fraudulent Patent in the United States’ *Patent World* April 1999.

¹⁰³ CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) p. 37.

¹⁰⁴ *Ibid.*

¹⁰⁵ Médecins Sans Frontières ‘Two Pills a Day Saving Lives: Fixed Dose Combinations of Anti-Retroviral Drugs’ (MSF Briefing Note February 2004) 3. In: <http://www.accessmed-msf.org/documents/factsheetfdc.pdf> (19 April 2005)

the production of medicines (for example, stability). Some companies have sought to use patents on polymorphs as a means to extend the monopoly protection of a known active ingredient. For instance, GlaxoSmithKline's predecessor company applied for a patent on a polymorph of cimetidine approximately five years after the original patent was granted. That patent, however, was nullified in the UK and other countries on the grounds that the polymorph was obtained in the ordinary course of research by applying the process already claimed in the original patent.¹⁰⁶

Some countries have permitted patenting of non-novel (and also therefore obvious) processes (sometimes called "analogy processes") if the resulting chemical is novel and displays unexpected properties. The USA has held "analogy process" claims to be unpatentable unless they are inventive in themselves,¹⁰⁷ but has carved out an exception for biotechnology.

The products and processes of biotechnology have posed hard problems for applying the inventive step standard, since many biotechnology "inventions" repeat previously-invented processes in slightly different contexts. This problem led to a statutory amendment of US law in 1995, which lowered the non-obviousness standard by deeming a biotech process claim non-obvious if it involves new and non-obvious starting materials or produces a new and non-obvious result.¹⁰⁸ While this solution, targeted only to biotechnology, may be deemed discriminatory, and hence inconsistent with article 27.1 of the TRIPs Agreement, it has been extended by case law to other fields of technology.¹⁰⁹ Thus the lowered standard now applies to all such processes in any field of technology in the USA.

¹⁰⁶ B Hansen and F Hirsch *Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law* (Wiley-VCH Berlin 1998) p. 113.

¹⁰⁷ PW Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law, Practice and Strategy* (4th edn Oxford University Press Oxford 2005) p. 206.

¹⁰⁸ J Dratler *Intellectual Property Law: Commercial, Creative, and Industrial Property* (Law Journal Press New York 1991) §2.03[3].

¹⁰⁹ PW Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law, Practice and Strategy* (4th edn Oxford University

The benefits of such protection remain unclear, and the research cycle of biotechnology research suggests that there is no need for the patent incentive to encourage the use and development of biotechnology processes that are familiar to a person with ordinary skills in the field.

Another issue is the patenting of compounds that are optically active enantiomers¹¹⁰ of a compound previously known only in racemic¹¹¹ form. While some patent offices, such as the EPO, have ruled that such enantiomers may be deemed novel, the existence of inventive step should be denied, since it is obvious that, in such types of molecules, optically active forms can exist and it is routine to test whether one or the other enantiomers in isolation is more active than the mixture of both (“racemic mixture”). Today, it is generally accepted that one optical isomer will typically have much higher activity than the other, so that superior activity for at least one of the isomers as compared to the racemic mixture is to be expected.¹¹²

III. THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY (TRIPS)

III.1. What are the TRIPS Requirements?

TRIPS is not specific with respect to the issue of inventive step. Article 27.1 establishes that patents shall be granted to protect inventions which “involve an inventive step” and, in a footnote, it allows member countries to interpret “inventive step” as synonymous with “non-obvious”.

Press Oxford 2005) p. 207.

¹¹⁰ Enantiomers are chemical compounds which behave in relation to one another as an image does to its mirror image. B Hansen and F Hirsch *Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law* (Wiley-VCH Berlin 1998) p. 113.

¹¹¹ A racemic mixture is one in which multiple isomers are mixed without separating out any individual isomer or enantiomers. *Ibid.* pp. 113–118.

¹¹² *Ibid.*

In addition, TRIPS does not allow discrimination as to the field of technology,¹¹³ making it difficult to legislatively apply industry-specific standards.

III.2. What are the TRIPS Flexibilities?

There is no agreement on harmonization of the standard of inventive step/non-obviousness. Attempts were made at WIPO in the SPLT process to fast-track harmonization of patentability requirements such as inventive step. Developing countries resisted such attempts, however, and the negotiating process is stalled. The main proponents of the treaty (the USA, EPO and Japan) have abandoned the idea of including, at least in a first phase, harmonized rules on inventive step. Any agreement must maintain the flexibility to adjust the level of requirements to suit the needs of industrial innovation and other public policies for developing countries.

IV. WHAT ARE THE EXISTING POLICY APPROACHES?

In deciding what policy to follow on inventive step, policy makers should recognize that there are subtle relationships between novelty and inventive step, which they will have to take into account. For example, if the inventive step standard is set very high, courts may be tempted to take a relatively soft and permissive attitude towards novelty, as was the case in the USA in the years preceding the establishment of the Federal Circuit Court of Appeals.¹¹⁴ When the non-obviousness bar is set very low, this permissive tradition may be anti-competitive and harmful to follow-on innovation by not filtering out patent requests that do not sufficiently depart from prior art.

The inventive step requirement is especially important in determining the kind of innovation policy a country will follow: First

¹¹³ Agreement on Trade-Related Aspects of Intellectual Property (15 April 1994) LT/UR/A-1C/IP/1 art 1.

¹¹⁴ CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) p. 39.

Inventor or Follow-On Innovator.¹¹⁵ A high inventive step requirement will tend to provide incentives to the First Inventor by making it possible to capture almost all the exclusive market power relating to the claimed invention. The standard gives the Follow-On Innovator a choice between pursuing niche improvements or taking more ambitious steps. A lower inventive step requirement would have the First Inventor share market power with Follow-On Innovators who would have an incentive to carry out niche improvements. This pattern, however, only holds true where the First Inventor and Follow-On Innovators share equivalent access to capital to fund research. Where Follow-On Innovators have little access to the same capital resources as First Inventors, as is the case in developing countries, a low inventive step requirement poses the danger of first inventors capturing *all* the possible market power and having the capacity to extend such market power beyond the life of the original patent. It is in such cases that the interaction of inventive step with claim scope becomes crucial. A low inventive step requirement combined with broad claim scope is the worst of all possible worlds for Follow-On Innovators in developing countries. In implementing any policy on inventive step, developing countries should keep in mind how such a standard will interact with the breadth of claims allowed. Developing countries should also keep in mind that all First Inventors can become Follow-on Innovators themselves, which suggests that incentives need to be strongly maintained for Follow-on Innovators.

In the specific case of pharmaceuticals, policy makers may wish to distinguish between two primary modes of innovation. The first, mostly carried out by large brand-name pharmaceutical companies, can be characterized as “discrete” innovation, aimed at the production of new chemical entities (NCEs) or drugs.¹¹⁶ NCEs rarely challenge the inventive step requirement. Research and development into NCEs is, however, quite costly and intensive, and courts and commentators in developed countries have argued that strong patents are necessary to maintain the incentive to innovate in the pharmaceutical industry.¹¹⁷ A

¹¹⁵ US Federal Trade Commission *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (Federal Trade Commission Report October 2003) ch 3 [5].

¹¹⁶ *Ibid.* ch 3 [4].

¹¹⁷ *Ibid.* [n21] ch 3 [5].

high inventive step requirement accomplishes the task of creating strong patents, since the primary inventor will have an effective defence against potential infringers and challenges to the validity of the patent. It also effectively creates broad patents by making it difficult for anybody, including the First Inventor, to make only minor improvements and patent them. All such actors will have to pay a licence for any uses of the First Inventor's patented product or process and will have little or no incentive to carry out any improvements on the patent subject matter. However, an unfortunate side effect of this process is that it will increase the tendency of the First Inventor to rely on only a few NCEs ("blockbuster drugs")¹¹⁸ and encourage them to extract rents in the form of licensing and marketing activity rather than to carry out further discrete innovation. This is especially true if there exist mechanisms which allow them effectively to extend the patent term by patenting the results of their own incremental research.

The second form of innovation found in the pharmaceutical industry is Incremental Innovation. This generally involves modifications and improvements of existing NCEs, for example new uses, or new forms (for example salts, ethers, esters) with slightly different chemical properties. Products and processes that come about because of this kind of research present a constant challenge to the inventive step standard. It is not clear that it is the kind of research which requires the patent incentive to be carried out since much of it occurs as a matter of course. In addition, much of it falls foul of the requirement that a claimed invention present a least a *significant* step beyond the existing prior art. A consequence of lowering the inventive step requirement to allow the patenting of this kind of developments is that large brand name companies may not only gain patents on NCEs but may then, by virtue of superior cash resources, proceed to claim all possible variations and modifications of their primary NCEs, extending past the date of the primary patent (that is, "evergreening" the primary patent). This freezes the innovation process, reducing inventing around and the introduction of generic competition.

Developing countries face a difficult dilemma, especially those with fledgling pharmaceutical industries that they may wish to protect

¹¹⁸ Ibid. ch 3 [5].

and encourage. If they endorse a high inventive step requirement, there will be no protection for the products of incremental innovation on which most such fledgling industries rely. However, if they endorse a low inventive step requirement, the large multi-national pharmaceutical companies will capture not just the NCE market but also the incremental innovation market through mechanisms that extend the effective reach of their NCE patents. Developing countries will need the flexibility to alter the standard to fit the changing needs of industrial and innovation policy and should choose legislation, regulations and guidelines that will institutionalize and operationalize that flexibility. In any case, a good starting point will be to begin with a stringent standard for inventive step and to attempt to encourage their own industries by limiting the scope of patent claims, while providing limited protection for generic and other producers of incremental innovation products. There is some evidence from US practice that such a two-tiered approach may be successful.¹¹⁹ The following sections outline the legislative, regulatory and guidelines approach of several countries, and draws lessons from them in the construction of model approaches to legislation, regulations and guidelines.

A final caution should also be noted. While much of this paper addresses itself to the pre-grant approval process, the issues and concerns it addresses are just as relevant to those countries which do not have a patent grant examination process. Those countries that rely on the court system to weed out invalid or incorrectly granted patents should consider embedding the recommendations made here in whatever section of the law, legislation or regulations which controls the interpretation of the law by courts. While embedding such standards in legislation may reduce the flexibility available by requiring a long statutory process to make any adjustments or changes, the trade-off is well worth the ability to determine a healthy patent policy. In addition, those countries that do not have an examination system may wish to create specific patent or intellectual property courts with exclusive jurisdiction. However, countries should beware of the potential for subject matter capture as such courts may become overly influenced by major patent holders. Strong legislative and regulatory guidance to

¹¹⁹ Ibid. ch 3 [11] noting the success of the 180-day exclusivity period for the first generic producer to challenge successfully the validity of a patent.

examiners and courts will have to be given to ensure that their decisions conform to the policy priorities of the developing state.

IV.1. The United States

IV.1.1. Legislative approach

As codified by the US Congress: “A patent may not be granted [...], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. [...]”.¹²⁰

The US legislative approach is a non-obviousness standard that attempts to leave as large an amount of room for the applicant as possible. The person skilled in the art becomes the person of ordinary skill in the art. “Ordinary” may be considered a level below even that of “average” as only a basic minimal level of skill is required to satisfy it.

The requirement that the subject matter as a whole be obvious prevents the discarding of portions of the claims as obvious. As long as the claimed invention as a whole is not obvious it may pass the test, despite containing portions and elements that are themselves obvious. If applied carelessly, the standard could serve to enclose previously disclosed or trivial elements of an invention.

IV.1.2. Regulations and guidelines

The US examination guidelines are contained in the USPTO *Manual of Patent Examination Procedure* (MPEP). The manual is a reference work on the practices and procedures for prosecution of patent applications before the USPTO. It contains instructions to patent examiners, as well as other material in the nature of information and interpretation, and outlines the current procedures which the patent examiners are required or authorized to follow in appropriate cases in

¹²⁰ 35 USC § 103(a).

the examination of a patent application. The MPEP does not have the force of law or the force of the rules.¹²¹

a. The burden of proof

In the USA the burden of proof lies with the examiner to establish a prima facie case of obviousness without which the claim is deemed non-obvious.¹²²

b. The scope of prior art

If the claimed subject matter is lacking novelty under 35 USC 102, that lack of novelty can also be a basis for non-obviousness. In such a case, the distance of the gap between the claimed invention and the prior art is zero. The essence of the novelty test is to see whether the size of that gap is greater than zero. Once that gap is determined to exist, the obviousness test determines whether the step is large enough to be inventive. The basis of such a test is therefore the Person Having Ordinary Skill in the Art (POSA), and whether it would have been obvious to that person to reach across that gap to the claimed invention.

It should be noted that while the USA uses a narrower scope of prior art in 35 USC 103 than in 35 USC 102, this does not need to be the case. The prior art used for the purposes of non-obviousness can be broader, or more explicitly based on what the POSA would consider to be in the prior art. Especially in the case of the USA, where the requirements for the novelty standard are so narrow (for example requiring that the entirety of the prior art references be contained in the same reference), decoupling the prior art examination for obviousness from that of novelty may leave some flexibility for adjusting patent policy. To maintain such flexibility, developing countries should ensure that the prior art examination for inventive step is separate from that for novelty, since they aim at establishing different things.

¹²¹ USPTO website:

<http://www.uspto.gov/web/offices/pac/dapp/mpepmain.html>

¹²² USPTO, *USPTO Manual of Patent Examination Procedure*, section 2141: 35 USC 103; The *Graham* Factual Inquiries.

The USA places additional restrictions on the scope of the prior art used for the obviousness determination. The MPEP requires that “In order to rely on a [prior art] reference as a basis for rejection of an applicant’s invention, the reference must either be in the field of the applicant’s endeavour or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned”.¹²³ This is the requirement that any rejection must be based on analogous art, which must fulfil the requirements of 35 USC 102. In essence, it is a requirement that the examiner must show that the inventor would have been aware of, and had access to, the prior art reference.¹²⁴ The approach is not explicitly based on what the POSA would naturally have known or read. This narrows the scope of the prior art considerably. There is an objective element to the test which suggests that the standard requires relevance to the invention rather than awareness.¹²⁵ The key element in determining prior art for inventive step in the USA is, therefore, determining how broadly to determine the field of the invention and how broadly to seek out elements outside the field that would be relevant to the claimed invention. By not using the POSA as the standard, or by restricting that standard, the US approach removes any sense of initiative from the POSA who, depending on the field, might be expected to have reached to references from different fields, sought out collaborations with scientists tackling analogous problems in other fields. This problem is borne out by examples of patents for

¹²³ USPTO, *USPTO Manual of Patent Examination Procedure*, section 2141.01(a): Analogous and Non-analogous Art. Citing *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

¹²⁴ USPTO, *USPTO Manual of Patent Examination Procedure*, section 2141.01(a): Analogous and Non-analogous Art. “A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavour, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” Citing *Wang Laboratories Inc. vs Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993).

¹²⁵ USPTO, *USPTO Manual of Patent Examination Procedure*, section 2141.01(a): Analogous and Non-analogous Art “[W]here the general scope of a reference is outside the pertinent field of endeavour, the reference may be considered analogous art if subject matter disclosed therein is relevant to the particular problem with which the inventor is involved”. Citing *State Contracting & Eng’g Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1069, 68 USPQ2d 1481, 1490 (Fed. Cir. 2003).

holders for paper coffee cups which Barton points out to illustrate the operation of the MPEP non-obviousness MPEP guidelines.¹²⁶ He notes that despite the basic concept's being extremely similar, analogous solutions from closely related fields, such as existing slip-on cardboard holders for paper coffee cups, could not be compared to the claimed patent which had opposing slits to close the cardboard wrapper around the cup. Because the opposing slits were a solution used in a different field of cardboard manufacture and the solution was applied to coffee cup holders, these were considered sufficiently different fields and the opposing slits solution was considered to be applied to a different technical problem when applied to coffee cups.

It is important to note that on April 30, 2007, the US Supreme Court in *KSR International v. Teleflex Inc.*, No. 04-1350, denied non-obviousness affirmed to a combination that was known to solve a similar problem. It stated:

[G]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, for patents combining previously known elements, deprive prior inventions of their value or utility.

The Supreme Court unanimously held that the Court of Appeals erred in rigidly applying the "teaching-suggestion-motivation" (TSM) test, by failing to acknowledge that a "person of ordinary skill in the art is also a person of ordinary creativity, not an automaton" and by adopting "[r]igid preventative rules that deny factfinders recourse to common sense". The Court noted that what matters is whether there was at the time of the invention "an obvious solution" for a "known problem". The "first error" of the Court of Appeals, the Supreme Court concluded, was to look "only to the problem the patentee was trying to solve". It argued that "any need or problem known in the field or endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed".

¹²⁶ J Barton 'Non-Obviousness' (2003) 43 *IDEA: The Journal of Law and Technology* 475 p. 481.

The Supreme Court found that a second error of the Court of Appeals was to assume that a person having ordinary skill in the art would be led only to those elements of prior art designed to solve the same problem. It is common sense that familiar items may have obvious uses beyond their primary purposes, and a person of ordinary skill will often be able to fit the teachings of multiple patents together like pieces of a puzzle.

c. Novelty: Determining the existence of a gap between the prior art and the claimed invention

Normally, in a system using the same scope of prior art for novelty as for inventive step, the novelty determination is also the same. In a system that uses different standards, it becomes necessary to re-examine the novelty issue because lack of novelty is also a basis for rejection on grounds of non-obviousness. This should generally be a somewhat separate examination.

In establishing the existence of a gap between the prior art and the claimed invention, it is generally necessary to consider not only the knowledge derived from a single prior document, but also the combined knowledge of existing literature, patent documents and other prior art. Current US practice disfavours such an approach, however, and holds that “the subject matter of a claim is not rendered obvious by prior art unless there is some specific suggestion or teaching in the prior art that points the way to it”.¹²⁷ This in practice means that the disqualifying prior art must be contained in a single published document. Thus, the general knowledge of the POSA about what would be considered part of the prior art is read out of the test. That omission is what enables the patenting of equivalents, substitutes and combinations. The USA uses a narrower scope of prior art for the obviousness test, and then limits it further by limiting the application of the POSA to determining what such a person would have considered to be part of the prior art elements that he would have used to bridge the gap to the claimed invention. If developing countries use a different scope of prior art for each test, they should ensure that the test to determine the existence of a gap between

¹²⁷ J Dratler *Intellectual Property Law: Commercial, Creative, and Industrial Property* (Law Journal Press New York 1991) §2.03[3].

the prior art and the claimed invention is based not just on a single document but on the POSA's level of skills and knowledge. The consequences of this are discussed further below.

d. The substitution of one substance for another, when the substances are equivalent for the same purpose

MPEP 2144.06 states:

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents.¹²⁸

The effect of this rule is to disallow the use of judgment on the part of the examiner. Where the examiner can determine for himself, even if there is no single reference in the prior art, that the two substances function in the same manner and are indistinguishable for the purposes of the invention, the rule does not allow him or her to make a determination of obviousness. The rule also injects and elevates novelty as the standard for determining inventive step in such cases.¹²⁹ This inability to go beyond the prior art leads to absurdities in areas where there is little literature on a subject *because* the changes are so obvious.¹³⁰ While there does not need to be an express suggestion of equivalence in the prior art (conforming to all the single reference requirements of 35 USC 102), there must be sufficient motivation in the prior art to suggest that there is equivalence. Such a conclusion cannot be reached by the examiner as a matter of general knowledge or the knowledge of the POSA. In fairness, this restriction is based on the argument that the recognition of such equivalence may itself be inventive. However, such an argument fails to distinguish between an inventive product and a discovery about its properties, something that most countries may wish to do.

¹²⁸ USPTO, *USPTO Manual of Patent Examination Procedure*, section 2144.06(a): Art Recognized Equivalence for the Same Purpose.

¹²⁹ J Barton 'Non-Obviousness' (2003) 43 *IDEA: The Journal of Law and Technology* 475 p. 483.

¹³⁰ *Ibid.* p. 481.

e. Combinations of known substances, elements or structures

MPEP 2143.01 states:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.¹³¹

This, again, reads the judgment of the patent examiner out of the process entirely. Where the existing prior art elements can be combined, and where it would have been obvious to do so, unless there was a sign in the prior art suggesting that combination in particular, the rule would not allow a finding of obviousness. Obviousness requires a suggestion in the prior art. The standard for combinations only reiterates this. The standard can be modified by asking whether the POSA would have thought to make the combination, but this is restricted by the requirement that the POSA must first have the prior art reference in front of him or her. Thus the reference must be in a single document and the prior art must suggest the combination. The fact that the level of skill of the POSA (including general knowledge) would itself have suggested the combination is insufficient.¹³²

However, such a standard fails to acknowledge the increased likelihood of obviousness from combinations of known elements or substances. While it could be argued that all inventions are products of new combinations of elements or substances, there are standard methodologies in research sciences such that any product of those methodologies is the inevitable result of such research, even if the end product is novel. It is better to establish a rule that non-novel processes cannot produce inventive products, unless those products are themselves exceptionally beyond what would have been expected by a person skilled in the art. This would be more in line with the rationale for patent protection which is to provide incentives for research that would otherwise not occur in the absence of patent protection. These issues are analysed further below.

¹³¹ USPTO, *USPTO Manual of Patent Examination Procedure*, section 2143.01: Suggestion or Motivation to Modify the Prior Art References.

¹³² *Ibid.*

IV.1.3. Further analysis

a. Bridging the gap between the prior art and the claimed invention

Having established the scope of the prior art, and having established the existence of a gap between the prior art and the claimed invention, the third part of the obviousness determination in the USA is whether the gap could have been bridged by the POSA. The nature of the POSA becomes crucial, because he or she can be determined to have motivations of their own or be limited only to what is in the prior art. In the USA, the determination of the gap and the examination of whether it could have been bridged by the POSA are essentially conflated by strongly linking any knowledge that the POSA might have only to specific references in the prior art.

Thus, in the USA, we simultaneously examine whether all or a significant portion of the elements contained in the claimed invention were in the prior art and whether the combination or use of those elements in the claimed invention would have been obvious to the POSA. This examination implicates analogy processes, combinations of known elements, and use of known or obvious methods or tools to make novel products or processes. The conflation of whether a gap exists between the prior art and the claimed invention and an assessment of whether, given the existence of a gap, the person skilled in the art would have had the knowledge and capacity to bridge the gap, has led to the patenting of many novel but non-inventive products and processes. In the USA, the practical effect of the precedents in the field of combinations and pre-existing knowledge is that the examination ends with a determination that the product or process is not contained in the prior art, an effective novelty standard. This may have changed, however, after the already-mentioned decision in *KSR International v. Teleflex Inc.*

While the examinations are very similar, developing countries may find it easier to provide a coherent standard if they understand, and make clear, that determining the existence and size of the gap between the prior art and the claimed invention is an entirely different examination from a determination of whether that gap could have been bridged by a person skilled in the art, even if both require a

determination of the knowledge and capacity of the person skilled in the art. In essence, if the claimed invention contains elements or processes, all or a significant portion of which are present in the prior art, then there must be a separate determination of whether the use of these elements is actually contained in the prior art or lies outside the prior art. The easy part is whether the invention, as a whole, was anticipated by the prior art. This is the model used in the USA. The more important and difficult examination is whether the *use* of known elements contained in the claimed invention is anticipated by the prior art. In this examination, the knowledge and capacity of the person skilled in the art should be considered part of the prior art. In the USA, this is not the case; only if the use of elements is anticipated in a single document of prior art is the claimed invention considered to be anticipated by the prior art in an inventive step analysis.

b. The person skilled in the art

The person skilled in the art is the standard by which the USA determines whether the use of known elements (combinations or substitutions) in the claimed invention are actually contained in the prior art. For example, a claimed invention that consists of a known substance A, and a known water-soluble gel container in which the substance is placed (a new combination of elements), would be examined first to see whether the container holding substance A is anticipated as a whole by the prior art. Then there would be an examination of whether the elements which make up the claimed invention were part of the prior art. If the answer were yes, as it is in this case, the examination would determine that the elements were most likely not anticipated by the prior art because no single document suggested putting the particular substance A into the water-soluble gel container. That would end the determination of non-obviousness. An alternative would be to require an examination of whether, given the knowledge and capacity of the person skilled in the art, such a person would have had the skills and motivation to combine the elements in this way. Such a motivation could be determined by assessing whether this was a research path others had been pursuing. In the USA the person skilled in the art is essentially no more than the sum of the prior art references. They are given no general knowledge and no sophisticated knowledge of the functioning of the scientific method or the direction of

research. Developing countries should note that they are free to define the person skilled in the art to reflect motivation and skill more accurately and to go further than a person unable to go beyond a single written reference. Such a person may be deemed to be aware, for instance, of the technologies used by a specialist working in a pharmaceutical company for the formulation of drugs, even if these are not contained in specific written documents.

It is worth mentioning that in *KSR International v. Teleflex Inc.* the Supreme Court held that “[A] person of ordinary skill is also a person of ordinary creativity, not an automaton” and raised the threshold for assessing the non-obviousness of combinations.¹³³

c. Doctrines guiding the examination of combinations and substitutions

Unexpected or surprising results

The difficulty with the examination of uses of known elements (substitutions and combinations) lies in the fact that research into the properties of products is part of the ordinary process of R&D work and that every piece of research aims at discovering something new. The examination entails a determination of the regular *expected* results of workaday research methodologies and whether the research methodology used (combination or substitution) was either so new, or took the research in such an unexpected direction, that the results of the research would not have been part of the expectations of an ordinary researcher. This can also be viewed as the “surprise” standard. The examination is in some sense circular, but also technically difficult, especially when carried out by a court rather than examiners who are specialists in their field. US courts, however, currently reject this approach and stress that patentable inventions may result from painstaking research, slow trial and error, or serendipity.¹³⁴

In *Pfizer v. Apotex* the Court of Appeal of the Federal Circuit held, in March 2007, that finding the unpredictability of a product does not result in non-obviousness: “[A] rule of law equating unpredictability

¹³³ *KSR International v. Teleflex Inc.*, No. 04–1350, p. 17.

¹³⁴ J Dratler *Intellectual Property Law: Commercial, Creative, and Industrial Property* (Law Journal Press New York 1991) §2.03[3].

to patentability, applied in this case, would mean that any new salt would be separately patentable, simply because the formation and properties of each salt must be verified through testing. This cannot be the proper standard since the expectation of success need only be reasonable, not absolute.”

On the other hand, many countries’ case law holds that there is no inventive step whenever it would be obvious, for a person skilled in the art, to test new matter (combinations or substitutions) with a significant likelihood of success. This entails an examination of expectation of success. The question lies in whether it is the expectation of the inventor that is assessed, or the expectation of the ordinary person skilled in the art. Where it is the expectation of the inventor that is assessed, it will almost always seem obvious since few if any inventors try a methodology without some notion that it will be successful. In resource-intensive research this can only be truer, as choices as to which line of research to follow are made solely on that basis. Where it is the expectation of the ordinary/average researcher in the field, it becomes easier to find that there would be no expectation of success. Either approach suffers from the problem that knowledge of the methodology is taken as a given despite the fact that the surprise may lie in the unexpected choice of method leading to an unexpected result. However, this approach also aims to reduce the danger of granting a patent on the product of an unexpected methodology that leads to a known result.

Obvious-to-try

An analogous approach is the *obvious-to-try* doctrine. In the chemical and pharmaceutical field, there is often a close structural relationship between a compound which is claimed as new and inventive, and known compounds, such as salts of acids, bases, isomers and homologues. In these cases it may often be deemed obvious-to-try the new compound, thus leading to its non-patentability. The EPO, for instance, has taken the view that the fact that certain advantages were predictable made it obvious to prepare a new compound.¹³⁵ In the USA, by contrast, the

¹³⁵ Case T-0154/82 IPD 7031 *Australian Nat. University* [1983] EPO Technical Board of Appeal.

presence of a predictable advantage is not generally deemed sufficient to exclude patentability.¹³⁶

Objective tests for non-obviousness in the USA

The USA has a generally “soft” approach to the non-obviousness standard.¹³⁷ In part, this appears to be the result of the courts relying on “secondary” factors to support their decisions on non-obviousness.¹³⁸ While these tests are meant to provide support and confirmation for a decision on non-obviousness, it is clear that they have become a significant means of initially determining non-obviousness itself.¹³⁹

The first of these is the “suggestion” test. For example, courts generally ask whether:

- the prior art
- would have *suggested* to a person of ordinary skill in the art
- that the process should be carried out
- and that there would be a reasonable likelihood of success.¹⁴⁰

The prior art is defined very narrowly for the purposes of the suggestion test, essentially requiring that the claimed invention as a whole be described in a single document before obviousness can be established.¹⁴¹ The motivation must come from the document itself and this definition in fact refuses to address the contribution of motivation that comes from the regular research process of a person skilled in the art. As noted above, the practice of the USA seems to have read the judgment of the person skilled in the art out of the process.

¹³⁶ PW Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law, Practice and Strategy* (4th edn Oxford University Press Oxford 2005) p. 196.

¹³⁷ US Federal Trade Commission *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (Federal Trade Commission Report October 2003) ch 4 [8].

¹³⁸ *Ibid.* ch 4 [9].

¹³⁹ *Ibid.* ch 4 [9].

¹⁴⁰ *Ibid.*

¹⁴¹ *Ibid.* ch 4 [10].

The second test is the “commercial success test” which is ostensibly used to reflect back on the post-grant history to see whether the claimed invention filled a particular need. The thinking behind the test is whether it fulfilled a clear need that had not been articulated or met before. If so, it is support for non-obviousness in that if a need had been articulated or met, it would have been obvious to fill it and it would have been filled. That it was not filled before the advent of the claimed invention suggests that the claimed invention was not an obvious solution to the need or that the need had not been articulated. While ostensibly considered after a determination of *prima facie* obviousness or non-obviousness, the courts in the USA have consistently determined that such factors must come into play before any conclusion on obviousness is reached.¹⁴² The danger posed by using such factors is that they will be used to rebut a *prima facie* case of obviousness. In addition, the validity of the test relies on a chain of inferences¹⁴³ that rests on assumptions which range from what the pre-market, pre-claimed invention conditions were, to what would be an appropriate measure of success. For example, a measure of success could be level of sales, but leaves out what the level of sales would be compared to. If there is no like product in the market, what would count as an appropriate comparison? The basic premise is circular in that the test claims that because there was a need, the claimed invention sold well, but that the way to satisfy the test for whether there was a need in the first place is whether the claimed invention sold well.

The core points against the commercial success test are that it is only applicable after the grant and that it has little bearing on the issue of whether the invention is a “technical” advance over the prior art.¹⁴⁴ Under such circumstances the probative value of such a test is at best questionable and at worst dangerous. Despite the fact that US policy and courts have seen fit to retain the test, even if in modified form, developing countries should be aware that such “objective” factor tests, while appealing because of their apparent ease of administration, may instead subvert the process of determining actual inventive step.

¹⁴² Ibid. ch 4 [15].

¹⁴³ Ibid. ch 4 [16].

¹⁴⁴ Ibid. ch 4 [18].

The low standard in the USA tends to lead to patent thickets or undue proliferation of patents that block innovation and competition, particularly through allowing the capture of incremental innovation by patent owners who make minor improvements to medicines based on known NCEs. In addition, such patenting may lead to a chilling of inventing around as the primary patent owner encroaches on that territory through aggressive defence of the original patent.

Both the combination and substitution standards embody the US approach to the obvious-to-try doctrine. This is a result of the conflation of two examinations: the first, the existence and size of the gap between the prior art and the claimed invention; the second, whether that gap could have been bridged by a person skilled in the art. The approach is essentially to ignore it, although there is an MPEP reference which states that for something to be obvious-to-try there must have been an expectation of success on the part of the person skilled in the art.¹⁴⁵ Since, however, the person skilled in the art is effectively read out of the obviousness determination in these two cases, the guideline amounts to a nullity.

IV.1.4. Conclusion

The US approach can be considered an object lesson in how not to apply the inventive step standard if one wishes to ensure high-quality patents and to maintain public access to medicines. Poor-quality patents enclose crucial areas of research which are better left for further development. Developing countries should take care not to repeat the errors of the USA, which now has to deal with the difficult and complex problems posed by decades of low and permissive inventive step standards. The extent to which the Supreme Court decision in *KSR International v. Teleflex Inc.* will influence future developments on the matter remains to be seen.

¹⁴⁵ USPTO, *USPTO Manual of Patent Examination Procedure*, section 2143.02.

IV.2. The European Patent Office (EPO)

IV.2.1. Legislation

The controlling legislation on inventive step is EPC article 56: “An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents are not to be considered in deciding whether there has been an inventive step.”

IV.2.2. Regulations and guidelines

As mentioned, the EPO utilizes the *problem-solution* approach to inventive step. The goal of the method is to determine whether a claimed invention would be obvious to a skilled person based on a three-step test.¹⁴⁶

Regulations for the EPO are found in the regulations of the EPC. It is here that support for the problem-solution approach can be found in Rule 27(1)(c):

The description shall ... disclose the invention, as claimed, in such terms that the technical problem (even if not expressly stated as such) and its solution can be understood, and state any advantageous effect of the invention with reference to the background art.

a. Burden of proof

Unlike in the USA, it seems that an application does not create a presumption that must be rebutted by the examiner establishing prima facie lack of inventive step.¹⁴⁷ No presumption exists in either the examiner’s or the patent applicant’s favour. However, in rejecting an

¹⁴⁶ B Hansen and F Hirsch *Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law* (Wiley-VCH Berlin 1998) p. 195.

¹⁴⁷ EPO *Guidelines for Examination in the European Patent Office* (European Patent Office Munich 2005) ch 4 sec 9.

application the examiner must give reasons based on which elements of the conventions have not been satisfied.¹⁴⁸

b. The substitution of one substance for another, when the substances are equivalent for the same purpose

The EPC standard notes:

A skilled person's selecting from the materials known by him as suitable for a certain purpose the one which was the most appropriate had to be regarded as forming part of his normal activities. The skilled person should therefore be at liberty, within the constraints of standard technical progress, to use alternative means known by him to have the same effect.¹⁴⁹

This embeds the knowledge of substitutes in the judgment of the person skilled in the art rather than making it the exclusive preserve of the prior art.

c. Combinations of known substances, elements or structures

The EPC standard is that:

the skilled person can be expected to take account of solutions to the individual problems proposed in different secondary documents in the same or neighbouring technical fields.¹⁵⁰

This enables the examiner to use judgment and limits the use of obvious combinations.

¹⁴⁸ EPC art 96.

¹⁴⁹ J Barton 'Non-Obviousness' (2003) 43 *IDEA: The Journal of Law and Technology* 475 p. 500.

¹⁵⁰ *Ibid.* p. 503.

IV.2.3. Further analysis

a. The closest prior art: Structural and functional similarity

The closest prior art for chemicals is generally the substance that is most structurally similar to the claimed invention. The prior art substance must have been disclosed and enabled such that a skilled person could obtain it.¹⁵¹ Structural similarity functions essentially as an objective measure of similarity of function. Thus, where the most structurally similar compound does not have a sufficiently similar function in the same field, a less structurally similar but more functionally similar one has tended to be chosen.¹⁵² In a sense, the closest structural compound addresses a different problem than does the claimed invention. Comparison with other compounds already on the market is also considered in cases where it would not be reasonable to expect the skilled person to use that substance as the starting point in attempting to solve the problem as defined.¹⁵³

The closest prior art test requires an independent establishment of the most structurally similar substance before considering either of these two deviations (functional similarity or comparison with product already in the market). This is an objective determination that does not require a determination of reasonableness. Nevertheless, the acceptable deviations do allow for situations where the closest structurally similar compound is not the best way to determine the starting point from which a skilled person would attempt to solve the problem. The point is to establish an objective approach to determining the prior art.

The danger is that, where little information is available, there will be a tendency to rely on the art as disclosed by the patent applicant. For developing countries with little capacity, however, the easy administrability of such a standard for prior art may be attractive. If they consider such an approach, they should preferably embed it in their guidelines rather than making it the general approach to patents. They

¹⁵¹ B Hansen and F Hirsch *Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law* (Wiley-VCH Berlin 1998) p. 195.

¹⁵² *Ibid.* p. 196.

¹⁵³ *Ibid.*

should also at least ensure that the claims of the applicant as to the closest prior art would be in general agreement with an evaluation by other researchers in the field. This could be accomplished by requiring the applicant to provide support from the literature. Another option would be to have an appointed list of experts with whom the examiner could consult as to the accuracy of the claim. Such experts would, of course, be bound to maintain the confidentiality of the request until the patent application was published. This approach also appears to have the benefit of reducing the issue of substitution or combinations. Thus, even if the compound is the result of substitution or combination, the product will still have to be measured against its closest structural or functional equivalent. This test can be seen as an analogue to the novelty requirement in the non-obviousness approach, in the sense that, where the claimed invention is identical in structure or function to a pre-existing compound, it will fail the novelty or prior art portion of the test. It appears that simple substitutions will therefore be easily addressed by this examination. However, if the substitute is new and can be shown to be the cause of the claimed advantages, the test then moves to the second part of the test to determine whether the claimed invention solves the technical problem in a way that has advantages over the closest previous solution or is presenting the same solution to a problem that has been already solved.

b. Technical advantage over previous solutions

The use of substitutions and combinations may often escape the net of the closest prior art test. These, however, may also be caught in the second part of the test, by showing that they do not present technically advantageous solutions to the technical problem that they are meant to be solving. This will capture some of the obvious use of substitutions or combinations. However, the primary point at which the EPO approach addresses the issue of whether a substitution or combination is obvious is in the third part of the test, where “further prior art” is considered.¹⁵⁴ Such further prior art would therefore include the knowledge of the person skilled in the art as to whether the use of known elements in the manner of the claimed invention were obvious.

¹⁵⁴ EPO *Guidelines for Examination in the European Patent Office* (European Patent Office Munich 2005) ch 4 sec 9.8.3.

Defining the technical problem

In defining the technical problem addressed by the claimed invention, the *problem-solution* approach attempts to exclude any element of subjectivity. In that sense, the problem as defined by the examiner or court can be different from the technical problem as perceived by the inventor or from that documented in the application.¹⁵⁵ Hansen and Hirsch point out that this essentially reduces to what advantages the claimed invention has over the prior art, and that the examination focuses on the advantages as described in the application.¹⁵⁶ This bears some similarity to determining whether a gap exists between the prior art and the claimed invention (as seen in the *non-obviousness* approach). The problem to be solved must, however, be more than trivial itself. As Hansen and Hirsch point out, the EPO deems solutions to normal technical problems (the regular workaday processes of research), such as optimizing parameters, removal of deficiencies, and time and energy savings, as non-inventive, unless they present something exceptional and unexpected.¹⁵⁷ This is essentially a statement that known and obvious methodologies cannot produce inventions unless those inventions are themselves so new and unexpected that they would not have been expected by a person skilled in the art carrying out those operations.

The scope of the technical problem: relation to claim scope

In the problem-solution approach, determination of the scope of the technical problem should be independent of the scope of the claims. The claims must therefore encompass a complete solution to the technical problem, and all embodiments of the claims must present a solution to the problem, even if some embodiments do so more effectively than others. They cannot be a solution to only part of the technical problem.¹⁵⁸ The burden of establishing that the claims do

¹⁵⁵ B Hansen and F Hirsch *Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law* (Wiley-VCH Berlin 1998) p. 197.

¹⁵⁶ *Ibid.*

¹⁵⁷ *Ibid.* p. 208.

¹⁵⁸ *Ibid.* p. 198.

encompass, and present a solution to, the technical problem as defined lies with the applicant.¹⁵⁹

At first glance there appears to be a paradox at the core of this approach. Placing the burden of establishing the advantages on the applicant seems reasonable, especially given how this is buttressed by the requirement of disclosure and enablement. However, where an examiner relies on the claims to define the scope of the problem, the definition of the problem cannot really be determined independently of the claim scope. In chemical inventions, the way this seems to be overcome is by requiring comparative testing by the applicant. Thus the closest prior art is matched against the claimed invention, and the claims are substantiated on the basis of those results. In all relevant circumstances where the prior art is used, the claimed invention must present an advantage.¹⁶⁰ Comparative testing raises the question of whether the comparative testing must show advantages at every stage of functioning of the claimed invention or only in the end result claimed. In any case, the scope of the examination is controlled by what advantage is claimed. Each advantage claimed under each embodiment must be substantiated by comparative testing. Even if the embodiments have different degrees of advantage they must all show the advantage.

Unexpected or surprising results

Comparative testing is not conclusive, however. If, in the case of new products, it is impossible to show comparative tests, on the basis that there really are no sufficiently similar products, this is not fatal to the application.¹⁶¹ If the person skilled in the art would have expected the results from the changes made by the claimed invention to the prior art, only then would a finding of lack of inventive step be made.¹⁶² This examination therefore implicates the issues covered in the examination of the non-obviousness approach above: the nature of expectation, determining the normal course of research, the issue of known methods producing unknown results, and whether the unknown results would be expected by a person skilled in the art. This test forms the basis of how

¹⁵⁹ Ibid.

¹⁶⁰ Ibid. p. 199.

¹⁶¹ Ibid. p. 201.

¹⁶² Ibid.

the third test of the EPO works, especially with respect to substitutions and combinations.

c. Further prior art

If a test passes the hurdles of the first two, relatively objective, tests, including that of comparative testing, it must still pass the test for “further prior art” which asks the obviousness question as to whether, given the elements of the closest prior art, or the known methodology, or the change made in relation to the closest prior art, the effects of the changes would have been expected by a person skilled in the art. The other part of the test is whether, according to general technical knowledge, the effects of the changes made by the claimed invention would have been obvious to a person skilled in the art. Unfortunately, this approach does not unpack the examination of combinations sufficiently. This may make it difficult to deal with a situation where a known methodology produces a new and unexpected result. Hansen and Hirsch point out that the EPO has clarified this by stating that the new and unexpected result can be patented only if it would not have been accomplished as an inevitable result of the actions of the person skilled in the art. Not only must it have been new and unexpected, it must have been so far outside the expectation of the person skilled in the art that its production and effect could not have been deduced from the steps taken by a person skilled in the art.¹⁶³ This is recognition of the *but-for* principle at the core of the patent grant. Where the patent incentive does not play a role in the motivation for the research, there is no reason to grant a patent.

Obvious-to-try

As with the USA, combinations and substitutions present different facets of the obvious-to-try doctrine. Since the European approach does include the person skilled in the art, it becomes clear that the person skilled in the art must have some expectation of success for the claimed final product or process tried to be obvious. Where that expectation is missing, the product must be considered to be inventive. The European standard is that for the product to be obvious there must be a reasonable

¹⁶³ Ibid. p. 203.

expectation of success of the chosen method on the part of the person skilled in the art. The European approach makes it clear that “even if an experiment is obvious to try for the skilled person, it is not necessarily true that this person would have any reasonable expectation of success when embarking on it”.¹⁶⁴ This approach aims to protect the serendipitous results of obvious methodologies. The question must be whether such an approach is worth the risk of granting obvious patents. If the patent incentive works a priori to the invention, it seems unnecessary to reward serendipity that occurs in the course of regular incremental research. Such serendipity cannot be rationally incentivized.

The European approach does not seem to distinguish clearly between whether the method chosen is inventive and whether the end product is inventive. Where the method chosen is inventive (not obvious to the person skilled in the art) then the method is considered to be inventive, and in most cases the product of that process is more likely to be inventive. Where the method chosen is not inventive, the possibility that the end product will also not be inventive is very high. An appropriate obvious-to-try doctrine takes account of these factors. It is a matter of policy whether developing countries wish to account for inventive products which are the product of non-inventive methods.

d. Further indicia of inventiveness

The EPO may also consider further indicia of inventiveness, although there appears to be even less clarity than in the USA about whether these can confirm a decision in favour of inventive step or can be used to overturn a prima facie case of lack of inventive step.¹⁶⁵

If a long-standing need can be identified and the claimed invention fills that need, it may be possible to show inventive step.¹⁶⁶

¹⁶⁴ J Barton ‘Non-Obviousness’ (2003) 43 *IDEA: The Journal of Law and Technology* 475 p. 505.

¹⁶⁵ EPO *Guidelines for Examination in the European Patent Office* (European Patent Office Munich 2005) ch 4 sec 9.10.4.

¹⁶⁶ B Hansen and F Hirsch *Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law* (Wiley-VCH Berlin 1998) p. 216.

However, a sufficiently long period of time must elapse between recognition of the problem and need, and the solution presented. If only a few years have elapsed, the need cannot be seen as long-standing.¹⁶⁷ Given this formulation of the test, one can see that determination of such a need in cases that do not, or only barely, meet the criteria of the main test can establish inventive step. The application of the test needs to take into account what is the scope of the prior art. What is clear is that it does not apply the person skilled in the art to determine whether there had been a long-standing need.

IV.2.4. Conclusion

The European approach has the virtue that it more closely ties the inventive step requirement to the nature of the technical problem solved. However, the same underlying problem that exists in the USA exists in the EPO, mainly that the inventive step standard for minor technical advances is too low and works to limit public health access by unnecessarily closing off research paths and products. The patent incentive in this case is disproportionate to the value of the products protected.

V. THE SITUATION IN DEVELOPING COUNTRIES

Many developing countries do not have examination systems and only test the validity of inventive step during litigation, which may never occur. In most countries with registration systems, there exist no examination guidelines which in the USA and Europe determine the level of inventive step. By leaving such issues to litigation, most developing countries thereby lose any capacity to direct their innovation policies properly. The following section outlines the legislative and, where existent, regulatory and guideline approaches of several developing countries.

¹⁶⁷ Ibid.

V.1. Example of Text and Language from Developing Countries

India has an examination system. The legislative text that most recently defines the inventive step requirement is the recent Patents (Amendment) Act of 2005 which states;

“inventive step” means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.¹⁶⁸

The addition of “economic significance” as a way of meeting the inventive step requirement is peculiar to India. The Manual of Patent Practice and Procedure (2005) of the Indian Patent Office further clarifies the definition, although it goes no further to explain the criteria of economic significance other than to say “**Here definition of inventive step has been enlarged to include economic significance of the invention apart from already existing criteria for determining inventive step.**”¹⁶⁹ (emphasis in the original).

a. The scope of the prior art

The guidelines state that “For the purpose of determination of inventive step the prior art shall include the prior publication in relevant field”.¹⁷⁰ This suggests an acknowledgment that the scope of prior art for inventive step is not equivalent with that for determining novelty. In addition, the prior art is not limited to prior publications.

b. The person skilled in the art

The inventiveness is measured against the person skilled in the art: “An invention shall not be considered as involving an inventive step, if, having regard to the state of the art, it is obvious to a person skilled in

¹⁶⁸ Patents (Amendment) Act of 2005 (No. 15 of 2005) sec 2(f).

¹⁶⁹ Indian Patent Office *Manual of Patent Practice and Procedure* (Indian Patent Office Mumbai, 2005) sec ch 2 sec 2.3: Inventive Step (Non-obviousness).

¹⁷⁰ *Ibid.*

the art.”¹⁷¹ The person skilled in the art “should be presumed to be an ordinary practitioner aware of what was general common knowledge in the relevant art at the relevant date. In some cases the Person Skilled in the Art may be thought of as a group or team of persons rather than as a single person”.¹⁷²

c. The substitution of one substance for another, when the substances are equivalent for the same purpose

The guidelines make no explicit mention of this.

d. Combinations of known substances, elements or structures

With respect to this issue, the Indian guidelines state:

If a claim comprises mere juxtaposition of parts or components, for example, a composition comprising known ingredients such a juxtaposition is likely to be obvious, unless it leads to some effect, say synergistic effect.

This suggests a strong disapproval of combinations. However, the guidelines also state that “in general, where an invention comprises a collection of known or obvious parts, it must be shown, before an objection of obviousness can be made, that it was obvious to combine these parts”.¹⁷³ This, it seems, asserts not only that there must be some motivation but that the motivation must itself be obvious.

e. Further text and language

While determining the inventive step in the invention, the following may be considered by the examiner:

a) scope and content of the prior art to which the invention pertains

¹⁷¹ Ibid.

¹⁷² Ibid.

¹⁷³ Ibid.

- b) assessing the technical result (or effect) and economic value achieved by the claimed invention.
- c) differences between the relevant prior art and the claimed invention
- d) defining the technical problem to be solved as the object on the invention to achieve the result
- e) final determination of non-obviousness, which is made by deciding whether a person of ordinary skill could bridge the differences between the relevant prior art and the claims at issue.

This final element suggest that the “economic significance” criterion is applied in lieu of the technical result standard such that, even if a product is not necessarily a significant technical advance on the state of the art, it may still be patented because of the economic significance it would have for the domestic economy. This would represent a dilution of the technical advance standard normally embodied by the inventive step requirement, especially since economic significance alone could fulfil the requirement. However, full evaluation of this standard will have to wait until it is seen how it is applied by the patent office.

The benefit to India of the economic significance test is unclear, although it may allow for patenting of further incremental innovation embodying a product of major economic importance. It also remains unclear whether such a standard accrues to the benefit of follow-innovators or to the primary product innovator. The primary product patent owner could use such a standard to extend his patent further through patenting anew a variation of the patented product and claiming economic significance in order to bypass technical advance requirements. On the other hand, if a competitor of the primary product patent owner makes a small improvement and can show that it significantly lowers the price, the patent examiner may determine that this could be economically significant and therefore patentable.

VI. CONCLUSIONS AND RECOMMENDATIONS

A possible option for developing countries is to define and apply strict criteria for inventive step, in order to avoid the granting of patents that may unduly block competition in health-related products and processes. It may be argued that such strict criteria may prevent the protection of locally developed “minor” innovations. This would be a matter of particular concern for middle-income or faster-developing countries such as China, India, Brazil or South Africa, which all have domestic pharmaceutical industries that engage in some small-scale forms of R&D activities. While this may be a concern, such industries may be better served through a system of utility or petty patents rather than a wholesale dilution of the inventive step requirement.

A model legislative approach to inventive step for developing countries could be based on the following rule:¹⁷⁴

- a) Patents shall not be granted in respect of products or processes which would be obvious to a person skilled in the art at the time of the filing of the patent claim.
- b) In particular, an invention shall be deemed obvious when:
 - i) the prior art provides motivation to try the invention, or
 - ii) when the method of making a claimed product is disclosed in, contained in or rendered obvious by a single piece or any combination of pieces of prior art.

This rule is not intended to work alone. Combined with one or several of the model regulations and guidelines, a comprehensive system of addressing the standard of inventive step can be created, in a flexible and targeted manner. The proposed rule aims to provide sufficient level of specificity to establish that no patent may be obvious, and to establish the nature and scope of the way inventive step relates to the prior art

¹⁷⁴ CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) p. 47.

examination. It eliminates the dangers of granting patents on products and processes that are obvious to try, or which are the result of obvious methodologies.

States may prefer to leave a definition of the scope of the prior art to regulations or guidelines so as to maintain maximum flexibility in determining innovation policy over the short term and adjusting it to different public policy needs (see Annex).

ANNEX I

MODEL REGULATIONS AND GUIDELINES ON INVENTIVE STEP

Regulations

1. The Person Skilled in the Art

- a) A person skilled in the art means a person with knowledge and skill in the technical field of the claimed invention at the relevant date. The knowledge referred to consists of the knowledge that an experienced person in the field concerned can reasonably be expected to have. It includes, in particular, knowledge contained in handbooks, textbooks, specialized books and journals and information known or used in relation to the type of product or processes claimed in the application. The general knowledge does not need to exist in writing, but may form part of the general or specific body of know-how of the average/advanced skilled person.¹⁷⁵

This model provision should ensure that, for those countries using an obviousness standard or which measure inventiveness against the knowledge and methodologies of other workers in the same field, the level of inventiveness is sufficiently high to provide a real incentive while deterring the patenting of trivial works. For instance, in determining what would be a person with average skill, if an application is made for the patenting of recombinant hormone growth, the “person skilled in the art” should, *at the least*, be a professional with a university degree who is familiar with the application of biotechnology in pharmaceuticals, rather than a general biologist or a biotechnologist experienced in other fields of biotechnology. Developing countries will want to ensure that the person skilled in the art is defined in an international and global manner, encompassing all workers in the field

¹⁷⁵ Based on CM Correa ‘The WIPO Draft Substantive Patent Law Treaty: A Review of Selected Provisions’ (Working Paper No 17 South Centre TRADE Series March 2004) p. 3.

or sub-field, not just those in the country of the inventor or of application. In particular, special weighting should be given to populations of researchers in a field where work in the field is particularly advanced. This would ensure that the best possible sample for determining the person skilled in the art is used, rather than one that is skewed to populations where there is minimal skill in the art.

2. The Definition and Scope of Prior Art¹⁷⁶ for Inventive Step

Model Regulation

- a) The prior art shall comprise everything made available to the public in any country by means of a written or oral description, by use, or in any other way.
- b) The prior art, as defined in paragraph (a) above, shall include knowledge developed by, or in possession of, a local or indigenous community.
- c) The prior art shall also comprise unpublished patent applications filed at the national Patent Office, where such applications are subsequently published.
- d) Where the core of the separate elements of a claimed invention are contained in the prior art, the prior art for the claimed invention shall be deemed to consist of the knowledge of the person skilled in the art.

This definition may be equivalent to the legislative definition outlined in the scoping note of Novelty, but it serves to embed it as a particular operational definition for the purposes of inventive step, which can be altered by regulation and is not dependent on the legislative amendment process.

¹⁷⁶ From CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) p. 41.

Examination Guidelines

1. Functional and Mechanical Equivalents

a. The substitution of one substance for another, when the substances are equivalent for the same purpose

Model Guideline

- a) Where a substance or combination of substances is substituted for another substance or combination of substances contained in an existing patent claim or other piece of prior art, and that substance or combination of substances performs an equivalent function, the claimed invention shall be deemed to lack inventiveness.
- b) Where a structure or combination of structures is substituted for another structure or combination of structures contained in an existing patent claim or other piece of prior art, and that structure or combination of structures has an equivalent mechanical effect, the claimed invention shall be deemed to lack inventiveness.
- c) The determination of whether a substance or combination of substances performs the same function shall be determined with reference to the knowledge of the person skilled in the art.
- d) The determination of whether a structure or combination of structures has an equivalent mechanical effect shall be determined with reference to the knowledge of the person skilled in the art.

This model should prevent the extension of patent terms through making essentially cosmetic changes to chemical entities, or by making analogues of existing chemical entities. There is little danger of preventing the innovation of possibly cheaper or more efficient ways of creating the same effect. Such research is a normal and active part of

any business process and does not need the incentive of patent protection to encourage it.

2. Combinations

a. Obvious-to-try approach: Products that are the result of methodologies contained in the prior art

Model Guideline

If the claimed invention consists of a combination of two or more products or processes by a method contained in the prior art or a method that would be obvious to a person skilled in the art, such a product or process shall be deemed to lack inventiveness [, unless the applicant can show that the product or process embodied by the claimed invention would not have been obvious to/expected by the person skilled in the art and that it possesses clear advantages over other products or processes in the state of the art].

If a process is also inventive one can claim the both process and the product. However, if the process is obvious the product itself must be inventive or more than normally so, to qualify for patent protection. This embodies both the concept of technical advance and does not extend patent protection to advances that would occur in the natural course of events. This model deals with the issue of methods or additions that are the results of combinations. A slight change in the wording may also apply to all products of methods that were themselves obvious to try:

Model Guideline

If the claimed product or process is produced by a method contained in the prior art or a method that would be obvious to a person skilled in the art, such a product or process shall be deemed to lack inventiveness [, unless the applicant can show that the product or process embodied by the claimed invention would not have been obvious to/expected by the person skilled in the art, and that it

possess clear advantages over other product or processes in the state of the art].

This essentially accomplishes the same task with respect to elements that would be obvious to try, thus eliminating changes in dosage, administration or other trivial changes from patentability. The exception under both these approaches is optional, taking into account whether developing countries would wish to protect the unexpected results of methods that were obvious to try. The “obvious” standard requires the product to be inventive independently of the process that produced it, which is quite a high standard. The “expected” standard allows a consideration of the nature of the method which produced the claimed invention. The application of this standard can cut in two directions: The first is that if the inventiveness of the method is established, it will be easier to establish the unexpected nature of the product. The other is that if the method chosen lacks any inventiveness, it becomes less likely that the result will itself be deemed inventive.

CHAPTER 3

INDUSTRIAL APPLICABILITY/UTILITY

I. INTRODUCTION

The utility or industrial applicability criterion is found in most patent laws.¹⁷⁷ The rationale is that patent protection should not be available for abstract ideas or purely intellectual creations that cannot be put to any use. A patentable invention has to be concrete and should have a technical character. Industrial applicability is used as a threshold to exclude some inventions from patentability. “Industrial” is used in a very wide sense, irrespective of the for-profit or not-for-profit nature of the industry.¹⁷⁸ But the interpretation of industrial applicability/utility as a criterion has evolved over the years with changes in the guidelines of patent offices, judicial interpretations and technological advances. In practice, the threshold for utility or industrial applicability varies widely from country to country. A quick overview shows this clearly.

For instance, under the EPC there is no need to prove that the invention can actually be applied in the industry. All that is needed is that it should be susceptible to or capable of industrial application. In other words, there is no need to prove that it can be put to use in industry; it is enough if it is demonstrated that it is capable of being put to use in industry.

¹⁷⁷ According to TRIPS Article 27(1) of the Agreement, the criteria of novelty, non-obviousness (inventive step) and utility (industrial applicability) determine patentability. For the purposes of this provision, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms non-obvious and useful, respectively.

¹⁷⁸ *Chiron v. Murex* (1996) RPC 535.

According to the EPO guidelines, industrial applicability refers to any activity that belongs to the “practical arts”, that is, distinct from those done for aesthetic purposes only. The threshold of utility or industrial applicability is very low. Comparatively speaking, utility in the context of US patent law and practice is used in a broader sense than industrial applicability in the context of European patent law and practice. Over the years, the patent subject matter has expanded thanks to judicial pronouncements and USPTO practices.

The USPTO indicates that the concept of “industrial applicability” is applied only to those applications filed under the PCT in the International Stage, while National Stage applications are examined based on 35 USC. Sections 101 and 112(1). It explains that “industrial applicability” is not coextensive with the utility requirements, as discussed below. The definition under 35 USC 101 is a minimal definition, and the judicial pronouncements and examination guidelines have further illuminated the idea of utility.

The JPO requires that for an invention to be patentable it must be industrially applicable. According to the JPO, a “product that can be used” is interpreted as meaning a product that can be used in an industrially applicable way; and this should be shown in the detailed description of the invention. The JPO guidelines list inventions that fall beyond the scope of industrially-applicable inventions. Industry is interpreted in a broad sense and includes telecommunications, transportation and so on.

Under the Indian Patent Act 1970 also, industrial application is a criterion. The Act defines an invention as “a new product or process involving an inventive step and capable of industrial application” (S. 2(1)(j)). In *Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries* 118 it was held that “Section 26(1)(f) of the 1911 Act recognized the lack of utility as one of the grounds on which a patent could be revoked” (AIR 1982 SC 144). According to the Indian Patent Office Manual, “Capable of industrial application, in relation to an invention, means that the invention is capable of being made or used in an industry (S.2 (1)(ac))”. It further states: “An invention is capable of industrial application if it satisfies three conditions, cumulatively:

- can be made;

- can be used in at least one field of activity;
 - can be reproduced with the same characteristics as many times as necessary.
- 1) An invention, to be patentable, must be useful. If the subject matter is devoid of utility it does not satisfy the requirement of invention.
 - 2) For the purpose of utility the element of commercial or pecuniary success has no relation to the question of utility in patent law.
 - 3) The usefulness of an alleged invention depends not on whether by following the directions in the complete specification all the results not necessary for commercial success can be obtained, but on whether by such directions the effects that the application/patentee professed to produce could be obtained.
 - 4) The meaning of usefulness is therefore useful for the purpose indicated by the applicant or patentee whether a non-commercial utility is involved.
 - 5) The usefulness of the invention is to be judged, by the reference to the state of things at the date of filing of the patent application, if the invention was then useful; the fact that subsequent improvements which have replaced the patented invention render it obsolete and commercially of no value does not invalidate the patent.
 - 6) Speculation or imaginary industrial uses are not considered to satisfy the industrial application requirement.”

From these examples we can see that, although the concepts of utility or industrial applicability are applied in almost every system and may appear to be synonymous, there is a great deal of difference between them, in theory and in practice, and the threshold varies from country to country.

In this chapter the analysis is focused on pharmaceutical patents. Our interest lies primarily in the policy implications of industrial applicability/utility as a requirement in the patent laws of developing countries. While we try to provide a comparative analysis of US, EPO

and JPO requirements on utility, a detailed examination of each country's approach is beyond the scope of this chapter.

II. INDUSTRIAL APPLICABILITY AND UTILITY

The Paris Convention states:

Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.

Here the term "industry" also includes commerce and is extended to extractive industries and any type of manufacture. "Industry" is generally understood in its broad sense as including any physical activity of "technical character". For applicability it is necessary to test that the invention can really be manufactured and is sufficiently disclosed; thus, medical treatment per se is excluded from the scope of industrial application.

Under the EPC, article 57, "An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture".¹⁷⁹

Under PCT article 33(4):

For the purposes of the international preliminary examination, a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry. "Industry" shall be understood in its broadest

¹⁷⁹ The EPC.

In: <http://www.european-patent-office.org/legal/epc/e/ar57.html#A57> (last visited 28 December 2005)

sense, as in the Paris Convention for the Protection of Industrial Property.

A study done for WIPO identified two types of definitions for industrial applicability: In Type I an invention shall be considered as susceptible of industrial application “if it can be made or used in any kind of industry, including agriculture”. The interpretation of the word “industry” is to be understood in the broadest possible sense. Under type II the definition of “industrial application” is broader than the one above (type I) or, at least, clarifies the scope of the term “industry”.. The study noted that some patent offices and guidelines specifically exclude certain subject matter as inventions not applicable in industry.¹⁸⁰

The notions of industrial applicability and utility have undergone changes over the years as the subject matter and criteria set by laws and patent office guidelines have been revised for many reasons, including the need to harmonize with multilateral or bilateral agreements. Both industrial applicability and utility cannot be decided in isolation from other aspects of the invention as they relate to substantive conditions of patentability.

The notion of utility in US law and practice is broad enough to cover inventions without industrial application (such as business methods).

The American utility requirement precludes less subject matter from patentability than either the European or Japanese industrial application standards. For example, the USA does not prohibit the patenting of medical methods. Furthermore, the Federal Circuit has

¹⁸⁰ Further, home remedies, household remedies, an idea for a penal reform by the substitution of voluntary corporal punishment, and a method for regulating city traffic are other examples given by the Patent Offices of inventions that are not considered as being applicable in “industry”.

The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws ‘Informal paper prepared by the International Bureau 2001’.

In: http://www.wipo.int/scp/en/documents/session_5/pdf/scp5_inf.pdf (last visited 1 January 2006)

ruled that the utility requirement can no longer be asserted as a bar against inventions that are used to deceive the public. In contrast, both the EPC and JPO Guidelines exclude medical methods from patentability based on lack of industrial application. In Europe, as well as in Japan, inventions that are contrary to public order or morality are also excluded from patentability; however, this exclusion is not specifically based on lack of the invention's industrial application. This difference between utility and "industrial application" has a real-world effect. A stricter standard of utility coupled with enablement and disclosure requirements may be an effective barrier to the patenting of certain categories of subject matter. According to a note submitted by USPTO in relation to the draft SPLT:¹⁸¹

In addition, as the United States of America currently employs a utility standard, we are concerned of differences between the utility standard and industrial applicability more generally. For example, it appears that an industrial applicability standard would allow for rejection of a broader area of inventions, such as inventions of a "private" nature. We are very curious as to the extent of this difference as well as any other areas of invention that would be excluded by industrial applicability but would not be excluded by utility.

In the USA, inventions which do not produce any technical effect are also patentable. The utility criteria under US law and practice can be met if there is a practical application and if an invention produces a useful and specific result. Such a result need not be susceptible to industrial application. The US rule permits the patentability of purely experimental inventions which cannot be made or used in an industry, or which do not produce what is known as a technical effect, as illustrated by the large number of patents granted in the USA on methods of doing business, and by the patenting of research tools, such as expression sequence tags (ESTs) and single nucleotide polymorphisms (SNPs).¹⁸²

¹⁸¹ In: <http://listbox.wipo.int/wilma/scp-eforum/2003/msg00002/USPTO.doc> (last visited 1 January 2006)

¹⁸² UNCTAD-ICTSD Project: Resource Book on TRIPS and Development : Cambridge: Cambridge University Press (2006) p. 361.
In:

III. TECHNICAL EFFECT UNDER EUROPEAN LAW

The requirement of “industrial applicability” is often linked to the concept of “technical effect” elaborated on under European law. There is, however, no definition for “technical effect”. It may be broadly defined as an improvement in technology, within the patentable area of technology. Technical effect is linked to technical contribution which has been defined as “a contribution to the state of the art in a technical field which is not obvious to a person skilled in the art”.¹⁸³

In the words of the Board of Appeal (T 1173/97 and T 935/97), for instance, “the technical effect must go beyond the ‘normal’ physical interactions between program and computer. If such an effect can be found, the program is not excluded and hence a patentable invention. A technical effect can be, for example, a reduced memory access time, a better control of a robotic arm or an improved reception and/or decoding of a radio signal. It doesn't have to be external to the computer on which the program is run; reduced hard disk access time or an enhanced user interface could also be a technical effect.”¹⁸⁴

In the EPO, a problem and solution approach is applied to determining patentability, which involves the following four steps:

- Identify the “closest prior art”.
- Assess the technical results achieved by the invention when compared with the “closest prior art”.

http://www.iprsonline.org/unctadictsd/docs/RB2.5_Patents_2.5.1_update.pdf (last visited 1 January 2006). The most recent case on ESTs and the utility requirement in the US context is *Re Fisher* (421 F.3d 1365 (Fed. Cir. 2005)). In this case the majority in the Federal Circuit upheld USPTO guidelines on utility standard for ESTs. For a discussion on this see P Davis et al. (2005) ‘ESTs stumble at the Utility Threshold’ 23 *Nature Biotechnology* 10 pp. 1227–1229.

¹⁸³ Proposal for a directive of the European Parliament and of the Council on the patentability of computer-implemented inventions, 20 February 2002, COM (2002), 92 final.

¹⁸⁴ Software Patents Under the European Patent Convention

In: <http://www.iusmentis.com/patents/software/epc/> (last visited 2 January 2006)

- Define the technical problem to be solved as the object of the invention to achieve these results.
- Examine whether a skilled person, having regard to the state of the art, would have suggested the claimed technical features for obtaining the results achieved by the invention.

The basis for this approach can be found in the regulations on implementing the EPC, and in particular 27(1)(c). Under this an invention must be disclosed in such terms that the technical problem (it need not be expressly so stated) and its solution can be understood.

This is not, however, the only approach and there is no necessity that it should be applied in all cases without exception. In fact in decision T 465/92, the Board said that the “problem and solution” approach was not *sine qua non*.

Technical effect is closely linked to inventive step. Whether there had been any inventive step or not, it would be necessary to find out whether the invention solved a technical problem. In T939/92 *Triazoles/AGREVO*, the Technical Board of Appeal raised the question as to whether an invention that did not solve a technical problem could ever have had any inventive step.¹⁸⁵

Applying the technical effect concept would imply that broad claims would have to be substantiated by the technical contribution and the level of inventive step. The solution should be something that could not be obvious to one skilled in the art. Thus while assessing the technical contribution, the prior art would be taken into account. If the technical effect is minimal or non-existent then the inventive step might be non-existent or negligible. If the technical effect results, for instance, in a novel compound that was not obvious in the light of prior art, and a person skilled in the art would be able to achieve the same result by practising the invention or process in the application, then there is a substantial inventive step.

¹⁸⁵ J Crump ‘Inventive Step in the EPO : Problem Solution’.
In: www.ficpi.org/library/APAA_FICPI_Newport/P5_Crump.doc (date of document not known)

Technical effect is a concept used in Europe; there is no corresponding concept in the USA. While the concept helps in assessing the level of the inventive step and in examining the contribution made by the invention to the art, the process is complicated, and only when the prior art is well established or fully documented can such an exercise be undertaken.

IV. UTILITY IN US LAW AND PRACTICE

The utility requirement is set forth in US law in Section 101.¹⁸⁶ The specification should contain enough information to enable one to make and use the invention. In other words, the invention should possess utility, and the specification should enable one to make and use the invention. Thus the utility requirement and enablement requirement are linked.

Under the US law an invention must be capable of some beneficial use. However, defining this has not been easy and the courts have interpreted the utility requirement differently in many cases.¹⁸⁷

¹⁸⁶ Under 35 USC 101, the invention must be minimally operable towards some practical purpose. “The claimed invention as a whole must accomplish a practical application. That is, it must produce ‘a useful, concrete and tangible result.’” *State Street 149 F. 3d at 1373, 47 USPQ2d at 1601-2*.

¹⁸⁷ To be useful, an invention must be capable of some beneficial use in society. See, for example, *In re Swartz*, 232 F.3d 862, 863, 56 USPQ2d 1703, 1703-04 (Fed. Cir. 2000), discussed at § 4.04[1] (“The utility requirement of § 101 mandates that the invention be operable to achieve useful results. See *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992).”); *Juicy Whip Inc. v. Orange Bang Inc.*, 185 F.3d 1364, 1366, 51 USPQ2d 1700, 1702 (Fed. Cir. 1999), discussed § 4.03[2] (“The threshold of utility is not high: An invention is ‘useful’ under section 101 if it is capable of providing some identifiable benefit. See *Brenner v. Manson*, 383 U.S. 519, 534 (1966); *Brooktree Corp. v. Advanced Micro Devices Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) (“To violate § 101 the claimed device must be totally incapable of achieving a useful result”); *Fuller v. Berger*, 120 F. 274, 275 (7th Cir. 1903) (Test for utility is whether invention “is incapable of serving any beneficial end”). *Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 6 USPQ2d 1065, 1101-02 (D. Del. 1987), *aff’d*, 865

In *Lowell v. Davis* the term “useful” was interpreted by Justice Story who stated, “[A]ll that the law requires is that the invention should not be frivolous or injurious to the well-being, good policy or sound morals of the society. The word ‘useful’, therefore, is incorporated into the act in contradistinction to mischievous or immoral.”¹⁸⁸ This negative definition of utility linked with the concept of morality allowed for the patenting of an invention as long as it was not harmful to society. This definition was used for many years and the USPTO granted many patents for chemical compositions without ascertaining their utility until 1950.¹⁸⁹ The judgment of the Supreme Court in *Brenner v. Manson* was a turning point. In this case the application, claiming a novel process for making certain known steroids, was rejected by the USPTO as the applicant did not disclose any use for the steroid. Instead an article published a little before the filing of the claim was cited, which claimed that a homologue of a steroid produced by the claimed process had been demonstrated to have tumour-inhibiting effects in mice. Neither the USPTO nor the Court of Customs and Patents Appeals (CCPA) accepted the contention that this was an acceptable proof of utility. The Supreme Court also rejected the claim and pointed out that, as minor variations in chemical structure could result in larger changes

F.2d 1247, 9 USPQ 1461 (Fed. Cir. 1989) (citing Treatise, “To be ‘useful’ under section 101, the invention must (1) be operable and capable of use, *i.e.*, it must perform a designed function; (2) achieve some minimum human purpose; and (3) that purpose must not be illegal, immoral or contrary to public policy.”) D Chisum *Chisum on Patents* (Matthew Bender New York 2005) ch 4.

¹⁸⁸ *Lowell v. Davis* 15 F. Cas. 1018 (D. Mass 1817) at q019.

¹⁸⁹ “Until recently it was also rather common to get patents on chemical compounds in cases where no use was indicated for the claimed compounds or in which a very broad indication or suggestion as to use was included in the application. [*Brenner* and another later ruling] ... have put an end to this practice.” Wolffe, ‘Adequacy of Disclosure as Regards Specific Embodiment and Use of Invention’ (1959) 41 *J. Pat. Off. Soc.* 61, 66. The Government’s brief in this case is in accord: “It was apparently assumed by the Patent Office [prior to 1950] ... that chemical compounds were necessarily useful ... and that specific inquiry beyond the success of the process was therefore unnecessary ...” Brief for the Commissioner, p 25. See also Cohen & Schwartz, ‘Do Chemical Intermediates Have Patentable Utility?’ (1960) 29 *Geo. Wash. L. Rev.* pp. 87, 91.

in biochemical function, experimentally established utility of a homologue did not establish the utility of the claimed compound.¹⁹⁰

However, this judgment did not answer an important question – what was the degree of “specific benefits” necessary to establish utility? In subsequent cases this issue was raised and debated. *In re Kirk* the CCPA addressed the question of utility and declared that a steroid compound could not be deemed to possess utility merely because a closely related compound only in a structural sense was known to be useful. In other words the utility had to be demonstrated at the time of application and what mattered was whether the disclosed compound had any utility or not at that time. Potential utility could not be a ground for establishing actual utility. This case concerned new compounds but the specification did not disclose the utility that they had. The Court observed:

While the affidavit may show that three of appellants’ claimed compounds do in fact possess specific anabolic, anti-inflammatory or glucocorticoid activity or usefulness as oral progestational agents, that is not the issue before us. It is what the compounds are disclosed to do that is determinative here.¹⁹¹

¹⁹⁰ “Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of the monopoly are not capable of precise definition. It may engross a vast, unknown and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point, where specific benefits exist in currently available form, there is insufficient justification for permitting an application to engross what may prove to be a broad field. [A] patent is not a hunting license ... It is not a reward for the search, but compensation for its successful conclusion. (A) patent system must be related to the world of commerce rather than to the realm of philosophy.” *Id.* at pp. 534–36. Cf. *Therriault v. Garbe*, 53 USPQ2d 1179, 1183 (Bd. Pat. App. & Int’f 1999) (“Invention of a composition is not complete unless its utility is obvious or is established by proper tests.”)

¹⁹¹ 376 F. 2d 936 (CCPA 1967) at 941.

Extending this analysis further in *re Joly* the CCPA argued that in the case of closely related compounds of known usefulness, the end product should possess properties in common with the closely related compounds with known uses. It pointed out that it “cannot be presumed that a steroid chemical compound is ‘useful’ under 101 ... simply because the compound is closely related only in a structural sense to other steroid compounds known to be useful”.¹⁹²

The Federal Circuit interpreted the utility requirement in such a manner that the claimed invention must have a “specific” and “substantial” utility. In other words, it had to be a real-world utility and not a hypothetical utility based on structural resemblances between the claimed compound and the compound with known uses. The utility had to be disclosed by the applicant. It should not be a utility that would be obvious. Another issue was whether utility that was not very substantial but of limited degree was sufficient to claim patentability. We can take the case of *Cross v. Lizuka* (753 F.2d at 1051) (1985) as an example of the kind of utility that the Federal Circuit found acceptable.

This case was over utility for imidazole derivatives. The applicant claimed that the derivatives inhibited thromboxane synthetase in vitro and the stated utility was for treating inflammation. The application also disclosed that the parent compounds also possessed an inhibitory action for thromboxane synthetase. Expert evidence was produced showing that in vitro tests for that pharmacological activity generally predicted the in vivo test outcomes. The Court stated that in vivo results are sufficient to prove practical utility. It also concluded that in vitro testing may also establish a practical utility in appropriate contexts. In other words, there was no need to disclose an obvious utility. In this case the applicant furnished in vitro data to back up the claim, and also disclosed the common inhibitory properties of the parent components while the expert evidence served as cumulative evidence.

In re Brana the question was whether the furnished information was an adequate proof of an asserted utility. The very important observation of the Court in *re Brana* was: “FDA approval is not a

¹⁹² 376 F.2d 906 (CCPA 1967) at 908.

prerequisite for finding a compound useful within the meaning of the patent laws. ... Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further R&D. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans.”¹⁹³

On the question of what was the evidence needed to convince a person having ordinary skill in the art as to the utility of the compounds, the Court pointed out that the declaration of the expert in this case was adequate. It also observed that “an alleged pharmaceutical property for a compound by statistically significant tests with standard experimental animals is sufficient to establish utility”.

In *Nelson v. Bowler* 206 USPQ 881 (CCPA 1980), it was observed that the data on “pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use”.

Thus, an inventor need not wait for FDA approval nor need do clinical trials in humans to prove utility. Tests on animals and evidence that the compounds have the claimed characteristics, in these cases the capacity to cure or to inhibit, would be sufficient to be considered to show utility. However, the expert evidence can be used as supplemental evidence in addition to the evidence from in vivo or in vitro testing. It is not necessary to have final proof to claim utility

¹⁹³ 51 F.3d 1560 (Fed. Cir. 1995) “The Commissioner ... confuses the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug ... and FDA approval ... is not a prerequisite for finding a compound useful within the meaning of the patent laws. ... Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on many promising new inventions”

In the 1995 USPTO guidelines for utility, the standard set was that an invention must have a “credible” or “well established” utility to be patentable. This was different from the standard specified in *Brenner v. Manson* which was “specific and substantial”. The utility guidelines were revised partly because of the criticisms that the USPTO granted too many gene patents with no or dubious utility. In 1999, the USPTO issued a new set of Guidelines. Under the revised Guidelines of 1999 “specific” and “substantial” utility has to be shown in addition to “credible” utility. The “well established” utility standard of 1995 was retained. Thus the new requirements raised the bar for patent applicants in meeting the utility requirement. According to the USPTO:

Credibility: An assertion is credible unless (A) the logic underlying the assertion is seriously flawed or (B) the facts on which the assertion is based are inconsistent with the logic underlying the assertion.

Specificity: a utility that is specific to the subject matter claimed. For example, a claim to a polynucleotide whose use is disclosed simply as a “gene probe” or a “chromosome marker” would not be considered to be specific in the absence of disclosure of a specific DNA target.

Substantiality: a utility that defines a “real world” use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities.

For example, claiming a new protein as an animal food supplement or a shampoo ingredient would, according to the USPTO materials, meet neither the requirement of being substantial nor specific since the only properties claimed are properties common to all proteins.¹⁹⁴

¹⁹⁴ In: www.uspto.gov/web/patents/biochempharm/documents/road.pps
In: <http://nys-stlc.syr.edu/lawlibrary/patent/patreq.aspx>

It has been pointed out that in both the 1999 and the 2001 guidelines, “substantial utility” should be “real world” utility. The “real world” utility criterion is derived from the observation of the Supreme Court in *Brenner v. Manson*. The USPTO’s test for determining “real world” utility is whether the invention needs any further research to identify an immediate benefit or use. If the answer is positive then the utility criterion is not met. An immediate identifiable benefit should be shown. For example, if a nucleic acid is used to identify genes that have a known link to a specific disease then the “real world” test is met. It is an entirely different question whether this is a commercially viable utility.

A utility is considered “specific” when it is particular to the subject matter claimed. According to the Guidelines, stating that a gene is useful as a “diagnostic” is ordinarily not sufficiently specific if the condition that is diagnosed is not identified; that is, a diagnostic utility must identify at least one condition that is being diagnosed. The standard of “credible” utility is decided by the criterion of whether a person with ordinary skill in the art would accept that the invention is “currently available for such use”. In other words, the asserted utility would not be a “credible” one if a person with ordinary skill in the art would not accept that the invention was currently available for such use. For example if a compound X is commonly used to treat disease Y then any asserted utility based on this logic would be acceptable as long as it was not proved to the contrary, or the facts on which the assertion were based contradicted the underlying logic of the assertion. In other words, the asserted utility should not be obviously false in the eyes of a person skilled in the art or the asserted utility fly in the face of known facts. For example, if it is known to a person ordinarily skilled in the art that a particular compound has proved to be a failure in treating a particular disease, any asserted utility that claims otherwise will not be a “credible” one unless the applicant proves that it is by adducing sufficient evidence.

The “specific, substantial and credible” utility test has thus evolved from past experience and court decisions on the utility criteria. The heightened utility guidelines have acted as a disincentive for patent applicants who wanted to obtain patents on ESTs and gene sequences merely on the basis of some vague assertions or potential utilities.

Under the “well-established utility” test, a person of ordinary skill in the art should be able immediately to find out why the invention is useful, based on the features of the invention. Under the new guidelines there are two separate tests but an application that meets the “well established utility” test should meet the “specific, substantial and credible” standard also.

Under the comments accompanying the Utility Guidelines, assertions based on homology are not inadmissible per se. It is also stated that the examiner must accept the utility asserted by the applicant unless there is sound scientific reasoning to repudiate that assumption. For example, if the asserted utility is based on an assumption that goes against the known laws of physics or chemistry, or if the applicant is trying to assert a utility based on assumptions that are impossible or false in the light of available scientific knowledge, the USPTO can reject the utility on this ground. Any use for an invention should satisfy Section 101 if it is credible and does not violate a law of nature, for example laws of thermodynamics (*Newman v. Quigg* 877 F. 2d 1575, 1581). However, when the examiner expresses doubt about the asserted utility it becomes the responsibility of the applicant to prove that the utility can meet the “well-established utility” criterion.

For therapeutic inventions that assert particular utility, evidence that supports that specific use should be provided. In *Fujikawa v. Wattansin* the Federal Circuit ruled that when a particular utility is recited there must be adequate evidence for that particular utility instead of any pharmaceutical activity.¹⁹⁵ In the case of therapeutic inventions involving genetic materials, the results should support the breadth of the claims. In other words, an applicant cannot assert broad claims based on limited results or evidence, or if such claims are doubted in the literature. In *Ex parte Aggarwal* (23 USPQ 2d 1334) the The Board of Patent Appeals and Interferences (BPAI) affirmed the rejection of the claim by an examiner. In this case the examiner contended that at the time of filing there was an unpredictability of the treatment of tumours with lymphotoxin and the limited results were not commensurate with the broad claims of the applicant.

¹⁹⁵ *Fujikawa v. Wattansin*, 93 F.3d (Fed. Cir. 1996).

Credibility of the asserted utility is evaluated by taking into account the disclosure, other evidence such as test data, affidavits, declaration of experts, patents, printed publications, and so on. It is essential that expert testimony provided by the applicant should be a supplementary proof. For meeting the utility criterion it is enough that the applicant provide “one credible assertion of specific and substantial utility”. But if the applicant tries to meet this criterion with “throw away” or “insubstantial” or “non-specific” utility then such utilities are not acceptable. For example, use of an organic compound as a potential source of carbon is regarded as a “throw away” utility.

IV.1. Enablement, Utility and Section 112

Enablement under Section 112 is also required. The “how to use” test of Section 112 is linked to utility under Section 101 as, under the law, the specification should disclose a practical utility for the invention (*In re Ziegler* 992 F.2d 1197). The crux of Section 112 is that the claimed invention must enable a person skilled in the art to make and use the invention “without undue experimentation”.¹⁹⁶ According to Section 112:

¹⁹⁶ The Federal Circuit has repeatedly held that “the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation’”. *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). All that is necessary is that one skilled in the art be able to practise the claimed invention, given the level of knowledge and skill in the art. Further, the scope of enablement must only bear a “reasonable correlation” to the scope of the claims. See, for example, *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003). *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003) (alleged “pioneer status” of invention irrelevant to enablement determination). USPTO in: http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2164_08.htm See also ‘Pioneer Patent Not Entitled to Lower Standard of Enablement Patent’ *Trademark & Copyright Journal* 14 January 2003.

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out this invention.

Courts have interpreted Section 112 and identified various factors to decide whether the specification is adequately enabling.¹⁹⁷ *In re Wands* 858 F.2d 731, 737 the following factors were specified by the Federal Circuit:¹⁹⁸

- 1) Nature of invention
- 2) State of prior art
- 3) Level of one of ordinary skill
- 4) Level of predictability in the art

In: <http://ipcenter.bna.com/pic2/ip.nsf/id/BNAP-5J4PVJ?OpenDocument>

¹⁹⁷ “To be enabling under § 112, a patent must contain a description that enables one skilled in the art to make and use the claimed invention.” *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir.1984).

¹⁹⁸ In *Wands*, the court noted that there was no disagreement as to the facts, but merely a disagreement as to the interpretation of the data and the conclusion to be made from the facts (*In re Wands*, 858 F.2d 731, at 736-40, 8 USPQ2d 1400, at 1403-07). The Court held that the specification was enabling with respect to the claims at stake and found that “there was considerable direction and guidance” in the specification; there was “a high level of skill in the art at the time the application was filed”; and that “all of the methods needed to practice the invention were well known”. (858 F.2d 731, at 740, 8 USPQ2d 1400, at 1406). After considering all the factors relating to the enablement issue, the court concluded that “it would not require undue experimentation to obtain antibodies needed to practice the claimed invention” (8 USPQ2d 1400, at 1407). Bruno de Vuyst, “Enablement” and “Written” Description in USPTO Patent Applications In the Biotechnological and Pharmaceutical Sectors : A Primer – 2005. In: <http://www.lawfort.be/files/Biotechnology1.pdf> (last visited 2 January 2006).

See also the discussion on enablement requirement under section 112 ‘An Enzo White Paper: A New Judicial Standard for a Biotechnology “Written Description” under 35 USC § 112, para. 1’ Harold C Wegner *Review of Intellectual Property Law* Vol. 1 No 2, 2002.

- 5) Existence of working examples
- 6) Amount of direction provided by the inventor
- 7) Quantum of experimentation necessary to make or use the invention, based on the
- 8) Contents of the disclosure, and
- 9) Breadth of the claims.

The application need not disclose everything needed to practise the invention as the applicant can omit what is well known to one skilled in the art (*In re Buchner* 929 F. 2d 660, 661). The time of filing of the application is important as the specification must be enabling at that time. The standard of “without undue experimentation” is not found in the statute; it was judicially created.¹⁹⁹ The key point is that the emphasis is on “undue” rather than on “experimentation”. (*In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988); *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988)).

In the case of inventions in new or emerging fields of technology, the level of unpredictability is important in determining whether the disclosure is sufficient when the predictability in the art is low. The USPTO also evaluates whether disclosure is commensurate with broad claims in a technological field where predictability is low.

199 “Another way in which the patent system promotes future innovation is through public disclosure. Upon issuance, a patent communicates a considerable amount of information that can help other would-be inventors including rival firms. Beyond the patent claims, which may speak volumes to those skilled in the art, the requirement that the disclosure be enabling – that is, that it enable one skilled in the art to make and use the invention – normally assures that the patent document is not so abstract as to be useless to the skilled reader. The judicially developed doctrine that a person skilled in the art must be able to make or use the invention without undue experimentation, *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991), also appears calculated to avoid wasteful R&D expenditures.” Kenneth W Dam ‘The Economic Underpinnings of Patent Law’ John M Olin Law & Economics Working Paper No. 19 (2D Series) 1993 p. 21. In:http://www.law.uchicago.edu/Lawecon/WkngPprs_01-25/19.Dam.Patent.pdf (last visited 2 January 2006)

Lack of enablement can be a ground for invalidating broad claims even after the patent has been granted.

An example of a rejection by the USPTO on the ground that disclosure does not warrant grant of broad scope of protection when the subject matter is not well developed and highly unpredictable is *re Vaeck 947 F 2d 488*. In this case the USPTO disallowed a broad claim as the disclosure was based on the working example of a single species of cyanobacteria whilst there were more than 150 different genera of cyanobacteria. Further, these bacteria were poorly studied and the field was unpredictable.²⁰⁰ Thus, while broad claims were refused, the USPTO permitted narrower claims that pertained to a specific genus and species.

²⁰⁰ *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). (The evidence did not show that a skilled artisan would have been able to carry out the steps required to practise the full scope of claims which encompass “any and all live, non-pathogenic vaccines, and processes for making such vaccines, which elicit immunoprotective activity in any animal toward any RNA virus”). *In re Goodman*, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993). (The specification did not enable the broad scope of the claims for producing mammalian peptides in plant cells because the specification contained only an example of producing gamma-interferon in a dicot species, and there was evidence that extensive experimentation would have been required for encoding mammalian peptide into a monocot plant at the time of filing). *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). (Where applicant claimed a composition suitable for the treatment of arthritis having a potency of “at least” a particular value, the court held that the claim was not commensurate in scope with the enabling disclosure because the disclosure was not enabling for compositions having a slightly higher potency. Simply because the applicant was the first to achieve a composition beyond a particular threshold potency did not justify or support a claim that would dominate every composition that exceeded that threshold value.)
In: http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2164_08.htm
(last visited 2 January 2006)

IV.2. Proof and the Issue of More than One Utility

According to the 2001 US Utility Guidelines:

[t]he patentee is required to disclose only one utility, that is, teach others how to use the invention in at least one way. The patentee is not required to disclose all possible uses, but promoting the subsequent discovery of other uses is one of the benefits of the patent system.

When an applicant has asserted more than one utility the USPTO may ask him to exclude uses that are incredible or misleading, particularly in the case of uses relating to treatment of diseases. Normally it is enough that the applicant describes, in a sufficient manner, a utility for one purpose. The general principle is that disclosure of a single utility is sufficient to validate a patent application.

In *Ex parte Lanham* (1958) the applicant asserted that the compound was useful as a solvent and softening agent for many resins and as an insecticidal and fungicidal composition. The Board of Appeal found that there was sufficient proof for one of the asserted utilities, viz. use as a solvent, and stated:

In order to sustain a patent it is only necessary that a single utility be disclosed. In this case we see no objection to retaining references to the other proposed uses unless they are incredible or misleading.

Applying this principle of “incredible or misleading” utility in *Ex parte Moore* the Board observed, “[I]f the additional proposed uses are in fact incredible or misleading, they should not be retained in the issue patent.” The CCPA affirmed this principle in subsequent cases (*In re Citron* (1963), *In re Gottlieb* (1964)).

From the case law and the USPTO guidelines one can cull some basic principles relating to utility in therapeutic and pharmaceutical inventions:²⁰¹

²⁰¹ This is based on, inter alia, RC Komson and PK Wittmayer ‘Obtaining

- 1) The correlation between evidence and asserted utility should be reasonable. It need not be absolute and a reasonable correlation can be proved by producing evidence such as scientific publications, test data, statistically relevant data, in vitro test data, in vivo test data and data based on animal models etc. As the USPTO is not the FDA there is no need to supply evidence that the invention would be fit or safe for use in humans.
- 2) For therapeutic utility, animal testing or in vitro data is acceptable to support the asserted utility. While there is no need to adhere to a specific animal model for a particular disease, it is necessary that that one person skilled in the art should accept that the tests are reasonably predictive of utility in humans, and the evidence from these tests should be deemed to be enough to support the credibility of the claimed utility. As often happens, animal testing is only a preliminary stage in the process of drug discovery and testing. In many cases the invention may work well in animals but may not be suitable for humans. When an applicant produces in vivo data and in vitro data with supporting evidence (for example evidence for similar use of animal model, scientific literature) these are normally considered to be sufficient proof of asserted utility.
- 3) Human clinical data is not required to establish the utility of an invention for treatment of human diseases. The absence of an animal model for a particular disease does not mean that human clinical data should be available as a proof. As it has been made amply clear, all that is needed is that the utility should appear credible in the eyes of one skilled in the art, and reasonable predictive utility as acceptable to one skilled in the art is sufficient.³¹

Patent Protection for the Treatment of Disease with Genetic Materials' (2000). In: http://www.morganfinnegan.com/news/articles_publications/0075 (last visited 2 January 2006), and in D Chisum *Chisum on Patents* (Matthew Bender New York 2005).

³¹ "The Examiners are advised that if the applicant has asserted that the claimed invention is useful for any particular purpose and this assertion would be

- 4) It flows from 2 and 3 that research results in the preliminary stages can be used to meet the criterion of utility. But as the investigation progresses further, additional evidence would be required to support the asserted utility and the scope of asserted utility should be commensurate with the evidence provided.
- 5) The requirements of the FDA and the USPTO are different. The USPTO is not expected to seek evidence of safety or efficacy in treatment for humans as evidence for utility. But this does not mean that the USPTO will not examine the nature of disease *vis à vis* the asserted utility. In the case of diseases known to be incurable at the time of filing, the examiner will review the asserted utility bearing this in mind. Claims for curing or preventing a disease generally require greater proof of utility when compared to claims for method of treatment or treating a symptom, and in the latter case adequate test data can be a sufficient evidence for utility.
- 6) In the case of biotechnological inventions, particularly patenting of genes, DNA sequences, ESTs, and SNPs²⁰² the

considered credible by a person of ordinary skill in the art, in view of all the evidence of record, or if the invention has a well established utility wherein a person of ordinary skill in the art would immediately appreciate why the invention is useful then a rejection based on lack of utility is not to be made. If the applicant asserts that the claimed process is useful for treating a human or animal and this utility is credible, the Examiner should not require that the applicant demonstrate that the therapeutic agent is safe or fully effective. The applicant has to provide a 'reasonable correlation between the activity and the asserted use' Data from in vitro or animal testing even if not in an art recognized model is generally sufficient to support the asserted utility and the Examiner should not require the submission of clinical data. If the applicant, however, has not asserted any specific utility for the claimed invention and the invention does not have a well-established utility, a lack of utility rejection under 35 USC § 101 is to be made." USPTO Utility Guidelines. In: <http://www.ladas.com/Patents/Biotechnology/USPharmPatentLaw/USPhar05.html>

²⁰² SNP: "A single nucleotide polymorphism, or SNP (pronounced *snip*), is a DNA sequence variation occurring when a single nucleotide - A, T, C, or G - in the genome (or other shared sequence) differs between members of a species (or

utility standard has undergone change. Some of the earlier decisions of the USPTO had been controversial and the USPTO has raised the bar for utility. One reason for difficulty in getting patents for biotechnological inventions as therapies is that they may be rejected for lack of utility under Section 101 and enablement or failure to teach how to use the invention under Section 112. Another reason is that many applicants assert broad claims. These claims often fail to meet the utility criterion. In the absence of a “specific, substantial and credible” utility a broad claim will be difficult to substantiate.

Regarding pharmaceutical compositions, it is not necessary that the applicant should understand why a compound is effective, but it is helpful to disclose the physical and biological characteristics of the effective compound and, if possible, those of similar compounds. If the application is rejected for lack of *in vivo* data it can be argued that structurally similar compounds with similar properties have been proven effective *in vivo* and due to similarity of compounds and/or properties one skilled in the art can recognize that the claimed compound can also be effective *in vivo*.²⁰³

between paired chromosomes in an individual).”

In: http://en.wikipedia.org/wiki/Single_nucleotide_polymorphism

²⁰³ *In re Jolles* 206 USPQ 885 (CCPA 1980). According to Lipton, “The Federal Circuit does not interpret the utility requirement of §101 as requiring a rigorous correlation between *in vitro* and *in vivo* activity because of the ‘firm conviction that one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment in humans’. The same reasoning would explain why sufficient structural similarity between two compounds will often support a finding of practical utility. In both situations, the Federal Circuit has interpreted §101 as reflecting Congress’s desire to provide incentives to industry to pursue pharmaceutical research and development. If the utility requirement were construed too narrowly and companies were not able to procure patent protection based on *in vitro* testing or structural homology, the costs of further research and development might simply be prohibitive.” M Lipton ‘Biopharmaceuticals: The Patent System and Incentives for Innovation’ Harvard University Law School 2004.

In: <http://leda.law.harvard.edu/leda/data/641/Lipton.pdf>

The USPTO Utility Guidelines have not been tested in the Supreme Court. Generally courts take them into account but are not bound by them. Moreover the interpretation of the utility criterion by the Courts is not necessarily congruent with that of the USPTO. According to one commentator:

The CAFC and its predecessor the CCPA, however, have been quite liberal in upholding and enforcing patents in the pharmaceutical and biotechnology fields. In fact, as long as the slightest evidence has been put forward to support a disclosure of utility, the CCPA has ruled in favour of the applicant. Only in those cases where the applicant was unable to come forward with any relevant evidence of utility did the CCPA rule against the applicant. In addition, it has been the CAFC's position that minimal utility is all that is required to obtain a patent. The CAFC tends to give expert and PHOSITA [person having ordinary skill in the art] evidence great weight. If any of this evidence is credible, it seems to find in favour of the applicant, regardless of the [US]PTO's ruling. Though the CAFC has rejected gene-related applications under the written description and enablement requirement, the CAFC has intimated it might take a more lenient approach. It believes that, by having only the amino acid sequence of a protein, one can be in possession of the entire genus of DNA sequences that encode a disclosed partial protein sequence, "even if individual species within that genus might not have been rendered obvious". ... More recently, criticizing the CAFC, a publication decrying the "broken patent system" has complained that "certain aspects of biotechnology such as genetic sequences are all technologies for which the courts have expanded the range of patentable subject-matter beyond what was perceived to be patentable at the end of the 1970s". As a result, if utility is the only issue before the CAFC on a DNA fragment application, it is likely the CAFC would rule in favour of the applicant.²⁰⁴

²⁰⁴ Cynthia D Lopez-Beverage 'Should Congress Do Something About

Thus while the USPTO may be conservative and prefer to adopt a higher threshold of utility, the CAFC may take a different view.

From the above analysis it is clear that while in theory the utility threshold is high, this can be overcome in practice. The stumbling block may be meeting the requirement under Section 112. But prima facie this seems to be more the case with inventions in biotechnology and other unpredictable arts than with patents on pharmaceutical compounds and drugs. There are some important public policy lessons for developing countries from the US law and practice, which are discussed below.

V. INDUSTRIAL APPLICABILITY IN EUROPE

According to Rule 27(1) (f) of the EPC²⁰⁵ the patent description should:

indicate explicitly when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry.

To prove utility, solving the technical problem is sufficient. Evaluation of the proof is done under the rule:

Facts adduced by a party will ... normally be deemed true, even without supporting evidence, if it is clear that no doubts exist concerning them, if they do not contradict one another or if no objection is raised. In such cases facts need to be supported by evidence.²⁰⁶

Thus unless there is a ground to doubt the effects mentioned in the application, additional proof in the form of experiments would not

Upstream Clogging Caused by the Deficient Utility of Expressed Sequence Tags?' (2005) 10 *J. Tech. L. & Pol'y* 35.

²⁰⁵ In: https://www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/epo/gec/chap2.htm

²⁰⁶ EPO Examination Guidelines E IV 2.

be required. In fact there is no need even to report experiments. In T 946/92 the Board of Appeal stated that in the case of compounds that were closely related structurally to compounds known to have the use as indicated in the claim it could be assumed that these compounds have similar characteristics. According to Domeij:

The most instructive part of the judgment, though, was the Board's conclusion that if a biological effect is so probable, due to structural considerations, that examples are not necessary, then effect cannot at the same time be used as support for the existence of inventive step.²⁰⁷

As in the USA, in Europe there is also no need to do experiments on humans to prove industrial applicability. Tests done on animals or in vitro tests would suffice for the purpose of patent law. Thus the industrial applicability threshold is not very high. According to decisions of the EPO, predicted utility is enough. The proof need not be absolute and what is important is that the data supplied or the reference is credible under the circumstances.

According to Domeij:

The test for industrial applicability tends to be more at work when an opponent questions the reliability of the tests that have been done by the applicant. Then the actual effects of the invention may be judged. Both parties will be in a position to carry out practical experiments and the Office can make a comparison between the proof that is presented to it.²⁰⁸

Whether the invention is commercially viable or whether it is a "good" invention or not, is immaterial for the purpose of granting patents. However, the lowering of the threshold of "industrial applicability" in specific industries, such as biotechnology, has resulted in patenting of genes and gene fragments without any proof of credible industrial applicability. Thus, although industrial applicability is a

²⁰⁷ B Domeji *Novelty in Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) 144 p. 21.

²⁰⁸ Ibid.

much narrower concept than utility in American law and practice, the basic governing principles are the same. The major difference is that while in the USA patents cover medical processes including therapies and diagnostic methods, in Europe, generally, they are excluded for lack of industrial applicability.

VI. CONCLUSIONS AND RECOMMENDATIONS

Developing countries should take into account the pros and cons of different thresholds for the industrial applicability/utility criterion. A low threshold may encourage more patenting and can result in patents with dubious utility or no utility. That can also result in patent thickets and may result in an anti-commons situation. A heightened standard will eliminate patents with dubious utility. As TRIPS does not give any specific standard or guidelines, developing countries can opt for a standard that ensures that the invention has a real industrial application. A distinction can be made between an invention “made” and “used” in industry. The former puts a higher threshold as the latter may lead to allowing patents on subject matter such as a method of doing business in a given industry or computer programmes as such. The stricter the criteria, the lower the number of patents that may be obtained for speculative purposes or with the aim of foreclosing the competitors’ room for innovation and production.

CHAPTER 4

THERAPEUTIC, SURGICAL AND DIAGNOSTIC METHODS

I. INTRODUCTION

Therapeutic, surgical and diagnostic methods are used to produce effects on the human or animal body, directly or indirectly. These methods do not fit within the usual patentability requirements because they lack any industrial application or effect. However, not all countries adhere to this perspective. In the USA, for example, patenting of medical methods is possible if they meet the other criteria for patentability, as only “utility” is required as discussed in Chapter 3.

According to TRIPS, patents have to be granted in all technological fields to inventions that are “new, involve an inventive step and are capable of industrial application”. According to article 27.3(a), members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. The indicative word is “may” and hence it is left to the discretion of the member states whether to allow such patents. There is no obligation that member states should exclude them from patentability. This approach is reflected in other agreements. For example, under article 1709(3)(a) of the North American Free Trade Agreement (NAFTA), parties are permitted to exclude from patent protection “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”. The direct exclusion approach is also followed at the national level by several countries. For example, the Indian Patents Act states that “any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products” is not an invention within the meaning of the Act.

However, a direct exclusion in this manner is not the only approach. Under article 52(4) of the EPC, the rationale for exclusion is that these methods do not meet the requirement of industrial applicability. Article 52(4) states:

Methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

The “lack of industrial application” approach is also taken by other countries. In the UK, the Patents Act 1977 provides that a “method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human body is not to be taken as capable of industrial application and is therefore not patentable”

The presence of this exclusion in the TRIPS agreement reflects the reality that prior to the TRIPS agreement many countries, either directly or for lack of industrial applicability, refused to allow patents on therapeutic, surgical and diagnostic methods. The rationales varied, but the practice was widespread. In the post-TRIPS environment many countries continue to maintain the exclusion, exercising their discretion under the agreement.

Thus, Egypt’s Intellectual Property Code No. 82 of 2002 does not extend patent protection to diagnostic and surgical methods for humans and animals.²⁰⁹ Similarly, the Argentinean Patent Act under article 6(e) states that methods of surgical, therapeutic or diagnostic treatment applicable to the human body or to animals are not patentable subject matter. In Canada, although there is no specific exclusion of methods for treating humans in the Patents Act, the judicial interpretation has affirmed such an exclusion.²¹⁰

²⁰⁹ N Al-Ali ‘The Egyptian Pharmaceutical Industry After Trips – A Practitioner’s View’ (2003) 26 *Fordham Int’l L.J.* p. 274.

²¹⁰ T Scassa ‘Patents for Second Medical Indications and their Potential Impact on Pharmacare in Canada’ (2001) 9 *Health L.J.* p. 23.

Even in the USA, recognition of this exclusion has been partially granted. In 1996, the US Congress amended 35 USC 287.c and provided for a limited exception in the wake of a controversy over a patent on cataract surgery: “35 U.S.C. § 287(c)(1) provides that ‘medical practitioners’ or a ‘related health care entity’ conducting a ‘medical activity’ shall not be liable for infringement under 35 U.S.C. §§ 271, 281, 283, or 285 of the Patent Act. Under 35 U.S.C. § 287(c)(2)(B), the term ‘medical practitioner’ means ‘any natural person who is licensed by a State to provide a medical activity’, or ‘who is acting under the direction of such person’. In turn, 35 U.S.C. § 287(c)(2)(A) defines ‘medical activity’ as ‘the performance of a medical procedure on a body’. However, three caveats are included in this regard. The term ‘medical activity’ does not include the use of ‘a patented machine, manufacture, or composition of matter in violation of such a patent’. Neither does it include a proprietary method of using a patented machine, manufacture, or composition of matter. Finally, the term ‘medical activity’ does not include the practice of a process infringing upon a ‘biotechnology patent’.”²¹¹

It is worth noting that Congress chose not to exclude surgical methods from patentability but provided for a limited exception. In view of the history of patents on medical processes and so on, this exception was provided to protect doctors and surgeons from patent infringement suits.

II. THE RATIONALE FOR THE EXCLUSION OF THERAPEUTIC, SURGICAL AND DIAGNOSTIC METHODS

There are public policy reasons for excluding surgical methods and methods of treatment from patentability. According to David Vaver,

The exception for medical treatment springs from ethical or emotional reasons based on a desire not to hamper the

²¹¹ A Rueda ‘Cataract Surgery, Male Impotence, Rubber Dentures and a Murder Case – What’s So Special About Medical Process Patents?’ (2001) 9 *U. Balt. Intell. Prop. L.J.* p. 109.

saving of life and the alleviation of suffering. Medicine is also a profession whose members should share their skills and should not foreclose others from applying them; an operating surgeon or prescribing physician should not have to worry about patent infringement.²¹²

Morality can be a reason to exclude some methods from patentability. According to article 27.2 of TRIPS: “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”

This is very similar to article 53(a) of the EPC, which provides that “European patents shall not be granted for ... inventions the publication or exploitation of which would be contrary to ‘ordre public’ or morality, provided that the exploitations shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting Parties.”

However, defining morality or ordre public is not easy. In the case T 356/93, the Board of Appeal of the EPO outlined some of the scope, observing:

It is generally accepted that the concept of “ordre public” covers the protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. Accordingly, under article 53(a) of the EPC, inventions the exploitation of which is likely to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to “ordre public”.

²¹² Cited in T Scassa ‘Patents for Second Medical Indications and their Potential Impact on Pharmacare in Canada’ (2001) 9 *Health L.J.*

In the case of plant biotechnology, the Board of Appeal of the EPO has taken the view that plant genetic engineering is not a technical domain that, as such, may be deemed contrary to morality or public order. According to Margo Bagley, “By providing this morality-based safe harbor, TRIPS accommodates both the US view that ‘anything under the sun made by man’ is patent-eligible, and the views of many other countries that deny patents on certain morally controversial inventions. The idea that morality concerns may be the basis for denying patent protection appears to be a common theme across world patent systems.”²¹³ The fact that some technologies may be controversial and their impact on environment or health is in dispute is, by itself, insufficient to make the technology contrary to morality or public order.²¹⁴

Some patent laws do deny patents on ethical grounds and specify exclusions from patentability. For instance, the European Biotechnology Directive states that the human body and its elements in their natural state shall not be considered patentable inventions. Similar exceptions are found in the French Patent Act and the Patent Act of Australia. However, this has not prevented the patenting of human genes and cells in these jurisdictions. It appears that as long as the criteria for patentability are met, human genes and cells are patentable. (We shall discuss this in detail in the note on the products of nature.)

Thus, invoking article 27.2 is possible only when commercialisation of the invention would negatively affect morality, human or animal health, or the environment. As morality is a relative concept, what was once considered immoral may not be considered so in

²¹³ Margo A. Bagley *A Global Controversy: The Role of Morality in Biotechnology Patent Law* University of Virginia Law School Public Law and Legal Theory Working Paper Series Paper 57 (2007) p. 335.

In: <http://law.bepress.com/cgi/viewcontent.cgi?article=1097&context=uvalwps>
²¹⁴ For a discussion on the limitations and weaknesses of the “ordre public” or morality clause see Christoph Baumgartner ‘Exclusion by Inclusion? On Difficulties with Regard to an Effective Ethical Assessment of Patenting in the Field of Agricultural Bio-Technology’ (2006) *Journal of Agricultural and Environmental Ethics* Vol 19 No. 6 pp. 521–539.
In: <http://www.springerlink.com/content/d441447t8282p474/>

the present. For example, in the USA patents on gambling devices were once refused on this very ground.²¹⁵

According to article 27.2 the mere fact that such exploitation is prohibited by law cannot be a reason to exclude from patentability. Rather, the nexus or link between the invention and morality, environment or health has to be established. The basis of this formulation is that patent rights by themselves do not grant the right to produce or to market or offer a service. A patent on a machine is necessary but not sufficient to manufacture and market that machinery. A patent can still be granted while commercialisation is prohibited by law. In the final analysis, laws can be changed and once the law is changed, the right of commercialisation should belong to the patentee.

Patent offices are not expected to play the role of the regulators of technology or assess their impacts in deciding about patentability unless there is a legal mandate. That job is best left to lawmakers and regulatory authorities. Thus patent offices may grant patents on the methods unless there is a bar on them. For instance a country may prohibit contraceptives and contraceptive devices or ban abortions, that is, medically induced termination of pregnancies, on moral grounds. This, however, need not prevent the granting of patents on contraceptive devices or equipment used in medical termination of pregnancies unless the law explicitly prohibits such patents on moral grounds. Thus, while the patent may be granted, the patentee may not get permission to commercialize the patent or invention on grounds of morality.

It is to be noted that the ban under article 27.2 can only be applied when the invention is not allowed for circulation in the country where protection was sought; that is, it is not possible to refuse a patent on the grounds spelled out in that provision and, at the same time, admit such a circulation.

²¹⁵ BD Enerson 'Protecting Society From Patently Offensive Inventions: The Risk of Reviving The Moral Utility Doctrine' (2004) 89 *Cornell L. Rev.* p. 685. See also M Bagley 'Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law' (2003) 45 *Wm and Mary L. Rev.* p. 469.

III. THE SCOPE OF THE EXCLUSION

An exclusion under article 27.3(a) is limited. While a new form of surgical procedure cannot be patented, the equipment and apparatus applied in the procedure are still patentable even if their one and only use relates to this new form of surgical procedure, and the only way to carry out the procedure is through the use of the apparatus and equipment. For example, if a laser device is used in a new form of surgical procedure to treat eye disorders and diseases, while the procedure per se is not patentable, the device is patentable, if it meets the criteria for patentability.

Defining diagnostic, therapeutic and surgical methods is left to the discretion of member countries, as TRIPS does not give explicit rules on this. Thus, for example, treatments used to enhance the appearance or beauty of a person, or methods for cosmetic treatment, may not be covered under the heading of diagnostic, therapeutic and surgical methods.

Even where a patent is granted, it is not necessary for the commercialisation or use of a product to be totally banned. It is quite possible that a country will regulate the use of a diagnostic method or use of a particular technology to meet public policy objectives. For instance, some countries (for example India) have regulations on the use of machines for pre-natal screening, although screening per se is not banned. In such a case if there is a method to determine the sex of the unborn child, such a method could be regulated or banned even if a patent is granted. The use of diagnostic, therapeutic and surgical methods is a question of public policy.

IV. THE PATENTING OF A NEW THERAPEUTIC EFFECT

An important issue is the patenting of a new therapeutic effect of a known pharmaceutical product. In this case a new way of using one or more known products is claimed. The recognition or granting of such claims is not mandatory under TRIPS. While the patent on a new

therapeutic effect lies within the area of exclusion of therapeutic methods, if applicable, this is overcome in some countries by drafting the claim as if it were a claim for use of a product to manufacture a medicine or drug. Such claims are also known as “Swiss claims”. A typical Swiss claim looks like this: “Use of substance X for manufacture of medicinal product Y to treat disease Z”. This approach does not contravene TRIPS but at the same time TRIPS does not mandate recognition of such claims. Even in countries that allow secondary-use claims there is no uniformity in approach.²¹⁶

For instance, in the case of patent claims directed to the use of a substance for treatment of specific diseases, the German Bundesgerichtshof considers the formulation and manufacture of the medicament, its dosage, its by-pack instruction, and its ready-to-use packing to be expressly covered by the use claim. A provision on a product sheet enclosed with a medicament to be put on the market is sufficient. In Germany, practice follows the rule that for known products, of which the medical effects are found for the first time, purpose-limited product claims are allowed. The claims can be written in the following form: “Substance X for use as a medicinal product”. Where a specific medical use has been incorporated in the claims as an essential element, the scope of protection of such claims in Germany is limited to the recited use.

In contrast, the present UK position on this issue is that methods of medical treatment as such are unpatentable. The difference between UK and German courts on this issue lies in the definition of what makes an invention susceptible to industrial application. In *Bristol-Myers Squibb Co. v. Baker Norton Pharmaceuticals Inc.*, strong comments indicated that the treatment exception contained in article 52(4) of the EPC should be narrowly construed to prevent patent law from interfering directly with what a doctor actually does to a patient.

The effect of this difference is evident from the decisions of German and UK courts in *Hydropiridine* and *Bayer AG (Meyer's) Application*. The first has allowed and the second has rejected claims

²¹⁶ See A Petrova ‘From The Amazon To The Alps: A Comparison Of The Pharmaceutical Biodiversity Legal Protection In Brazil And Switzerland’ (2003) 15 *Pace Int'l L. Rev.* p. 247. See also chapter 5.

relating to the use of hydropridine. The UK court strictly follows the decision of the Enlarged Board of Appeal in *Eisai Co.* and accepts second medical use claims only in the form of Swiss claims. According to German case law, the step of manufacturing can be left out of the second medical use claim, and a German court has allowed the following claim: Use of substance A for the treatment of disease B.²¹⁷

V. CONCLUSION

With the advent of genetics and genomics in health, new diagnostic tests and therapies either have been developed or are under development, including the use of stem cells. Some patent laws go beyond patents on genes and cover diagnostic methods and tests as well. Where such patents are granted, serious issues with respect to licensing such tests are raised. There are several examples of companies abusing the patent monopoly in their licensing practices.²¹⁸ In the absence of compulsory licensing provisions, or provision of the tests by public health services at nominal charges, such tests will simply be unavailable to the needy.²¹⁹

Developing nations can formulate patent policies taking into account the flexibilities in TRIPS and exclusions available under article 27.3(a). The exception under morality or *ordre public* will be of limited use to them. Similarly the other grounds such as public health or protection of the environment can be used only when the nexus between the patent and its impact can be established. They should be wary of allowing Swiss claims. In the case of patents on diagnostic methods and treatments based on genetics and genomics caution should be exercised in the grant of patents, particularly gene patents.

²¹⁷ S Bavec 'Scope Of Protection: Comparison of German and English Courts' Case Law' (2004) 8 *Marq. Intell. Prop. L. Rev.* p. 255.

²¹⁸ J Paradise 'European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy' (2004) 59 *Food Drug L.J.* p. 133.

²¹⁹ S Parthasarathy 'Comparing Genetic Testing for Breast Cancer in the USA and the UK' (2005) *Social Studies of Science* 35 pp. 15–40.

CHAPTER 5

SECOND INDICATIONS

I. DEFINING THE CONCEPT

I.1. Definitions

A medical indication is an illness, a syndrome (associated set of symptoms), or a desired bodily change from one physical condition to another. Pharmaceuticals (or drugs) are a means by which an illness is cured, a syndrome is mitigated or a desired change is brought about. The use of a pharmaceutical in such a manner is a method of treatment. Thus a pharmaceutical has an effect on the body; it is a therapy or medicine. Its medical indication can therefore be defined as the specific use to which it is put.

A medical indication of a pharmaceutical is not the same as its medical effect. The medical effect defines the entire set of possible bodily changes that a pharmaceutical is capable of inducing. A medical indication is a sub-set of the total set of medical effects. It is the specific, medically described and determined condition, illness, or syndrome that a pharmaceutical has been shown to address. A second medical indication is therefore an additional condition, illness or syndrome, which it is determined that the pharmaceutical could be used to treat. For the purposes of this note, we will refer to such first medical indications as “first indications” and all additional medical indications as second indications. In referring to both, this note will encompass them under the general term “new use”, when discussing general principles governing all new uses of known products. While this note is primarily concerned with new uses of known products, new uses of known processes are also an issue, albeit narrower and somewhat more complicated. Processes do not generally suffer from the same issue as product patents do with respect to new uses. Some new-use patents may

actually provide product patent protection, and other new-use patents may provide only “use” or process patent protection, narrowly limited.

At the time of patenting, it is usually clear that the full scope of effects of a pharmaceutical have not been described. Nevertheless, it can generally be understood that a pharmaceutical works through a specific mechanism and therefore any effects it has on the body will be closely related. The gap between what is known about the effects of the pharmaceutical at the time that it is applied for, or granted a product patent, and what may later be known about its effects is what Domeij has called the “prospect”²²⁰ of the pharmaceutical product patent. Domeij terms the prospect “the bonus that a patent applicant sometimes receives, in addition to the scope of protection that is granted to him in respect to production opportunities that he has disclosed in the application”.²²¹ The prospect exists in any patent system that allows product claims to be broader than the uses specifically disclosed in the application. For pharmaceuticals, product patent claims would cover any use, foreseen or unforeseen, of the patented product for the duration of the patent. It is important to note that this need not be the case. To ensure access to medicines through sufficient competition and room for innovating around, countries may want to limit the amount of the prospect held exclusively by one patent holder. There are four general approaches to determining the extent and scope of the prospect, as well as who is best suited to taking most advantage of the prospect.

Option 1: Patenting of pharmaceutical products limited only to the uses claimed and disclosed in the patent. Patents allowed on new uses of the patented product.

Option 2: Patenting of products encompassing all uses of the pharmaceutical product. Patents allowed on new uses of the patented product.

Option 3: Patenting of pharmaceutical products limited only to the uses claimed and disclosed in the patent. No patents allowed on new uses of the patented products.

²²⁰ B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 88.

²²¹ *Ibid.* p. 89.

Option 4: Patenting of products encompassing all uses of the pharmaceutical product. No patents allowed on new uses of the patented products.

These options are affected by the choice as to whether a country decides that it is better to allow primary inventors to carry out drug development and incremental research, or whether such activities should be carried out by third party or follow-on innovators. As Domeij notes, this is a decision as to “whether it is most efficient to permit only one actor to prospect unknown production opportunities, or if it is preferable to have a situation of free competition pertaining to the still unknown production opportunities”.²²² He goes on to note that if the latter is preferable then some form of limitation on the scope of the prospect by limiting the claim scope to uses declared in the application may be more appropriate.²²³ In addition, any system that allows new-use patents without consideration as to who will be able to make use of such patents, may fall into the trap where the primary product patentee, because of its greater access to capital, captures all subsequent uses.

This note examines the advantages and disadvantages of the four approaches and will argue that developing countries would be better off using either option three or four to support follow-on innovators and properly maintain access to drugs, while maintaining sufficient incentives for the development of new uses of existing drugs.

1.1.1. First medical indication of a known substance or composition that had no previously known medical indication

It is important to distinguish between second indications of a known pharmaceutical (as defined above) and the first indication. While both may be considered discoveries, they operate on entirely different sets of incentives, and affect research behaviour in different ways. First medical indications resemble the situation of drug development more closely in that they come into being because no one had previously thought to use the underlying product for medical purposes. The discovery of such uses may in fact need to be encouraged, and a stronger understanding of the

²²² Ibid. p. 92.

²²³ Ibid.

underlying mechanisms by which it works may lead to new therapies. Such research may be particularly relevant in developing countries whose research capacities may be better suited to exploring the properties of existing chemicals rather than seeking to formulate NCEs. Such exploration may need to be encouraged by providing some limited forms of exclusivity or rewards such as tax incentives for research, or cash prizes for particular achievement in a field. Such research, if properly encouraged, may be crucial to ensuring that the potential of existing chemicals to aid health care in developing countries is fully explored.

In contrast, research into second indications of pharmaceuticals that already have known medical indications needs little incentive to take place. Such research occurs as a normal part of the research cycle once a product has been developed and the product patentee (or a third party) performs clinical trials and further research into the underlying mechanism. Doctors perform such research as they prescribe such medicines for symptoms other than those for which the medicine is approved. In a US study, the authors found that 59 per cent of off-label drug therapy innovations in their sample were carried out by clinicians.²²⁴ In addition, such research can be carried out with relative ease even by facilities in developing countries.²²⁵ Such research could provide the basis for building indigenous industries in the pharmaceutical arena. In order to do so, however, such researchers must be free to experiment with drugs under existing product patents without fear of infringing a new-use patent. Further evidence that new uses are primarily an economic incentive mechanism rather than an innovation mechanism is the European approach. The Europeans began to allow the patenting of second indications to support the economic transition of their fledgling biotechnology industries, by providing a way to raise capital and create immediate return on investment. These firms made their initial profits from identifying the specific biological mechanisms

²²⁴ J DeMonaco, A Ali and E Von Hippel 'The Major Role of Clinicians in the Discovery of Off-Label Drug Therapies' MIT Sloan Working Paper 4552-05, August 2005) In: <http://ssrn.com/abstract=780544> (10 November 2005) p. 3.

²²⁵ However, establishing the safety and efficacy of the new indication would require new clinical studies that most companies in developing countries may be unable to finance.

underlying existing pharmaceuticals and identifying analogous and/or similar mechanisms underlying different diseases.²²⁶

1.1.2. Second indications as diagnostic, therapeutic or surgical methods

A second definitional matter is that since second indications are essentially patents on a use, some kinds of uses may actually be excluded as patent subject matter. This applies to the entire pharmaceutical field where many countries do not allow the patenting of diagnostic, therapeutic and surgical methods for the treatment of humans or animals. A patent on a second indication of an existing pharmaceutical describes a therapeutic method of treatment of a human or animal. This remains a strong barrier against the patenting of second therapeutic indications of pharmaceuticals in those countries which do not allow such patents. The European struggle to get around this restriction is described in more detail below.

1.1.3. Drug development and second indications as discoveries

It can be easy to confuse the concept of second indications with the issue of development or products derivative of the original patented drug, such as new salts, ethers, esters, polymorphs, combinations and so on.²²⁷ For the purposes of this paper and of a clear legislative approach, a first or second indication is defined as a new use of an existing product that does not make any changes to the structure of the chemical entity or active ingredient.

These definitions help to distinguish between drug development, which entails one kind of prospect, that is, the development of drugs based on a patented chemical entity, and second indications, which entail finding a new indication or use for a drug while making no change to its structure. In drug development, the final marketed product is a

²²⁶ B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 195.

²²⁷ WIPO Secretariat 'WIPO Secretariat Submission to the WHO Commission on Intellectual Property Rights, Innovation and Public Health', (WIPO Geneva 2005). In: <http://www.who.int/intellectualproperty/submissions/en/> (11 November 2005) which conflates the two concepts.

variant (sometimes with minimal changes) of an existing drug. For the patentee, the ideal is to ensure that the claim scope remains sufficiently large to encompass such derivatives. However, it may be better for developing countries to make small incremental changes to an existing drug unpatentable, eventually providing other more limited forms of protection such as improvement or petty patents for innovations that deserve some form of protection. Thus a first inventor can capture all of the value of the patent for drug development purposes without unduly enlarging claim scope by patenting every single small improvement or derivative along the way to a final product.

In contrast, second indications of the kind that concern this note are those that make no changes to the final marketed drug. In such cases, the new use is more accurately described as a discovery rather than an invention. Since discoveries are not patentable in most countries, the discovery of a new effect or use for an existing product or process should generally be deemed unpatentable. The USA is a major exception to this in allowing discoveries to be patented, with some limitations.²²⁸

1.1.4. The second indication as a biological mechanism

Generally speaking, a pharmaceutical works through a single mechanism or set of mechanisms. This means that any effects it has on the body will generally be closely related. This has implications for defining whether an indication is really new or novel. Medical indications are not initially defined for the purposes of patent law. The distinctions are made on the basis of the kind of doctor treating the patient, the location of the illness on the body of a patient, and historical inertia. A good example is headaches. A layperson makes no distinction between headaches. However, the causes of headaches can differ. Some are the result of inflammation of membranes in the cranium due to lack of fluids, for example. However, the medications to treat headaches which are the result of inflammation are also effective for treating some forms of arthritis pain due to inflammation of the membranes in the joints of the hand. If a medicine that worked to treat headaches is later discovered to reduce arthritis pain, is its use for

²²⁸ See 35 USC 101.

arthritis pain a new indication? If the drug is described as an anti-inflammatory, does this encompass all indications that are the result of inflammation of membranes in the body? This is only the beginning of the inquiry. The opposite may also be true. Headache pain can be the result of many different kinds of mechanisms in the body and yet a single medication can be indicated for headache pain without distinction as to the source or kind of pain. This would create a possibly overbroad patent with a medication indicated for pain.

1.1.5. Use patents and method-of-use/process-of use patents

Second indications can come in one of two ways: as a use patent, formulated as “use of pharmaceutical X as an analgesic”; or as a method-of-use/process-of-use patent, formulated as “a process using pharmaceutical X to do Y”²²⁹ Use patents generally depend on whether the use itself (for example as an analgesic) is novel and non-obvious. Method-of-use/process-of-use patents may be judged independently of the purpose of the use. Even if intended for a novel purpose, the key consideration in determining the patentability of a method invention is whether it could be anticipated by other methods.²³⁰ The difference may seem of little purpose but it essentially means that method-of-use/process-of-use patents are examined or treated as if they were process or method patents. The use patent approach is therefore outside the general patent practice and uses different standards for use patents as compared to other process or product patents. The use patent approach is dominant in Europe and the method-of-use/process-of-use patent is the US approach.

²²⁹ USPTO *USPTO Manual of Patent Examination Procedure*, Section 2112.02 Process Claims.

²³⁰ CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) p. 22.

In: <http://www.southcentre.org/publications/publichealth/publichealth.pdf> (11 November 2005)

I.2. History of the Concept

In Europe, the EPC ensured that a previously-known substance that had no known pharmaceutical indication would be patentable for its use for a medical indication.²³¹ Such a new use would be considered a product patent. Article 54(5) of the EPC allowed such substances to be patented despite the lack of product novelty, as long as the use as a medical indication was novel. The novelty examination was therefore only limited to the medical, therapeutic or surgical domain. This was an intended exception to the general patent system and was made explicit as an exception to the general ban on patents of diagnostic, therapeutic and surgical methods.²³²

The issue of further medical indications for a substance that was already known to have a medical, therapeutic and surgical effect presented many more difficulties for the European system in the 1980s.²³³ Domeij notes that the push to have patents for second indications was driven by economic reasons.²³⁴ As he puts it, “when the need to be able to patent new medical indications became clear, legal technicalities carried little weight”.²³⁵ Without amending the EPC, the Boards of Appeal recognized that the pharmaceutical industry was changing, especially with respect to its primary modes of research, and took it upon themselves to structure the patent system’s incentives to maintain European research advantages.²³⁶ His analysis suggests that industrial policy is implicit in the series of decisions that led to the recognition of patents for second medical indications.²³⁷ This policy drove the flexible interpretations that allowed for such patents. As a cause of this shift, Domeij notes that pharmaceutical research became increasingly driven by bio-pharmacologists rather than chemists, and that more and more research was focusing more tightly on the mechanisms and relationships between chemicals and chemical

²³¹ B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 178.

²³² *Ibid.*

²³³ *Ibid.* p. 181.

²³⁴ *Ibid.* p. 196.

²³⁵ *Ibid.*

²³⁶ *Ibid.*

²³⁷ *Ibid.*

receptors in the body.²³⁸ This biological focus, and the fear that Europe's fledgling biotechnology industry would be left behind, was all the prompting needed to find a way around the prohibition on the patenting of diagnostic, therapeutic and surgical methods, as well as the principle that discoveries are unpatentable.

The patenting of second indications as pioneered by the EPO Boards of Appeal is also now possible in the patent offices of Italy, Switzerland, Austria, the UK, France, Sweden and Germany. The Dutch, however, have rejected such an extension of the patent system for the moment.

Much less legal difficulty has surrounded second indications in the USA, which has never had a ban on patenting of diagnostic, therapeutic or surgical methods, although attempts were made in the early twentieth century.²³⁹ This ensured that the USA never encountered the legal difficulties that the Europeans had in allowing patents on first or second indications. The USA also allows discoveries²⁴⁰ to be patented and requires "utility" rather than "industrial applicability", thereby removing other barriers to second indications. As a subject matter therefore, second indications have in principle been patentable subject matter in the USA since the beginning of the twentieth century. The advent of the biotechnology revolution has only served to make such process-of-use patents more valuable and the past twenty years have seen the proliferation of such patents as biotechnology has made it possible to identify the active biological mechanism through which drugs operate, thus enabling better identification of the full scope of effects that a known drug has.

²³⁸ Ibid.

²³⁹ J Richards 'United States Patent Law and Practice with Special Reference to the Pharmaceutical and Biotechnology Industries' (Paper Presentation IIPRP and TIFAC Seminars Delhi and Hyderabad, India, January 2002). In: <http://www.ladas.com/Patents/Biotechnology/USPharmPatentLaw/USPhar01.html> (11 November 2005)

²⁴⁰ 35 USC 101.

II. WHAT ARE THE PUBLIC HEALTH ISSUES IMPLICATED?

II.1. Reduction of Access

In a situation where the only parties concerned are other innovators, Domeij is correct in arguing that there is little cost to society, in the first generation, in allowing patents for second indications.²⁴¹ However, subsequent innovators are excluded if the patentee (in all likelihood, the original product patentee) of the second indication receives patent protection, especially if such protection is for the biological mechanism through which the pharmaceutical produces its effect. The original product patentee can effectively extend its patent by waiting until the original product patent is almost ready to expire, and then patenting a second indication based on the biological mechanism.

In an arena where the aim is to increase public access to pharmaceuticals and to allow doctors as much freedom as possible to test pharmaceuticals on patients for new uses (a normal part of general practice as well as clinical trials), patents on second indications serve to close off knowledge and access, increasing the costs of finding novel solutions to development problems. The problem of encouraging research into neglected diseases and geographical areas is not helped by patenting of second indications. This is especially true where the previously-known substance or composition was already in the public domain. If it is necessary to provide incentives for research into new uses in developing countries, it may be best carried out by third parties rather than the original product patentee, and it is better to provide incentives through a targeted rewards system. In addition, patenting of second indications can be used strategically by primary product patentees to block the entry of generic products.²⁴²

²⁴¹ B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 197.

²⁴² S Musungu and C Oh *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?* (South Centre-WHO Geneva 2006) p. vii.

II.2. Biopiracy

Biopiracy happens through the patenting of known substances. Some countries, such as the United States, use the fiction that any unwritten prior art does not count in determining novelty if disclosed by other means outside the USA. First and second indications can also be ways to enable biopiracy by allowing the patenting of uses, defined in particular ways, for existing products from developing countries that may have similar or other uses.²⁴³ A prime example of this is the patenting of turmeric in the USA. Two Indians working at the University of Mississippi Medical Centre had been granted US patent no. 5,401,504 in 1995 on turmeric for use as a wound-healing agent.²⁴⁴ Despite the fact that general common knowledge of use of turmeric as a healing agent had existed for at least a millennium in India, the patent was granted; only when it was challenged by the Indian Council for Scientific and Industrial Research (CSIR) for lack of novelty was the patent revoked.²⁴⁵ However, the revocation only occurred because the CSIR was able to produce a document in Sanskrit, dating back centuries, that outlined the use of turmeric in the manner claimed by the patent, as well as a 1953 paper in the Journal of the Indian Medical Association.²⁴⁶

II.3. Promotion of Traditional Medicine

Traditional medicines play a major part in healthcare in developing countries. In fact, the majority of the population in developing countries is treated by traditional medicine practitioners rather than traditional doctors. Many traditional plants and medicines are already in use and there is an urgent need to identify the full range of effects and treatments

²⁴³ CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) p. 22.

²⁴⁴ UK Commission on Intellectual Property Rights *Report of the UK Commission on Intellectual Property Right: Integrating Intellectual Property Rights and Development Policy* (UK Commission on Intellectual Property Rights February 2003) p. 76. In: http://www.iprcommission.org/papers/word/final_report/chapter4wordfinal.doc (10 November 2005)

²⁴⁵ Ibid.

²⁴⁶ Ibid.

that such traditional medicines may be used for. Second indication patents may be a way to provide incentives to carry out this kind of research, and may be a way around a major problem with respect to patents: most traditional medicines lack novelty in the traditional patent law sense.²⁴⁷ However, existing limits on patents aimed at preserving public access to health may frown upon such expansion of the patent system, despite the need to use such traditional medicines. It should be noted that such patents will favour those with the most capital and research capacity, namely multinational corporations, leading to the appropriation of traditionally accessible knowledge into private hands. A full understanding of the pitfalls, challenges and benefits of new-use patents is needed if developing countries are to make an informed choice as to whether to use the patent system to promote traditional medicine or to opt for sui generis systems with more limited forms of exclusivity or other reward systems.

III. THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY (TRIPS)

III.1. What are the TRIPS Requirements?

Countries are free to ban therapeutic methods from patentability under TRIPS article 27:

3. Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

III.2. What are the TRIPS Flexibilities?

TRIPS does not require members to allow patenting of discoveries, so new uses may also be excluded from patentability on the basis that they are discoveries of existing properties of products rather than inventions. Under the TRIPS Agreement, which allows countries to provide greater

²⁴⁷ CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) p. 28.

protection, member countries are free to decide whether or not to allow the patenting of products for first indications.²⁴⁸

While members are obligated to protect processes, there is no requirement that they protect second indications, as either uses or methods of use.²⁴⁹ Countries are free to define processes in a manner that excludes second indications, although case law in the EPO and the USA has converged to the point where neither jurisdiction makes a distinction between a process and a new use (see below). This presents a dangerously broad interpretation that may be imposed on other countries through technical assistance, bilateral agreements or the WTO dispute settlement system, as global biotechnology competition heats up.

For the moment, the debate remains under the radar as to whether article 27.1 requires the protection of new uses. Developing countries should move to preempt the acceptance of any interpretation of new uses as processes by establishing their own legal precedents on this matter. Given the article 27(3) exception, however, countries are also still able to exclude new uses as subject matter on that basis. In addition, new uses can also be excluded as a general matter for failure to meet any of the patentability requirements of novelty and industrial applicability.

IV. WHAT ARE THE EXISTING POLICY APPROACHES?

This section will begin with a general examination of the approaches, and then describe in detail the issues and challenges faced by the EPC members and the USA in implementing their policy.

²⁴⁸ CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) p. 22.

²⁴⁹ *Ibid.* p. 24.

IV.1. Options on New Uses: Advantages and Disadvantages

IV.1.1. Option 1: Patenting of pharmaceutical products limited only to the uses claimed and disclosed in the patent. Patents allowed on new uses of products

In practice, most countries essentially follow option 2, by allowing a very broad claim scope, which allows the primary product patentee to capture all possible uses of the product, gaining not only patents just on those disclosed but further patents on all possible uses. In addition, any system that allows new-use patents without consideration as to who will be able to make use of such patents, may fall into the trap where the primary product patentee, because of its greater access to capital, captures all subsequent uses. However, if there is equivalent access to capital and information about the unexpected effects of a drug (often obtained as a result of routine post drug approval studies), a country may balance research incentives for the primary product patentee and the follow-on innovators by following this approach. This approach can be modified by allowing only process patents on new uses, thus making all further patents dependent on the underlying product patent, which gives greater control of the direction of production to the primary product patentee. Alternatively, the new-use patents could be product patents, allowing the follow-on innovators to produce the product only for the uses identified. This favours the follow-on innovators who could license their production to other third parties or even to the primary product patentee, giving them greater bargaining power.

IV.1.2. Option 2: Patenting of products encompassing all uses of the pharmaceutical product. Patents allowed on new uses of products

Domeij points out that, in this situation, “the prospect function of the patent system reduces incentives to search for new uses for all but the product patentee”.²⁵⁰ This is because any third-party patent granted on a new use would be dependent and any such third-party grantee would have to negotiate with the product patentee to be able to use its patent.

²⁵⁰ B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 94.

Such a system would, in effect, allow a product patentee to extend its exclusivity beyond the date of the original patent, by subsequently patenting new uses for the product, while excluding others from being able independently to exploit the outcomes of research into new uses during the lifetime of the original patent. There is much discussion as to whether innovation is best left in the hands of one primary innovator or many, but Domeij's analysis makes clear that, when viewing the incentives prospectively, the incentives for a primary innovator to invent around its own product are much reduced.²⁵¹ There will be a tendency to protect the primary product patent from competition and not to dilute the brand. The patentee will prefer to depend on the certainty of the steady income rather than the risk of further investment. As Domeij notes, the incentive "is all carrot and no whip (competition)".²⁵² A product patentee is more likely to maximize income from predictable revenue sources than to invest funds in speculative research ventures. In a sense, the level of risk that he is willing to tolerate is very much reduced. Third-party innovators, on the other hand, have every incentive to try and take advantage of the invention and discover new uses for a patented product, if they can take advantage of it. Grubb points out that, in fact, the vast majority of discoveries of new uses do not even take place in the R&D phase but during product development, customer service or even marketing.²⁵³ Customers themselves may identify new uses, such as doctors carrying out off-indication prescription.

Thus, given a choice between option 1 and 2, option 1 is more likely to produce innovations in discovering new uses of an existing product because it would, if applied strictly, allow third-party innovators to innovate around the product patent and research new uses.

There are important caveats to this, however. First, in most patent systems any patent on a new use under Option 1 would still be a dependent patent, because manufacture of the product would still have to be licensed from the product patentee. This may reduce third-party

²⁵¹ Ibid. pp. 95, 99.

²⁵² Ibid. p. 99.

²⁵³ PW Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law, Practice and Strategy* (4th edn Oxford University Press Oxford 2005) p. 208.

incentives to research such new uses. Second, in the absence of an ability to manufacture and sell the product, exercising such a patent is difficult for any third party. It would require tracking the use of the product by doctors and other therapists and distinguishing between uses for different indications. This entails an effort that equals tracking copyright uses in difficulty. Use patents are therefore most useful to the product patentee who can most easily determine and control uses by controlling production and marketing. Third, a situation where there is little or no research exception, or where the research exception defines commercial research into new uses as banned activity, would make it impossible for third parties to carry out the necessary research on the product to discover new uses.

This analysis confirms the suspicion that, in the present patent policy of most developed countries, new-use patents are really only useful to primary product patentees, who can use them to extend the period of exclusivity that they have had on a product. Second-indication patents that do not rest on the right to research into, manufacture, and sell the product present ineffective incentives to third parties and make it easier for product patentees to capture all the possible market power. Domeij notes again that the privileged access to research on the product even in a strict Option 1 system would still result in the inventor of the first medical use and product patent being the one who discovered any subsequent uses.²⁵⁴ In those developing countries where third party innovators or firms have less access to capital and information about potential new uses, primary product patentees will be able to capture all the market power as well. As will be noted below, it is recommended that developing countries should generally refrain from granting patents on incremental or small innovations if they wish to encourage domestic “inventing around” existing patents. For R&D of new uses, a better option may be rewards targeted at particular diseases that ensure a right to research, manufacture and sell the underlying product for the new use.

²⁵⁴ B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 100.

IV.1.3. Option 3: Patenting of pharmaceutical products limited only to the uses claimed and disclosed in the patent. No patents allowed on new uses of products

As noted, many second uses are discovered in phases other than the R&D phase. In large part, such discoveries occur during actual use, or testing by the original product patentee and third parties. If this is the case, then the basic incentive question is answered fairly clearly. Where such activities occur in due course, as part of normal follow-on activities, what need is there of the patent incentive to encourage them? As Domeij notes, the primary considerations in allowing patenting of second indications in Europe were economic: to maintain the competitiveness of its fledgling biotechnology industry.²⁵⁵ Developing countries may wish to take this example to heart, taking into account their own special circumstances. Restricting patents only to the uses disclosed in the claims²⁵⁶ of the patent application will free up the entire area of the prospect for third-party innovators to invent around the patent. This space would be maintained by having either no, or a very narrow, doctrine of equivalents. In addition, developing countries concerned with developing domestic innovation and ensuring speedy dissemination may wish to avoid allowing patents on second uses. Aside from the erosion of novelty and industrial applicability standards that allowing such patents entails, it may also enable large multinational corporations to capture all the innovation territory by virtue of their head start and greater access to capital. A better approach to developing domestic innovation would be not to allow such patents and to institute alternative reward systems. In applying any such system, it is crucial that the right to manufacture and sell the product for the new use is included. A broad research exception will also be necessary to allow research using the original patented product. Of all the options, option 3 may be best suited to countries that consist largely of follow-on or third-party innovators, with restricted access to capital.

²⁵⁵ Ibid. p. 196.

²⁵⁶ CM Correa 'Internationalization of the Patent System and New Technologies' (2002) 20 *Wis Int'l LJ* 523. He suggests that identified functions or uses be listed not only in the specifications but also in the claims, since the claims determine the scope of the patent when interpreted by courts.

IV.1.4. Option 4: Patenting of products encompassing all uses of the pharmaceutical product. No patents allowed on new uses of the products

In this option, the product patents are truly absolute and cover all uses in any field. The entire prospect is claimed by the original product patentee, for the duration of the patent. It has the advantage of clarity and certainty by establishing broad patent claims that will limit litigation, but the disadvantages of discouraging third parties to research into new possible uses of a drug and of limiting generic competition. This option should be accompanied by a narrow doctrine of equivalents. While any new uses would therefore fall within the ambit of the product patent, an explicit ban of patents on new uses would prevent the granting of exclusive rights that last beyond the expiry of the original patent.

IV.2. The USPTO and the EPO: Advantages and Disadvantages

IV.2.1. The European Patent Office

a. Which option?

The EPC ostensibly reflects Option 1 in its approach insofar as it deals with the first indication of previously known substances or compositions. Such a formulation essentially places a use limitation on the original patent and limits the new-use patent as well to the pharmaceutical domain. However, it allows the patentee to capture all pharmaceutical uses once the first pharmaceutical use has been defined. This is, therefore, effectively an Option 2 approach for NCEs and for first medical indications of a product with no known previous medical indication.

For second indications of known pharmaceuticals with a known first indication, the European approach is a mix of Options 1 and 2. Second indications of this kind are limited to the uses disclosed in the patent application. However, the patent on the product is an absolute product patent, covering all uses of the product. Effectively, the only person who can patent such a second indication under the European

system would be the owner of the original product patent, although the possibility of cross-compulsory licensing exists (and article 31(l) of the TRIPS Agreement allows for it). If a third party were to research and discover such a use, they would be obligated to negotiate with the original product patent holder.

b. The therapeutic methods issue

Article 52(4) section 1.3 of the EPC embodies the ban on medical methods. However, an exception was carved out in the EPC for the discovery of a first medical indication for a previously-known substance.²⁵⁷

The EPC has no explicit exception allowing the patenting of second indications of products that had a known first medical indication. This arose through the case law. The Board of Appeal decided in G 1/83 that a new use is indistinguishable from a method.²⁵⁸ Thus the ban applied. However, to get around the ban, the Board of Appeal decided to follow the “Swiss Formula”, which presented the new use as a process of manufacture of a pharmaceutical rather than as a new use.²⁵⁹ The claim is formulated as “the use of compound X for the preparation of an agent for the treatment of disease Y”.²⁶⁰ As a manufacturing process it would escape the ban. However, this only creates further problems; notably the process of manufacture for the new use is no different from that used to manufacture the original product. Such a process would lack novelty.²⁶¹

²⁵⁷ EPC art 54(5).

²⁵⁸ G 1/83, OJ EPO 1985, 64.

²⁵⁹ B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 182.

²⁶⁰ PW Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law, Practice and Strategy* (4th edn Oxford University Press Oxford 2005) p. 220.

²⁶¹ B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 183.

c. The discovery issue

The Boards of Appeal bypass this issue entirely, simply assuming that novelty of the second indication is sufficient to dismiss the concern that incentives should apply to actual inventive activity. The European approach seems to be that incentives must be placed primarily to reward or encourage investment, with no consideration about worth or contribution to the state of the art.

*d. Standard of novelty**Novelty of the process for manufacturing the product for the new use*

While novelty under the Swiss formula was a concern for the Boards of Appeal, they reasoned that it was legitimate to rely on the new use to provide the novelty for the production process (which would not qualify for novelty on its own), and to rely on the production process to establish a technical effect for the new use. This is despite the fact that established precepts of patent law in the European patent system require that it is the technical features of a product or process that form the basis for any novelty determination and which serve to differentiate it from the prior art.²⁶² If those technical features, such as the new use, are banned from patentability, then no novelty can exist. The Board's final explanation is that such an approach is analogous to EPC article 54(5) exception for first medical indications of a known substance with no previous medical indication, and that there is no reason why it should be treated differently.²⁶³ From the definition that this paper notes above, it is clear that different incentives function for the different uses, and that any exception has to be made explicit. Exceptions are to be construed narrowly, and to extend the exception by analogy is to treat it not as an exception but as part of the normal principles of patent law.

The biological mechanism or the final medical effect

Medical indications can be defined by the disease, or through the biological mechanism that the pharmaceutical works through to have a

²⁶² Ibid.

²⁶³ Ibid.

medical effect. Given that the impetus was to encourage the biotechnology industry, the EPO should limit the claims only to those based on the biological mechanism.

The use of a new biological mechanism to treat the same disease (which may already be addressed by a pharmaceutical with a use patent) is considered novel.²⁶⁴ This requires demonstration that the new biological mechanism is different from that operating in the uses already granted.²⁶⁵ In fact, it appears that the same substance having the same effect, but discovered to achieve that effect through more than one biological mechanism, may actually be able to be patented for each mechanism, despite the end medical effect's being the same.²⁶⁶ This broad application begins to blur the line between an explanation of how a pharmaceutical works and actual new use of a pharmaceutical. In recognition of this, the Boards of Appeal have required that the discovery of the new biological mechanism have at least some minimal consequences for how the pharmaceutical is used medically.²⁶⁷ However, the general standard of novelty remains very permissive for second indications.

e. Use limitation on claim scope

For a first indication, the original patent claim is read not to extend to the medical field unless a use in the medical field was claimed in the original product patent.²⁶⁸ As Domeij notes, because there is an already existing product patent, a use limitation is placed on both patents, the original and the first indication. The first indication gains exclusivity within the medical field, and the original, despite the broad claim scope and the prospect of the product patent, is retroactively limited.

The patent on the first medical indication is broad enough to include all medical indications of the new product, capturing the entire prospect for the person who discovers a new medical use for a

²⁶⁴ Ibid. p. 188.

²⁶⁵ Ibid. p. 189.

²⁶⁶ Ibid. p. 189, citing T 290/86, OJ EPO 1992, p. 414.

²⁶⁷ Ibid. p. 190.

²⁶⁸ Ibid. p. 179.

previously-known substance or composition.²⁶⁹ This is based on the Board of Appeal's insistence on treatment of first indication patents equal to that for NCE product patents.²⁷⁰ The patentee should have the right to the entire prospect within the disclosed field, despite any requirement to be specific about the indication it addresses. Such a broad claim would be formulated "Compound X for use as a pharmaceutical".²⁷¹ Given that developing countries are focused on follow-on research, this approach may be ideal for encouraging the development of an indigenous pharmaceutical industry, in an arena where third parties have much greater incentives than do pharmaceutical companies. Either patent law (limiting the scope of the claim only to the use disclosed) or more limited forms of exclusivity may be used, although as part of the general recommendations, activities representing discoveries in this fashion may be best dealt with outside the patent system, with one-time reward systems, provided that the right to manufacture and sell the product is included. This is necessary to provide bargaining power for those small industries which do not have sufficient manufacturing capacity of their own to license out their discovery of the first medical indication.

The claim scope of the second indication is limited only to those disclosed in the application.²⁷² It will not encompass further indications that are discovered. However, this may be affected by whether the underlying claim is addressed to the indication defined as a disease, or the indication defined by the underlying biological mechanism on which the pharmaceutical operates. Several diseases may have the same underlying biological mechanism, and yet each one constitutes a different medical indication.

It is clear that a claim to the underlying mechanism can be generally broader than the defined disease. However, the claim can also be formulated to cover a range of mechanisms while focusing on a particular medical indication. For example, a new use for alleviating headaches covers various different causes of headaches, even if the

²⁶⁹ T128/82, OJ EPO 1984, p. 164.

²⁷⁰ B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 179.

²⁷¹ *Ibid.* p. 180.

²⁷² *Ibid.* p. 186.

pharmaceutical's biological mechanism addresses only headaches caused by inflammation of the intra-cranial membrane, and not by any other mechanism.

f. Does it provide the exclusive right to manufacture and sell the pharmaceutical?

For the first medical indication of a known substance or composition, the new use was treated as a product patent as applied and used only in the medical field. This, of course, implied the right to manufacture and sell the product for the medical indication. Bulk sales or sales for the original purposes would not infringe the patent.²⁷³ Only sales for pharmaceuticals would infringe. Thus the right to manufacture and sell is not exclusive but shared.

Second indications are treated as pure process claims, making them, to all intents and purposes, dependent on the underlying product claim.²⁷⁴

g. Further analysis

The Boards of Appeal have also made it clear that for second indications the claim formula, the Swiss formula, is permitted only for patents on medical, therapeutic or surgical methods.²⁷⁵ Novelty cannot be determined in the same way for any other category of patents. The formulation has been interpreted broadly by the Boards of Appeal in subsequent cases.²⁷⁶ This limitation raises several concerns, a large one being the TRIPS requirement of non-discrimination among different fields of technology.²⁷⁷ The danger is that the EPO may be required to

²⁷³ PW Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law, Practice and Strategy* (4th edn Oxford University Press Oxford 2005) p. 218.

²⁷⁴ CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) p. 21.

²⁷⁵ B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 184.

²⁷⁶ *Ibid.*

²⁷⁷ Agreement on Trade-Related Aspects of Intellectual Property (15 April 1994) LT/UR/A-1C/IP/1 art 27(1).

extend such an erosion of the novelty standard to all other fields of technology.

New patient categories

A second indication may be patented if it applies to the same indication but for a new category of patients for whom it had not previously been known that it could be effective.²⁷⁸ The reasoning is that a medication is defined not only by its target disease but by the population that will use it.²⁷⁹ This of course also means that such a patent could be obtained for new uses of a pharmaceutical first used in pigs, to be used in dogs or humans. Developing countries should refrain from allowing such exclusivity as it would be possible for a single person to own and extend a patent on an adult-targeted HIV drug by targeting it at particularly needy groups such as infants with HIV. This is a particularly dangerous form of exclusivity as it can restrict access for neglected patient groups who would finally be able to access a drug more cheaply only to see the exclusivity extended to anyone in their population group.

New doses and methods of administration

In the EPO, the manner of administration of a pharmaceutical can also be sufficiently novel to be patented as a second indication.²⁸⁰ For example, oral ingestion of a drug previously only applied topically would qualify, despite the same mechanism and the same disease being addressed by the pharmaceutical.²⁸¹

h. Conclusion

What is clear is that in Europe there is little or no inventive step requirement for second indications, which escape the usual problem-

²⁷⁸ B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 191.

²⁷⁹ *Ibid.*

²⁸⁰ B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 192.

²⁸¹ T 289/84 of 10/11/1986, showing that an active ingredient that was previously injected could also be taken through topical application through the skin.

solution approach taken by the EPO. It is effectively a novelty standard, one that is highly permissive and broadly interpreted. This permissiveness, while embedded in an economic justification, recklessly extends exclusivity to new areas without necessarily considering the restrictions on competition, research and access to medicines.

IV.2.2. The United States Patent and Trademark Office

a. Which option?

New-use patents in the USA are patentable under 35 USC 100 as process-of-use claims. However, the claim cannot be formulated in the form “a use of X to do Y”.²⁸² The MPEP distinguishes between finding a new property of an existing compound (anticipated by prior art) and a new use of such a compound (as long as it is novel).²⁸³ As long as the claim is on a *process* for use rather than just a use,²⁸⁴ and as long as said process is novel, it is patentable subject matter. The process claim is then subjected to the usual requirements of definiteness. This approach is peculiar to the USA, which also treats such claims as process claims without distinction.

The USA makes no distinction between first and second indications, other than to note that process-of-use claims for already known products bear closer scrutiny for anticipation in the prior art.²⁸⁵

These principles, combined with the US preference for granting very broad claim scope, result in a strong Option 2 approach. The apparent doubt about whether new uses are patentable in the USA which seems to be exhibited in the MPEP guidelines arises from the fact that the initial patent scope for any patent claim is generally very broad, covering almost all the entire prospect. If the original patent identifies a use, the question then becomes how broadly the first “use” is defined.

²⁸² USPTO, *USPTO Manual of Patent Examination Procedure*, Section 2112.02 Process Claims, citing *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978).

²⁸³ USPTO, *USPTO Manual of Patent Examination Procedure*, Section 2112.02 Process Claims.

²⁸⁴ *Ibid.*

²⁸⁵ *Ibid.*

Using the doctrine of equivalents means that any process which operates in substantially the same way as the patented process, and produces substantially the same result, would infringe the original process patent.

b. The therapeutic methods issue

The United States has long allowed methods of treatment to be patented.²⁸⁶ Surgical methods are also patentable.²⁸⁷ However, to protect doctors from infringement suits, and in particular those practitioners using surgical methods, 35 USC 287(c) excludes the performance of a medical activity by a medical practitioner or hospital.²⁸⁸ In effect, there is no ban on the patenting of diagnostic, therapeutic and surgical methods in the USA and therefore no such bar to the patenting of first or second indications.

c. The discovery issue

Under 35 USC 101, discoveries are patentable, thereby posing no bar to new-use patents.

d. Standard of novelty

As process patents, new-use patents undergo the same scrutiny for novelty undergone by all other process patents in the USA. The MPEP notes, however, that simply reciting a known chemical structure or formula and then describing a property of the compound or the result of the property will not establish novelty.²⁸⁹ What must be added is the manner in which it will be applied to the body. This, however, is the only suggestion in the examination guidelines that use claims will bear some closer scrutiny for novelty. This limitation simply demands that a particular form be followed, rather than establishing a real substantive novelty requirement.

²⁸⁶ PW Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law, Practice and Strategy* (4th edn Oxford University Press Oxford 2005) p. 219.

²⁸⁷ *Ibid.*

²⁸⁸ *Ibid.* p. 220.

²⁸⁹ USPTO, *USPTO Manual of Patent Examination Procedure*, Section 2112.02 Process Claims.

e. Use limitation on claim scope

The use claim is a process claim and is given the same generally broad scope that all process claims receive in the USA. However, unlike the European treatment of first indications, only the process disclosed in the claim is protected and this does not extend to all possible uses in the pharmaceutical field. This is therefore a narrower claim scope for new uses in general, limited by the way the USA defines new uses as processes.

f. Does it provide the exclusive right to manufacture and sell?

Since the USA confines even first indications of known substances that had no known medical indication to what are termed process-of-use patents, second indication patents do not provide the exclusive right to manufacture or sell the product.²⁹⁰ These become process patents dependent on the original product patent.

h. Conclusion

The US approach to new-use patents has the virtue of simplicity. By essentially making no distinction between new uses and other processes, by allowing patents on discoveries, and by not banning patents on methods of treatment, the USA has avoided much of the painful twists and hoop jumping that the EPO has had to undergo over the past twenty years. However, it has done so at the price of a general degradation of the patentability requirements. The principle of non-discrimination between fields of technology ensures that all such loosening of restrictions must be applied to all fields of technology, not just pharmaceuticals and biotechnology. It is also an approach that clearly favours granting as much of the prospect as possible to the primary product patent holder rather than to third-party inventors. Combined with a restricted research exception, and lack of ability to manufacture and sell the product underlying the new use, new-use patents in the US can really only serve a defensive function for firms, by protecting existing patent assets while doing little actually to encourage inventive

²⁹⁰ CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) p. 22.

activity. Moreover, with mature capital markets and large established firms, even in the burgeoning biotechnology field, such an approach may make sense for the USA. However, questions remain as to how appropriate the patenting of new uses is, even for developed countries. While favouring large industries over small ones and favouring primary patent holders ensures that it is easier for patentees to attract capital to their ventures, research outside these firms may be stifled.

V. THE SITUATION IN DEVELOPING COUNTRIES

Many patent laws in developing countries make no specific reference to the availability of patents for uses, leaving unclear whether their protection for processes covers “uses” and “methods of use”.²⁹¹ That said, all states that do not allow the patenting of diagnostic, therapeutic or surgical methods exclude patentability of first or second uses. The same would be true if strict novelty and industrial applicability requirements were applied. Some countries have begun to address the issue of new uses directly. In the Musungu and Oh study, 55 per cent of the developing country laws reviewed had no specific exclusion of new uses²⁹² and 20 per cent (India, Pakistan, Chile, the Dominican Republic, Uruguay, the Andean Community (Bolivia, Colombia, Ecuador, Peru, Venezuela)) specifically excluded patentability of new uses. Only three countries (South Africa, China and Malaysia) specifically allowed new uses.²⁹³ Since the 2000 Amendments to its Patent Law, China appears to have removed language that specifically allowed for patenting of new uses but grants this type of patent in accordance with the examination guidelines of the State Intellectual Property Office (SIPO), despite the fact that it does not grant patents for scientific discoveries or “methods for the diagnosis or for the treatment of diseases”.²⁹⁴

²⁹¹ Ibid. p. 23.

²⁹² S Musungu and C Oh *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?* (South Centre-WHO, Geneva 2006) p. 38.

²⁹³ Ibid. Appendix 2.

²⁹⁴ Article 25 of the Patent Law of the People’s Republic of China. (Adopted at the 4th Meeting of the Standing Committee of the Sixth National People’s Congress on 12 March 1984). (Amended in accordance with the Decision of the

Each state needs to consider whether it needs to have an explicit statement that bans patents on new uses within or outside the pharmaceutical field. For developing country approaches to second indications or new uses see the table in Appendix 1.

V.1. Countries that Specifically Exclude New Uses

V.1.1. India

Section 3d of the Patents (Amendment) Act 2005 defines what are not to be considered inventions. New uses are not patentable as inventions. It excludes from patentability ‘the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant’.²⁹⁵ New uses, first or second indications, are ruled out by this rule.

V.1.2. Pakistan

Pakistan does not allow discoveries²⁹⁶ or diagnostic, surgical and therapeutic methods²⁹⁷ to be patented. The explicit ban on new uses is found in article 10 on industrial application, which states:

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 4 September 1992.) (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 25 August 2000).

In: http://www.sipo.gov.cn/sipo_English/flfg/zlflfg/t20020327_33872.htm (11 November 2005)

²⁹⁵ See also ‘Important Changes incorporated in the Patent (Amendment) Bill, 2005 as compared to the Patent (Amendment) Bill, 2003’, Press Release, Ministry of Commerce and Industry, Press Information Bureau, Government of India, 23 March 2005, Section 3(d). In: http://pib.nic.in/release/rel_print_page1.asp?relid=8096 (11 November 2005)

²⁹⁶ Pakistan Patents Ordinance 2000, art 7(2).

²⁹⁷ Ibid. art 7(4).

Subject to subsection (2), an invention shall be considered to be capable of industrial application if it can be made or used in any kind of industry. The industry shall be understood in its broadest sense. It shall cover in particular agriculture, handicraft, fishery and services.

(2) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application: Provided that a product consisting of a substance or composition shall not be prevented from being treated as capable of industrial application merely because it was invented for use in such a method.

This article bans new uses by relying on their lack of industrial capability rather than a lack of novelty in the process or product. It also ensures that product patents on pharmaceuticals are not accidentally banned for lack of industrial applicability simply because they are made for such a use.

V.1.3. Chile

Chile does not allow discoveries²⁹⁸ or diagnostic, surgical and therapeutic methods²⁹⁹ to be patented. In addition, article 37(e) of Law 19.039 explicitly addressed new uses as inventions by excluding:

new uses of articles, objects or elements known and already used for specific purposes, and changes of shape, dimensions, proportions or materials in the subject matter applied for, except where the qualities of the subject matter are essentially altered or where its use solves a technical

²⁹⁸ Article 37(a), Law No. 19.039 Establishing the Rules Applicable to Industrial Titles and the Protection of Industrial Property Rights (1991). In: http://www.wipo.int/clea/docs_new/pdf/en/cl/cl012en.pdf (11 November 2005)

²⁹⁹ Article 37(d), Law No. 19.039 Establishing the Rules Applicable to Industrial Titles and the Protection of Industrial Property Rights (1991) <http://www.wipo.int/clea/docs_new/pdf/en/cl/cl012en.pdf> (11 November 2005).

problem that did not previously have an equivalent solution.³⁰⁰

The exceptions to the exclusion are an interesting approach that finely calibrates the ban. It will allow new uses to be applied for if they are industrially applicable, that is they solve a previously unsolved technical problem. This is not quite an industrial applicability standard, but it leaves room for patenting uses that may go beyond simply reapplication of the same product in the same field. In any case, therapeutic methods are ruled out by the article 37(d) ban.

It will also allow changes to a product to be patented if they are substantial enough. This is not the same as requiring that the changes to the underlying product be inventive, but they must change something essential about the way the product works.³⁰¹

V.1.4. Uruguay

Uruguay does not allow discoveries³⁰² or diagnostic, surgical and therapeutic methods³⁰³ to be patented. Article 15 contains the direct exclusion of new uses from patentability, stating:

Pursuant to the provisions of this Law, products or processes already patented and included in the state of the

³⁰⁰ Article 37(e), Law No. 19.039 Establishing the Rules Applicable to Industrial Titles and the Protection of Industrial Property Rights (1991). In: http://www.wipo.int/clea/docs_new/pdf/en/cl/cl012en.pdf (11 November 2005)

³⁰¹ Law 19.996 of January 2005 amended the quoted article 37(e). The revised provision allows for the patentability of a new use if it solves a technical problem without previous equivalent solutions if, in addition, it requires a change in size, proportions or in the materials of the known article, object or element in order to obtain such a solution.

³⁰² Article 13(a) Law No. 17.164 Regulating Rights and Obligations Relating to Patents, Utility Models and Industrial Designs (1999). In: http://www.wipo.int/clea/docs_new/pdf/en/uy/uy002en.pdf (11 November 2005)

³⁰³ Article 14(a) Law No. 17.164 Regulating Rights and Obligations Relating to Patents, Utility Models and Industrial Designs (1999). In: http://www.wipo.int/clea/docs_new/pdf/en/uy/uy002en.pdf (11 November 2005)

art may not be the subject of a new patent simply because the purpose for which they are to be used differs from that in the original patent.³⁰⁴

Some confusion may be caused by the fact that this provision appears to apply only to materials that have already been patented and are part of the prior art. It may be that patents on traditional medicine that is part of the prior art but not patented may escape this prohibition, enabling misappropriation. Alternatively it may allow such traditional medicine to be brought into the patent system. If that is the aim, however, more explicitly-directed legislation would be appropriate. If, however, article 15 covers new uses of patented subject matter, it may be interpreted a fortiori that it also covers subject matter in the public domain.

V.1.5. Andean Community (Bolivia, Colombia, Ecuador, Peru, Venezuela)

The Andean Community does not allow discoveries³⁰⁵ or diagnostic, surgical and therapeutic methods³⁰⁶ to be patented. Article 21 expressly prohibits new uses, by stating:

Products or processes that are already patented and included in the state of the art within the meaning of Article 16 of this Decision may not form the subject matter of a new patent owing to the fact of having a use ascribed to

³⁰⁴ Article 15 Law No. 17.164 Regulating Rights and Obligations Relating to Patents, Utility Models and Industrial Designs (1999).

In: http://www.wipo.int/clea/docs_new/pdf/en/uy/uy002en.pdf (11 November 2005)

³⁰⁵ Article 15(a) Andean Community Decision 486 – Common Provisions on Industrial Property (of 14 September 2000).

In: http://www.wipo.int/clea/docs_new/pdf/en/ac/ac005en.pdf (11 November 2005)

³⁰⁶ Article 20(d) Andean Community Decision 486 – Common Provisions on Industrial Property (of 14 September 2000).

In: http://www.wipo.int/clea/docs_new/pdf/en/ac/ac005en.pdf (11 November 2005)

them different from that originally provided for in the first patent.

While direct and explicit in its approach, this formulation may suffer from the same confusion as the Uruguayan approach in that it applies only to products and processes that are already patented and form part of the prior art.

V.2. Countries that Specifically Allow New Uses

V.2.1. South Africa

South Africa does not allow discoveries to be patented.³⁰⁷ It does, however, allow first and second indications to be patented. Section 25(9) of the Patent Act states:

In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art immediately before the priority date of the invention shall not prevent a patent being granted for the invention if the use of the substance or composition in any such method does not form part of the state of the art at that date.

This addition was made in the amendments to the act in 1997, by s. 31 (c) of Act No. 38 of 1997. It essentially creates product patents for new uses, and ensures that such patents escape the novelty issue by using the novelty of the use to provide novelty for the product patent. Section 25(11) makes clear that the patent is for a product, and not for a method of treatment. It states that any method of treatment of the human or animal body will be deemed to lack industrial applicability.³⁰⁸

³⁰⁷ Section 25(2) of the Patent Act of 1978 (last amended by the Patents Amendment Act, No. 58 of 2002), Republic of South Africa.

³⁰⁸ Section 25(11) of the Patent Act of 1978 (last amended by the Patents Amendment Act, No. 58 of 2002), Republic of South Africa.

Section 25(12) ensures that this prohibition will not prevent product patents being granted for new uses.

The claim scope of such patents may be limited to only the use disclosed but this remains unclear. South Africa's is a patent registration system rather than one of substantive examination, so the validity and scope of such patents is usually determined in litigation.

V.2.2. Malaysia

Malaysia does not allow patents on discoveries or on methods of treatment,³⁰⁹ but it does allow patents on second uses. This takes place through a combination of several articles. Section 13(1)(d) notes that the ban on methods of treatment does not apply to products used in such treatment.³¹⁰

In the chapter on novelty requirements, section 14(4) states, "The provisions of subsection [14](2) shall not exclude the patentability of any substance or composition, comprised in the prior art, for use in a method referred to in paragraph (d) of subsection (1) of section 13, if its use in any such method is not comprised in the prior art."

This creates product patents for new uses limited to diagnostic, therapeutic and surgical methods, as long as the new use is itself novel. The claim scope of such patents may be limited to only the use disclosed but this remains unclear. Malaysia's is a patent registration system rather than one of substantive examination, and so the validity and scope of such patents is usually determined in litigation.

³⁰⁹ Malaysian Patents Act 1983 (last amended 2003).

In: <http://www.mipc.gov.my/> (11 November 2005)

³¹⁰ Malaysian Patents Act 1983 (last amended 2003) "(1) Notwithstanding the fact that they may be inventions within the meaning of section 12, the following shall not be patentable: ... (d) methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body: Provided that this paragraph shall not apply to products used in any such methods." In: <http://www.mipc.gov.my/> (11 November 2005)

V.2.3. China

Under the examination guidelines, SIPO accepts new-use patents as method-of-use patents as long as they are recited in the form of the Swiss Formula.³¹¹ These patents are process patents and therefore dependent on the underlying product patent.³¹²

VI. CONCLUSIONS AND RECOMMENDATIONS

Given the concerns about the restrictions on competition and those further imposed by new-use patents, and doubts about whether they present a real incentive for innovation, developing countries should approach the issue with caution. It is important that they have a policy which is reflected in legislation or regulations, but they should leave some room for fine-tuning their approach. However, other solutions for promoting incremental innovation are recommended, such as utility models, petty patents or direct-reward systems, rather than patents on new uses. If a developing country, even a fast developing country, wishes to have patents on new uses, it should limit such patents to first indications rather than second indications or any other new uses. It should place strict use limitations on the claim scope of such first-indication patents.

The recommended legislative option is that new uses for a patented product or any product in the public domain should not be patentable. In addition, in the case of a pharmaceutical product, the uses disclosed in the patent claim shall include, and be limited to, uses for the pharmaceutical that function in the same way, using the same biological mechanism or process, and having the same effect on the human or animal body. This option would protect the prospect function as it applies to drug development, and is a principle that could yet be applied to other industrial areas.

³¹¹ China Patent Guidelines ch 10 sec 3.5.1 – 3.5.2

³¹² Ibid.

APPENDIX I**TABLE OF DEVELOPING COUNTRY POLICIES ON SECOND INDICATIONS³¹³**

The review of patent legislation was undertaken on the basis of information compiled from national patent laws, where the laws were available. Additional information was sourced from the reports of the WTO TRIPS Council review of implementing legislation, which are available from the WTO website. Supplementary sources of information included unpublished data, including that collected for the WHO Network for Monitoring the Impact of Globalization and TRIPS on access to medicines. Below is a breakdown of the patent laws reviewed, and the sources of information.

BOTH patent legislation and WTO response reviewed	Patent legislation ONLY	WTO response ONLY	Other source ONLY
China	Cambodia	Brunei	Laos
Honduras	Vietnam	Philippines	Mozambique
Indonesia	India	Sri Lanka	
Nicaragua	Pakistan	Costa Rica	
Malaysia	Egypt	Dominican Republic	
Paraguay	Ghana	Jamaica	
Singapore	Malawi	Botswana	
Peru	Mauritius		

³¹³ S Musungu and C Oh 'The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?' Submission to the WHO Commission on Intellectual Property, Innovation and Public Health, 2005, appendix 1. In: <http://www.who.int/intellectualproperty/submissions/en/>) This table was extracted from the larger survey carried out by the writers.

BOTH patent legislation and WTO response reviewed	Patent legislation ONLY	WTO response ONLY	Other source ONLY
Thailand Trinidad and Tobago Argentina Uruguay Barbados Venezuela Belize Kenya Brazil Morocco Bolivia Nigeria Chile South Africa Colombia Tunisia Ecuador Guatemala	Sudan Swaziland Tanzania Uganda Zambia Zimbabwe		
26 countries	14 countries	7 countries	2 countries

Asia:

Country Sources consulted	Applicable patent law	Provisions/Mechanisms	
		Pharmaceutical products	Patentability exceptions – new use or 2 nd use patents
Brunei WTO review, Other source ^o	Chapter 72 Laws of Brunei <i>Emergency (Patents) Order 1999; not yet in force as at 2001</i>	Yes Registration of patents granted in the UK, Malaysia and Singapore	
Cambodia Patent Law	Law on the Patents, Utility Models Certificates and Industrial Designs 2002	No Patents excluded until 2016	Not explicitly excluded
China Patent Law, WTO review	Patent Law of PRC 1992	Yes	2 nd use patents allowed
India Patent Law	Patents Act 1970 Patents (Amendment) Act 1999 Patents (Second Amendment) Act 2002 Patents Ordinance 2004	Yes, with mailbox provision	2 nd use excluded
Indonesia Patent Law, WTO review	Patents Act, Law No. 14–2001	Yes	Not explicitly excluded

Country Sources consulted	Applicable patent law	Provisions/Mechanisms	
		Pharmaceutical products	Patentability exceptions – new use or 2 nd use patents
Laos Other source ^o	Patents, Petty Patents and Industrial Designs Decree <i>New patents law being drafted WTO Accession process</i>	No <i>Yes under draft law</i>	
Malaysia Patent Law, WTO review	Patents Act 1983 (latest amendment 2002)	Yes	2 nd use patents allowed
Philippines WTO review	Intellectual Property Code (Republic Act No. 8293)	Yes	Not excluded * Specifically permitted for certain new medical applications
Singapore Patent Law, WTO review	Patents Act 1994, amended 1995	Yes	Not excluded
Sri Lanka WTO review	Intellectual Property Code 1979 (last amended 2000) <i>Intellectual Property Bill 2003, not yet enforced as at 2004</i>	No	Not excluded
Thailand Patent Law,	Patents Act 1999	Yes	Not excluded

WTO review			
Country Sources consulted	Applicable patent law	Provisions/Mechanisms	
		Pharmaceutical products	Patentability exceptions – new use or 2 nd use patents
Vietnam Patent Law	Civil Code on Protection of Industrial Property (cif 1 July 1996) Decree 63/CP 1996, Decree 06/2001, Decree 54/2000	Yes	Not excluded
Pakistan Patent Law	Patents Ordinance 2000 Patents (Amendment) Ordinance 2002	Yes, post-2005, with mailbox provision	New and 2 nd use both excluded Mere change in “physical appearance of a chemical product where the chemical formula remains the same” also excluded

Latin America and the Caribbean

Country Sources consulted	Applicable patent law	Provisions/Mechanisms	
		Pharmaceutical products	Patentability exceptions – new use or 2 nd use patents
Argentina Patent Law, WTO Review	Law No. 24.481 1996	Yes, with mailbox provision	Not excluded
Barbados Patent Law, WTO Review	Patent Act No. 18/2001	Yes	Not excluded
Belize Patent Law, WTO Review	Patent Act Chapter 253/2000 Patents Bill 2000	Yes	Not excluded
Brazil Patent Law, WTO Review	Industrial Property Law No. 9.279 1996 (amended 2001, Law no. 10.196)	Yes, as of 2004 Mailbox provision * Patents have to be passed by Health Ministry	Not excluded
Chile Patent Law, WTO Review	Law No. 19.039, 1991, as amended January 2005 by Law No. 19.996	Yes	New use patentable if it “solves a technical problem without previous equivalent solution” if it requires “a change in size, proportions or in the materials of the known article, object or element in order to obtain such a solution”

Country Sources consulted	Applicable patent law	Provisions/Mechanisms	
		Pharmaceutical products	Patentability exceptions – new use or 2 nd use patents
Costa Rica WTO Review	Patent Law No. 7979/2000 Law No. 6867 of 1983, amended 2000	Yes	Not excluded
Dominican Republic WTO Review	Law No. 20-00 on Industrial Property 2000		New use excluded
Guatemala Patent Law, WTO Review	Decree 57/2000	Yes	Not excluded
Honduras Patent Law, WTO Review	Decree 12-99E Industrial Property Law 2000	Yes	Not excluded
Jamaica WTO Review	Draft Patents and Designs Act 2001	Yes, upon enforcement of draft legislation	
Nicaragua Patent Law, WTO Review	Law on Patents, Utility Models and Industrial Designs, No. 354 2000	Yes	Not excluded
Paraguay Patent Law, WTO Review	Patent Law No. 1.630/2000	Yes	Not excluded
Trinidad and Tobago Patent Law, WTO Review	Patent Act (Consolidation) 1996 (2000)	Yes	Not excluded

Uruguay Patent Law, WTO Review	Patent Law No. 17.164/1999	Yes	New use and 2 nd use excluded
Bolivia Patent Law, WTO Review	Decision 486 of the Andean Community	Yes	New use and 2 nd use excluded under Decision 486 Article 21 states: “Products or processes already patented and included in the state of the art ... may not be the subject of new patents on the sole ground of having been put to a use different form that originally contemplated by the initial patent.”
Colombia Patent Law, WTO Review	Decision 486 of the Andean Community	Yes	New use and 2 nd use excluded under Decision 486
Ecuador Patent Law, WTO Review	Intellectual Property Law 1998 Decision 486 of the Andean Community	Yes	New use and 2 nd use excluded under Decision 486
Peru Patent Law, WTO Review	Decree No. 823 on Industrial Property Decision 486 of the Andean Community	Yes	New use and 2 nd use excluded under Decision 486

Africa

Country Sources consulted	Applicable patent law	Provisions/Mechanisms	
		Pharmaceutical products	Patentability exceptions – new use or 2 nd use patents
Botswana WTO Review, Other source °	Intellectual Property Act 1996	Yes	
Egypt Patent Law	Intellectual Property Law 82 2002	Yes, post-2005 with mailbox provision	Not excluded
Ghana Patent Law	Patents Act 2003	Yes	
Kenya Patent Law, WTO Review	Industrial Property Act 2001	Yes	Not excluded
Malawi Patent Law	Patents Act 1992	Yes	Not excluded
Mauritius Patent Law	The Patents, Industrial Designs, and Trademark Act No. 25 2002	Yes	Not excluded
Morocco Patent Law, WTO Review	Law No. 17-97 on the Protection of Industrial Property 2000	Yes	Not excluded
Mozambique Other source °	Industrial Property Code: Decree No. 18/99 2004		
Nigeria Patent Law, WTO Review	Patent Law 1971 Draft Patents and Designs Act 2002	Yes	Not excluded

Country Sources consulted	Applicable patent law	Provisions/Mechanisms	
		Pharmaceutical products	Patentability exceptions – new use or 2 nd use patents
South Africa Patent Law, WTO Review	Patents Act 1978, amended 1997 Medicines Act 1997	Yes	2 nd medical use allowed
Sudan Patent Law <i>Currently in WTO accession process</i>	Patent Act 1971 Patent Regulation 1981 <i>A new draft bill is under consideration</i>	No <i>Draft bill will invoke 2016 transition period</i>	Not excluded
Swaziland Patent Law, WTO notification	Patents, Designs and Trade Marks Act 1936 (provides registration only for patents filed in the UK or South Africa) <i>New draft law: Patents, Utility Models and Industrial Designs Act No. 6 of 1997</i>		
Tanzania Patent Law	Patents Act 1987 (cif 1994)		Not excluded

Country Sources consulted	Applicable patent law	Provisions/Mechanisms	
		Pharmaceutical products	Patentability exceptions – new use or 2 nd use patents
Tunisia Patent Law, WTO Review	Law No. 2000-84 on Patents	Yes	
Uganda Patent Law	Patents Act 1993 <i>New draft law: Industrial Property Bill 2004</i>		Not excluded
Zambia Patent Law	Patents Act	Yes	Not excluded
Zimbabwe Patent Law	Patents Amendment Act 2002		Not excluded

Regional Patent Organizations

Regional organization	African Intellectual Property Organization (OAPI)	African Regional Intellectual Property Office (ARIPO)	Andean Community
Membership	16 member states: Benin Burkina Faso Cameroon Central African Republic Congo Cote d'Ivoire Equatorial Guinea Gabon Guinea Guinea Bissau Mali Mauritania Niger Senegal Chad Togo	15 member states: Botswana Gambia Ghana Kenya Lesotho Malawi Mozambique Namibia Sierra Leone Sudan Swaziland Tanzania Uganda Zambia	4 member states: Bolivia Colombia Ecuador Peru
Applicable treaty instrument	Bangui Agreement 1977, revision of 1999	Harare Protocol, 1982	Andean Community Decision 486
Pharmaceutical products	Yes	Yes	Yes
Patentability exclusions	No exclusion	Not explicitly excluded	New and 2 nd use patents excluded

BIBLIOGRAPHY

- 📖 Al-Ali, N., (2003) “The Egyptian Pharmaceutical Industry After Trips – A Practitioner’s View”, *Fordham International Law Journal*, vol. 26, pp274-314.
- 📖 Bagley, M.A., (2003) “Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World”, *Minnesota Law Review*, vol. 87, pp679-742.
- 📖 Bagley, M.A., (2007) “A Global Controversy: The Role of Morality in Biotechnology Patent Law”, *University of Virginia Law School Public Law and Legal Theory Working Paper Series Paper 57*.
- 📖 Bagley, M.A., (2003) “Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law”, *William and Mary Law Review*, vol 45, p 469-547.
- 📖 Baumgartner, C. (2006) “Exclusion by Inclusion? On Difficulties with Regard to an Effective Ethical Assessment of Patenting in the Field of Agricultural Bio-Technology”, *Journal of Agricultural and Environmental Ethics*, vol 19 (6), pp521-539.
- 📖 Bavec, S. (2004) “Scope Of Protection: Comparison of German and English Courts’ Case Law”, *Marq. Intellectual Property Law Review*, vol. 8, pp255-272.
- 📖 Bently, L., and B. Sherman, (2001) *Novelty in Intellectual Property Law*, Oxford University Press, Oxford.
- 📖 Chisum, D.S., *Chisum on Patents*, (2005) Matthew Bender, New York 2005.
- 📖 Chisum, D.S., and M.A Jacobs, (1992) *Understanding Intellectual Property Law*, Times Mirror Books, Legal Texts Series, New York.
- 📖 Cornish, W., and D. Llewellyn, (2003) (5th Edition) *Novelty in Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, Sweet & Maxwell, London.

-  Correa, C.M., (2006) *Guidelines for de examination of pharmaceutical patents: developing a public health perspective*, WHO-ICTSD-UNCTAD, Geneva.
-  Correa, C.M., (2002) “Internationalization of the Patent System and New Technologies”, *Wisconsin International Law Journal*, vol. 20, pp503-523.
-  Correa, C.M., (2000) *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, South Centre, Geneva.
-  Correa, C.M., (2002) *Protection and Promotion of Traditional Medicine Implications for Public Health in Developing Countries*, South Centre, Geneva.
-  Correa, C.M., and S Musungu, (2002) “The WIPO Patent Agenda: The risks for developing countries”, *Working Papers 12*, South Centre, Geneva.
-  Crump, J., “Inventive Step in the EPO : Problem Solution”, In: www.ficpi.org/library/APAA_FICPI_Newport/P5_Crump.doc
-  Dam, K.W. (2006) “The Economic Underpinnings of Patent Law”, *John M Olin Law & Economics Working Paper No. 19 (2D Series)*.
-  Dannemann, G.E., and M.T.Wolff, (Eds) (1999) *Global Perspectives of Contemporary Intellectual Property Issues*, J Sholna, Rio de Janeiro.
-  DeMonaco, J., A Ali and E Von Hippel (2005) “The Major Role of Clinicians in the Discovery of Off-Label Drug Therapies”, *MIT Sloan Working Paper 4552-05*.
-  Domeij, B., (2001) *Novelty in Pharmaceutical Patents in Europe*, (Kluwer Law International, New York).
-  Domeij, B., (2001) *Pharmaceutical Patents in Europe*, Kluwer Law International, New York.
-  Dratler, J., (1991) *Intellectual Property Law: Commercial, Creative, and Industrial Property*, Law Journal Press, New York.

- 📖 Enerson, B.D., (2004) “Protecting Society From Patently Offensive Inventions: The Risk of Reviving The Moral Utility Doctrine”, *Cornell Law Review*, vol 89, p 685-720.
- 📖 EPO, (2006) *Guidelines for Examination in the European Patent Office*.
- 📖 European Patent Office, (2003) *Trilateral Working Group - Substantive Harmonization of Patent Law (SPLT): The European Perspective*, European Patent Office.
- 📖 Grubb, P.W., (1999) *Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law Practice and Strategy*, Clarendon Press, Oxford.
- 📖 Hansen, B., and F. Hirsch (1998) *Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law*, Wiley-VCH, Berlin.
- 📖 Intellectual Property Advisory Committee (IPAC) UK, (2006) *The Patent Office Consultation on a Patent Grace Period*.
- 📖 Jiang-Schuerger, D., (2001) “A Topic of Harmonization: Relative and Absolute Novelty” *China Patents & Trademarks*, vol. 64(1).
- 📖 Kaiser, U., and T. Rønde, (2004) “A Danish view on Software Related Patents”, *Discussion Paper 2004–05 Center for Economic and Business Research*.
- 📖 Komson, R.C., and P.K. Wittmayer, (2000) “Obtaining Patent Protection for the Treatment of Disease with Genetic Materials”.
- 📖 Kotler, M.L., and G.W. Hamilton (2006) “A Guide to Japan’s Patent System”, *US Department of Commerce Office of Technology Policy Asia – Pacific Technology Program*.
- 📖 Ladas, S.P., (1975) *Patents, Trademarks, and Related Rights National and International Protection*, Harvard University Press, Cambridge.
- 📖 Li, X., and Y. Pai, (2008) “Patent Application as Indicator of the

- Geography of Innovation Activities: Problem and Perspectives”, *Paper prepared for Joint Session between South Centre and the World Institute for Development Economics Research of the United Nations University (UNU-WIDER) at Southern Engines of Global Growth: China, India, Brazil and South Africa (CIBS) at WIDER, Helsinki, Finland, 7–8 September 2007 (forthcoming South Centre research paper 2008).*
- 📖 Lipton, M., (2004) *Biopharmaceuticals: The Patent System and Incentives for Innovation*, Harvard University Law School.
- 📖 Lopez-Beverage, C.D. (2005) “Should Congress Do Something About Upstream Clogging Caused by the Deficient Utility of Expressed Sequence Tags?”, *Journal of Technology, Law & Policy* vol. 10, p 35-92.
- 📖 Maruyama, R., (2006) “The Grace Period: A Japanese Perspective”, in *Rethinking Intellectual Property: Biodiversity and Developing Countries, Extraterritorial Enforcement, the Grace Period and other issues: Proceedings of the 2000 High Technology Summit Conference, University of Washington, Seattle*, University of Washington CASRIP Symposium Publication Series No. 6.
- 📖 McCarthy, J.T., R.E Schechter and DJF McCarthy, (2004) (3rd Edition) *Desk Encyclopedia of Intellectual Property*, The Bureau of National Affairs Inc., Washington DC.
- 📖 Médecins Sans Frontières, “Two Pills a Day Saving Lives: Fixed Dose Combinations of Anti-Retroviral Drugs”, *MSF Briefing Note 3*.
- 📖 Merges, R.P., P.S Menell and M.A Lemley, (2000) (2nd Edition) *Intellectual Property in the New Technological Age*, Aspen Law & Business, New York.
- 📖 Moussa, F., (2006) “Statement in favour of the grace period”, *presented at the hearing of the European Commission on the grace period, Brussels 5 October 1998*.
- 📖 Mueller, J.M., (2003) *An Introduction to Patent Law*, Aspen Publishers, New York.

- Oh, C., and S. Musungu, (2006) *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines*, World Health Organization – South Centre, Geneva.
- Otieno-Odek, J., (1995) “Public Domain in Patentability after the Uruguay Round: A Developing Country’s Perspective with Specific reference to Kenya”, (1995) *TUL. Journal of International & Comparative. Law*, vol.4,.
- Paradise, J., (2004) “European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics”, *BRCA Patent Controversy’ 59 (1) Food and Drug Law Journal*, pp133-155.
- Parthasarathy, S. (2005) “Architectures of Genetic Medicine: Comparing Genetic Testing for Breast Cancer in the USA and the UK”, *Social Studies of Science*, vol.35 pp5-40.
- Petrova, A., (2003) “From The Amazon To The Alps: A Comparison Of The Pharmaceutical Biodiversity Legal Protection In Brazil And Switzerland”, *Pace International Law Review*, vol. 15, pp247-281.
- Richards, J., (2005) “United States Patent Law and Practice with Special Reference to the Pharmaceutical and Biotechnology Industries”, *Paper Presentation IIPRP and TIFAC Seminars Delhi and Hyderabad, India, January 2002*.
- Rueda, A. (2001) “Cataract Surgery, Male Impotence, Rubber Dentures and a Murder Case – What’s So Special About Medical Process Patents?”, (2001) *University of Baltimore Intellectual Property Journal*, vol.9, pp109-146.
- Scassa, T. (2001) “Patents for Second Medical Indications and their Potential Impact on Pharmacare in Canada”, *Health Law Journal*, vol. 9, pp23-60.
- Shiva, V., (2000) “Free Tree”, *Hindusthan Times Online*, 9 June 2000.
- Straus, J. (1988) *The Significance of the Novelty Grace Period for*

Non-Industrial Research in the Countries of the European Economic Community, Commission of the European Communities, Luxembourg.

-  Sung, L.M., and J.E Schwartz, (2004) *Patent Law Handbook 2004–2005*, Thomson West.
-  Thompson, W.S., (1993) “Reforming the Patent System for the 21st Century”, (1993) *AIPLA Quarterly Journal*, vol. 21, pp171-188.
-  UK Commission on Intellectual Property Rights (2003)*Report of the UK Commission on Intellectual Property Right: Integrating Intellectual Property Rights and Development Policy*, UK Commission on Intellectual Property Rights.
-  US Federal Trade Commission (2003)*To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Federal Trade Commission Report.
-  Wilson, E.O., (1988) *Biodiversity*, National Academy Press, Washington D.C.
-  WIPO Secretariat (2005) “WIPO Secretariat Submission to the WHO Commission on Intellectual Property Rights, Innovation and Public Health”, WIPO, Geneva.